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A PILOT STUDY EXAMINING THE DIFFERENCE IN COMMUNITY MENTAL HEALTH SERVICE USERS' SYMPTOMATOLOGY AND CONCORDANCE WITH MEDICATION REGIMENS AFTER COMPLETION OF THE QUATRO ADHERENCE THERAPY INTERVENTION

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Stephanie Hall Ford

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To: Dean Ronald M. Berkman
College of Health and Urban Affairs

This thesis, written by Stephanie Hall Ford, and entitled A Pilot Study Examining the Difference in Community Mental Health Service Users' Symptomatology and Concordance with Medication Regimens after Completion of the Quatro Adherence Therapy Intervention, having been approved in respect to style and intellectual content, is referred to you for judgment.

We have read this thesis and recommend that it be approved.

Sandra L. Lobar

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Kathryn Hoehn Anderson, Major Professor

Date of Defense: July 27, 2004

The thesis of Stephanie Hall Ford is approved.

Dean Ronald M. Berkman
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Florida International University, 2004

DEDICATION

This thesis is dedicated to all individuals who live with the illness of schizophrenia, their families, mental health care professionals trying to make a difference and the great number of friends and family in the US and abroad who made this thesis possible.

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Dr. Anthony David for permission to use the Scale for the Assessment of Insight.

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ABSTRACT OF THE THESIS

A PILOT STUDY EXAMINING THE DIFFERENCE IN COMMUNITY MENTAL HEALTH SERVICE USERS' SYMPTOMATOLOGY AND CONCORDANCE WITH MEDICATION REGIMENS AFTER COMPLETION OF THE QUATRO ADHERENCE THERAPY INTERVENTION

by

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Professor Kathryn Hoehn Anderson, Major Professor

A randomized, experimental pilot study of QUATRO Adherence Therapy examined differences at baseline and follow up in the dependent variables of severity of psychiatric symptomatology and medication concordance as measured by the *Positive and Negative Symptom Scale* and the *Personal Evaluation of Transitions in Treatment* for subjects with schizophrenia and schizoaffective disorder at a community mental health center. The sample was 23 subjects. A questionnaire developed for the study collected data at follow-up. Data were analyzed using descriptive statistics, *t*-tests, and repeat Anova to compare groups and determine significance of change following completion of the intervention. Program evaluation was positive. Statistical comparison indicated no significant differences were found in change scores for either group. Implications for further research are that a larger scale randomized controlled study is needed to produce statistical significance.

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Chapter 1

Introduction

Living with a mental illness, such as schizophrenia, characterized by psychosis is the life experience of approximately 2.2 million American adults (Narrow, as cited in National Institute of Mental Health [NIMH], 2002). Consider that each of these 2.2 million adults has family members and the number affected by this illness rises to 2.2 million families. Recently the World Health Organization (WHO) characterized active psychosis as producing a disability equivalent to that of quadriplegia and causing a burden of 2.3 million lost years of healthy life worldwide (Murray, & Lopez, 1996). The importance of schizophrenia as an illness requiring improved treatments cannot be underestimated.

Through the centuries, people with mental illness, who have been unable to care for themselves, have been outcast, or placed in the care of their families, religious orders, prisons, state hospitals, and more recently the communities in which they live. Schizophrenia and schizoaffective disorder are included in the *schizophrenias* or *psychotic disorders* for classification in the *Diagnostic and Statistic Manual of Mental Disorders – IV Revised* (DSM-IV R)(American Psychiatric Association [APA], 2001) and are chiefly characterized by disabling positive symptom of psychosis and a cluster of "negative" symptoms within a context of impaired social functioning.

The positive symptoms of psychosis are collectively described as a loss of contact with reality (National Health Services [NHS], 2004). Symptoms include hallucinations (hearing, seeing, smelling or feeling things that do not exist), and delusions (bizarre, false beliefs) (NHS). Severe thought disturbances and grossly abnormal behavior are also

defined as psychotic (NHS). Negative symptoms of schizophrenia can include: social withdrawal, lack of initiative, poor motivation, and paucity of thought. Until the 1950s, there were no effective treatments for schizophrenia. Theories of the brain's chemical neurotransmitter system gone awry have led to ongoing improvements in medications used to treat this illness since the 1950s (Seeman & Seeman, 2002).

From the 1950s through the 1980s, medications now referred to as *typical antipsychotics* were used to treat symptoms of psychosis (Mycek, Harvey, & Champ, 2000). Side effects, especially movement disorders, from these neuroleptic medications led to metaphors such as the *thorazine shuffle* to describe the dull-eyed stare and stiff-legged walk, suffered by many individuals taking these medications (Goode, 2003). Advances in pharmacological efficacy over the past 10 years have reduced these types of side effects dramatically with a group of medications called atypical antipsychotics (Seeman & Seeman, 2002)

Research reveals that antipsychotic medications used in the treatment of psychotic disorders are effective in reducing the symptoms of psychosis (The Schizophrenia Patient Outcomes Research Team [PORT], 1998). Taken according to a prescribed regimen, they may prevent these symptoms from returning (PORT). Antipsychotic medications reduce the symptoms of schizophrenia, but as with many illnesses, medication is only one part of the treatment strategy. Current treatment recommendations of community based psychosocial interventions paired with medications for people with schizophrenia result in better health outcomes and fewer relapses (McGuire, 2000; Oehl, Hummer, & Fleischhacker, 2000; PORT, 1998).

Community-based psychosocial interventions focus on two major areas of treatment; remediation of both the psychological and the social impact of schizophrenia. Medication can greatly reduce and even eliminate symptoms of psychosis but many individuals also experience the added difficulty of cognitive impairment, difficulty concentrating, and reduced psychomotor processing. These cognitive impairments are associated with the negative symptoms of schizophrenia such as: blunted affect, emotional withdrawal, poor rapport, social isolation, obstacles to abstract thinking, lack of spontaneity, and stereotyped thinking. Cognitive impairments are associated with difficulties managing social relationships, maintaining employment, functioning independently, and are not responsive to medications (Hughes et al., 2002). Community based treatment for schizophrenia, combining medication with social and cognitive interaction may more effectively treat the illness and has the potential to impact successful community living of individuals with schizophrenia (Sensky et al., 2000).

Background of the Problem

The World Health Organization (2003) reports that non-adherence to treatment across chronic diseases is a worldwide problem of great magnitude. The striking dilemmas caused by non-adherence include the morbidity of treatment resistance and appreciably increased health care costs (WHO). Support for the WHO's findings and initiatives regarding adherence abound in the literature.

The effectiveness of antipsychotic medication for treatment of schizophrenia is well established in the literature, but compliance rates are less than is desirable for the control of symptoms (Oehl et al., 2000). Across all illness categories, rates of medication compliance range from 24% to 90% (Cramer, & Rosenheck, 1998). Generally, people do

not take medications as prescribed by their health care providers, whether the medications are antibiotics, cardiac medications, or antipsychotics (Cramer, & Rosenheck; Jarboe, 2002; McCabe, 2002; PORT, 1998).

Hospitalization for the exacerbation of symptoms of schizophrenia is regularly associated with individuals not taking antipsychotic medications in accordance with prescribed regimens (Agarwal, Sharma, & Kumar, 1998; PORT, 1998). It is estimated that failure to take antipsychotic medications as prescribed contributes to approximately 40% of the annual costs of hospitalization for individuals with schizophrenia (Weiden, & Olfson, 1995). Amplifying the financial costs are the distressing human costs of life disruption, residential and employment instability, sub-optimal clinical response, poor continuity of care and relationship instability that accompany frequent hospitalizations (McCabe, 2002; Weiden, & Olfson). Further, the length of time to achieve symptom remission takes longer with each respective hospitalization (Beers, & Berkow, 2004). Service users with schizophrenia, their families, and their communities bear the burdens of the significant social and economic impact of poor treatment concordance.

Since 1996, research concerning improving medication concordance has focused on therapies based on cognitive behavioral therapy and motivational interviewing (Gray, Wykes, & Gournay, 2003). An intervention of *compliance therapy* was developed, based on the principles and techniques of these two therapeutic approaches (Kemp, Kirov, Everitt, Hayward, & David, 1998). Years of research developing compliance therapy (Kemp, Hayward, Applewhaite, Everitt, & David, 1996; Gray, David, & the Quatro Research group, 2001) combined with the efforts of the Quatro research group have resulted in the development of a new intervention called Quatro Adherence Therapy

(QAT). Quatro refers to the four countries in the European Union participating in the development and research of this intervention.

Experimental studies of new interventions that increase concordance with prescribed medication regimens will provide needed evidence-based practice guidelines and standards of care for clinicians. Quatro Adherence Therapy is designed to address the complex and individual variables associated with poor concordance (Gray, & Odunlade, 2002). This thesis represents the introduction of a QAT intervention in the United States.

Purpose

The purpose of this pilot study was to demonstrate whether any changes in severity of symptomatology or mediation concordance occurred as a result of adding an intervention of Quatro adherence therapy to service users' usual treatment at a local community mental health center. The pilot study provided a previously tested intervention as an adjunct to participants' current treatment. Dr. Richard Gray, research fellow at King's College London, assisted the principal investigator with QAT training, and provided the QAT Training Manual for use with this study (see Appendix A for copy of Dr. Gray's letter of consent).

Research Questions

This pilot study was designed to answer the following questions:

1) Is there a difference in the severity of symptomatology for service users with schizophrenia or schizoaffective disorder after participation in the QAT intervention?

2) Is there a difference in medication concordance for service users with schizophrenia or schizoaffective disorder after participation in the QAT intervention?

Definition of Terms Used in this Thesis

Schizophrenia. Schizophrenia is a chronic, serious mental illness. A diagnosis of schizophrenia is based on a clinical picture of overall functioning. Diagnosis requires that two or more of the following symptoms are evident for a significant portion of time in a one-month period: (a) delusions, (b) hallucinations, (c) disorganized speech, (d) grossly disorganized or catatonic behavior, (e) negative symptoms of lack of energy and motivation, and (f) affective flattening or loss of concentration (adapted from APA, 2001, p. 312). Diagnosis also requires disturbance of social and occupational functioning, with the duration of disturbance lasting for at least six months, and the exclusion of substance abuse or general medical condition as the cause of the disturbance (APA).

Motivational interviewing (MI). Motivational interviewing is a client centered, directive method of counseling, with a deliberate goal of enhancing intrinsic motivation to change, through exploration and resolution of ambivalence (Miller, & Rollnick, 2002). Motivational interviewing is rooted in the core concept of the intrinsic worth of human beings. This core concept characterizes the ethics of the nurse-client relationship and advanced practice nursing.

Cognitive behavioral therapy (CBT). Cognitive behavioral therapy is an action-oriented form of talk therapy that focuses on identifying faulty thinking patterns that lead to maladaptive behaviors, and negative emotions. Maladaptive behavior is behavior that is counter-productive or interferes with everyday living. The treatment focuses on

assisting an individual to identify thoughts (cognitive patterns) and assumptions (irrational beliefs) in order to change his or her behavior and emotional state (Ford-Martin, 2004).

Quatro Adherence Therapy (QAT). Quatro adherence therapy is a structured, pragmatic, therapeutic intervention based on the principles and counseling skills of motivational interviewing and cognitive behavioral therapy. In this intervention, the mental health worker uses one-on-one therapeutic conversation with the client to develop *importance* and *confidence*, two key components linked to resolving ambivalence about taking medication. (Gray, David, & the Quatro Research Group, 2003).

Importance. The term *importance* used in QAT, refers precisely to the value or significance an individual places in a belief. The context of *importance* in QAT is defined by the hypothesis that people tend to maneuver in the direction of their highly valued beliefs. Thus, decisions about behavior change often reflect self-defined important values. Therefore, the value of a belief weighs in heavily as a positive component of the changes that lead to resolving ambivalence (Miller, & Rollnick, 2002).

Confidence. The use of the term *confidence* in QAT corresponds to the service user's self-measurement of their ability to enact change. High confidence levels are equal to strong beliefs in abilities to change. Therefore, a large amount of confidence helps tip the scales toward change. Research on MI suggests that high confidence levels are strongly related to the ability to follow through with actions necessary to implement decisions (Miller, & Rollnick, 2002).

Nurse-patient relationship (NPR). The nurse patient relationship is a descriptive term coined by Hildegard Peplau (1952) to denote the construct of nursing practice. The

NPR is comprised of four components: (a) the nurse, (b) the patient, (c) professional expertise, and (d) client need. Peplau theorized that (a) the patients' presenting problems were identified, (b) an understanding of their problems and patterns was developed, and (c) the application, and testing of remedial measures occurring within the context of these four components (1991, p. 13). The goal of the NPR is to arrive at beneficial outcomes for patients (Peplau, 1952).

Theoretical Framework

The theoretical model guiding this pilot study is Hildegarde Peplau's theory of interpersonal relations in nursing. Peplau's theory proposes that nursing involves a significant, therapeutic, interpersonal process (Peplau, 1952). Peplau defines the therapeutic interpersonal process as when a nurse, "helps a patient to identify problematic elements in his current situation and to discover and understand something about what is happening to him during his illness" (1952, p. xiv). The QAT program is an example of a therapeutic, interpersonal process in action. In this pilot study, the collaborative relationship between the therapist and the individual participating in QAT denotes the interpersonal process.

Peplau also describes therapeutic interpersonal techniques, as verbal interventions used by nurses which promote a client's competencies in, "self-expression, stating thoughts, describing actions and naming feelings…related to resolution of focal attention dysfunction" (1989b, p.347). Congruent with Peplau's description, QAT employs specific pencil-and-paper and verbal interventions aimed at the resolution of ambivalence through identifying and voicing the client's unique self-view. These QAT interventions, which are integral to the interpersonal process, are detailed in Chapter III of this thesis.

The interpersonal process, common to both Peplau's theory and QAT's framework, is the vehicle for resolution of ambivalence to problematic elements in the individual's situation. Through this process, clients explore areas of ambivalence through focusing their attention on describing experiences and values and increasing self-understanding of the dynamics present in their illness.

Peplau's model of nursing is based on the idea that improved health outcomes are related to clients achieving altered self-views as the present experience is integrated with other life experiences through self-initiated processes of *self-renewal, self-repair and self-awareness.* The outcome is promoted by the experiences in the nurse-patient relationship (Peplau, 1952). Peplau describes illness events as opportunities for "experiential learning, self-exploration and growth" (1991, p.13) and she theorized that change is required as the individual adjusts to the facts of the illness and incorporates the experience into a new self-view (1952). In the initial publication of her theory in 1952, Peplau described four stages of the nurse-patient relationship that she termed: orientation, identification, exploitation, and resolution. Later, Peplau (1997) published updates to her theory of nursing which modified the phases of the nurse-patient relationship to orientation, working, and termination. These three overlapping phases illustrate the progression of the nurse-patient relationship (Peplau, 1997).

Peplau's theory of nursing emphasizes a view of the "self as a process, moving in a direction on a course of personal development, always open to revision... with a tendency towards a certain stability of self views" (Peplau, 1989a, p. 66). Peplau's view of self is congruent with the framework of motivational interviewing used in QAT, which states that change is a natural human process (Miller, & Rollnick, 2002). Peplau further

emphasizes that within the context of the interpersonal relationship between nurse and client, the nurse provides an opportunity for the client to "gradually examine and change the contents of the self-system by checking self views against reality" (Peplau, 1989c, p. 209).

Peplau also discusses the use of *verbal tactics* by nurses to undermine the presenting thought pathology associated with change in the client's use of language and thought (1999, p. 270). Peplau's strategy of verbal tactics is analogous to the use of cognitive behavioral techniques in QAT to develop *discrepancy of thought*, referred to as *cognitive dissonance*. This CBT technique increases self-awareness of the consequences of underlying thought patterns and the reasons for making a change in current behavior, by encouraging the client to express their values and voice their own reasons for taking medication (Gray, David, et al., 2003).

Three Phases of Nurse Patient Relationship

Orientation phase. The orientation phase initiates the nurse-patient relationship. Peplau characterizes the orientation phase as a time when the focus is on the patient as the nurse obtains essential information. The essential information is obtained through the nurse focusing on listening, assessing, encouraging descriptions and obtaining an understanding of the patient's experience (Peplau, 1997). For the purposes of this pilot study the initial sessions of adherence therapy, including the engagement phase, and assessment phase, correspond and are consistent with Peplau's orientation phase. The underlying principles of Peplau's theory and QAT emphasize use of active listening skills, and careful assessment of the client's health history, perceptions, and experiences.

Characteristics of human nature that Peplau describes as *preconceptions*, and QAT describes as assumptions, refer to forming an opinion about someone before having a personal experience with that person (Gray, David, et al., 2003; Peplau, 1997). To establish rapport and a therapeutic interpersonal relationship with the client, these characteristics are regarded as *traps* which the nurse or mental health worker must be vigilant to avoid throughout each encounter (Gray, Wykes, & Gournay, 2003; Peplau, 1997). These characteristics are regarded as traps because they interfere with the therapeutic process and can be unethical (Corey, 2001). Effective, ethical nursing care is based on the client's self report of values and cultural beliefs, which the nurse elicits rather than assumes to know. The QAT manual admonishes frequently, *do not make assumptions*. In a similar manner, Peplau asserts that the preconceptions and stereotypes inherent in the interpersonal relationship must be examined by the nurse and changed if necessary (1997).

Working phase. The working phase is the second phase of the nurse-patient relationship theorized by Peplau (1997). This phase develops as the conversation changes to focus on the patient's reactions to illness and the work needing to be done by the patient in order to regain health (Peplau). In this phase, Peplau depicts the nurse employing health teaching and enhancing learning for the patient by building on what the patient already knows or experiences (1997). In this phase, the nurse draws on the skills of attentive listening and inquiry to encourage greater self-understanding in the patient (Peplau, 1997, p. 164).

Peplau's working phase is distinguished by the concepts of facilitating greater self-understanding and struggling with the problem, *not the person* (Peplau, 1997, p.

164). Quatro Adherence therapy's therapeutic phase corresponds and is consistent with Peplau's working phase. Quatro adherence therapy guides the nurse to facilitate the self-expression and struggling with fears about medication without judgment or labeling, thus allowing a struggle with the problem, not the client to ensue (Gray, David et al., 2003). Peplau believed that, "attentive listening to the patient's narrative of a personal experience allows for greater self understanding in the patient" (1997, p. 164). This approach is compatible with QAT's use of social learning theory embedded in a motivational interviewing perspective: "As I hear myself talk, I learn what I believe" (Miller, & Rollnick, 2002, p. 21).

Further, Peplau emphasizes that psychotherapeutic approaches are persistently applied and have a demonstrable impact on that item of the client's behavior, which is either an asset or pathology (1999, p. 264). This is consistent with the QAT counselor skill base important to each phase of the therapy. Consistent use of (a) agenda setting to align expectations, (b) accurate reflective listening to reinforce self-generated positive statements about medication, and (c) eliciting or developing discrepancy to identify the *pathology* of cognitive dissonance, are three of several QAT approaches that impact ambivalence (Gray, David, et al., 2003, p. 12). Ambivalence is the hidden asset in each client and it is the starting point of change.

Termination phase. The termination phase is the third and final phase of the nurse-patient relationship (Peplau, 1997). This phase begins in the previous orientation and working phases when interactions intermittently focus on the limits of the interpersonal relationship. A summary of the work, the significant findings, and the outcomes emerging from the interpersonal relationship characterize the final phase.

Providing a sense of closure in relation to the work accomplished through the interpersonal relationship is an important step in this final phase. (Peplau, 1997, p. 165).

The evaluation phase of adherence therapy, which summarizes and considers progress, is the counterpart of Peplau's termination phase involving summarizing and providing closure (Peplau, 1968). Quatro adherence therapy defines the termination phase, which usually concludes in the final therapy session, as a review of: (a) treatment to date; (b) practical problems identified and any resolution of these; (c) side effects experienced; (d) client's readiness to take medication; (e) client's rating of importance and confidence in taking medication; (f) beliefs about medication, and (g) any plans made based on resolved ambivalence (Gray, David, et al., 2003). This summary of the assessment and the related concepts explored during therapy is consistent with Peplau's definition of the termination phase. Quatro adherence therapy's evaluation phase provides validation of the individual's expressed experience and closure of the therapeutic process.

The literature identifies ambivalence and lack of insight, or faulty understandings, as factors associated with poor medication concordance and exacerbation of symptoms (Gray, Robson, & Bressington, 2002). Resolution of ambivalence, positive practitioner-client relationship, and good insight are associated with a high level of treatment concordance and a reduction in symptoms (Gray, Wykes, Edmonds et al., 2002). Therefore, this model of QAT used as a nursing intervention to resolve ambivalence resulting in a reduction of symptoms follows Peplau's model of therapeutic communication in interpersonal relations which leads to the improved health and well being outcomes stressed in her theoretical framework (Peplau, 1952).

Significance

This pilot study was significant to advanced nursing practice for several reasons. As described in this chapter, even with care and treatment, many people with schizophrenia suffer distressing symptoms that disrupt their thoughts, emotions, and ability to function independently, and places them at a high risk for suicide (Simon, 2002). Research suggests that medication combined with psychosocial interventions for people with schizophrenia make a significant impact on health outcomes and assist some individuals to recover a relatively higher level of social functioning (McCann, 2001).

Investigating and focusing on relapse-prevention interventions is critical because of the demoralization that occurs with successive exacerbations for individuals with schizophrenia (Kane et al., 2004). This pilot study contributed the beginnings of research in the U.S. for QAT, an evidence-based program of care delivery for people with schizophrenia that promotes concordance, a reduction of symptomatolgy and aims to minimize the complications concomitant with poor treatment concordance in schizophrenia.

The body of literature relating to medication adherence includes a number of terms: compliance, adherence, and concordance. Although the longstanding term of compliance and the newer term of adherence feature prominently in the literature, it is proposed, that use of the term concordance more accurately describes the goals and experiences clinicians seek to develop with clients regarding medication regimens (Bebbington, 1995; Gray, Wykes, & Gournay, 2002). The word concordance is preferred and used in this thesis to reflect issues of compliance and adherence. However, when describing studies cited in this thesis the term used in the original work was utilized.

Concordance with a prescribed medication regimen implies that a state of mutual agreement exists between the health practitioner and the client. Concordance with a negotiated medication regimen is one of the goals of pharmacological treatment for schizophrenia and schizoaffective disorder.

Chapter II

Literature Review

Introduction

Literature regarding the significant impact of schizophrenia on life functioning has its beginnings before 2000 BC, and ranges in concept from global impact studies to molecular biology. Theories of the etiology of schizophrenia fluctuate from demonic possession to irregularities in the expression of receptors on nerve cell membranes. What is clear is that throughout history, the illness of schizophrenia has caused serious economic and personal burdens for individuals with this illness and their families (Grob, 1998; van Wijngaarden et al., 2003).

Since the second half of the twentieth century technology, science, and human nature have contributed vastly to improved treatments for this illness, leading to recovery for many individuals. Pharmacological interventions greatly reduce the hospitalization and morbidity associated with schizophrenia. However, many people do not take their medication as prescribed by their health care providers, including people with schizophrenia. Reasons why people do not take medications in accordance with the prescription are extremely complex and individual (Gray, & David, on behalf of the European Quatro Research Group, 2001; WHO, 2003).

The variables contributing to poor medication concordance for people with schizophrenia have been studied and used as the basis for developing therapeutic interventions. In recent studies, an intervention of QAT has been associated with improved outcomes for people with schizophrenia. Through the study of the effectiveness

of interventions, practitioners gain greater understanding of the etiology of the illness and may create improved treatments.

In just over 4000 years of recorded human history, the strides made in recovering from this illness are tremendous. However, health care workers are still overheard remarking, "Those people with schizophrenia, must have the devil in them" (personal experience, May 16, 2004).

History of Schizophrenia

Psychotic symptomatology and schizophrenic-like syndromes have been written about since ancient civilizations recorded descriptions of this illness before 2000 BC, in the ancient Egyptian Book of Hearts. The Greek physician Hippocrates dismissed the idea of a demonic cause of psychosis, instead suggesting that disorders of madness originated entirely from the brain. From the Middle Ages through the 1700s, witchcraft and demonic possession were considered the malevolent influences causing odd behavioral and thought disturbances (Korn, 2001).

In the medical community, psychiatric theory in the early 1800s began to focus again, as Hippocrates had, on the brain being the origin of mental disorders. By the late 1800s, German psychiatrist Emil Kraepelin combined numerous symptoms under a single diagnosis - dementia praecox (dementia of early life). Ten years later, Swiss psychiatrist Eugene Bleuler, coined the term schizophrenia referring to the splitting or fragmentation of an individual's thinking and feeling processes. At the start of the 1900s, a prevailing hypothesis was developing that all mental reactions had physiological counterparts (Grob, 1998).

In 1949, the American Psychiatric Association collaborated with the New York Academy of Medicine resulting in the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-I*), which was published in 1952. The classifications viewed psychiatric disorders as reactions of the personality to psychological, social, and biological factors. Two studies started in 1961 have suggested that new drug therapies were particularly effective in dealing with severe mental disorders (Grob, 1998). However, one opposing view existed within the medical community during the 1960s. Physician Thomas Szasz, argued that, "mental illness is a myth whose function it is to disguise and thus render more palatable the bitter pill of moral conflicts in human relations" (Szasz, 1960, p. 263).

The 1980s and 1990s brought a revolution in technological advancement and neurobiological inquiry (Murray, & Lopez, 1996). Today, in many ways, the health care community has come full circle to Hippocrates' physical basis of mental disorders, but with a greater understanding that there are many facets of this complex syndrome the medical community diagnoses as schizophrenia.

The Experience of Schizophrenia

The lived experience of schizophrenia offers a compelling description of how debilitating schizophrenia can be for those living with the illness. Phenomenological study describes aspects of a health situation as experienced by the person in it. Spence (2002) reviewed the clinical phenomenology of schizophrenia drawing connections with his 1997 (Spence et al.) study of the neural correlates of the experience of alien control. The occurrence of alien control in schizophrenia involves experiencing thoughts or movements as controlled by an outside force. This characteristic experience of schizophrenia is described clinically as a loss of subjectivity (Spence, 2002). Some

individuals with schizophrenia describe this as an experience of *unidentifiable external influence* that causes their intimate thoughts to be, "interfered with" directly, their moods to be, "put into them" from the outside and their physical movements, "belong[ing] to" another person (Spence, 2002).

The distorted perceptions involved in psychosis are described poignantly in the following observation: "She stares closely at people but asks that they do not look back at her. If they do, she seems to hear "voices" in the perceived movements of their eyes, or to experience others' thoughts as entering her head. She asks repeatedly what this means" (Spence, 2002, p. 164). These distorted perceptions experienced in schizophrenia may contribute to difficulty in recognizing the return of symptoms. These distortions were described in a doctoral student's first-person account of the relapse of psychosis. He noted that the relapse of his symptoms was so subtle it went unnoticed by colleagues. He related the following, "All of my consciousness seemed somehow externalized to the rest of the world at the same time. It was as though these thoughts, sensations, and even old childhood memories were not my own but instead community property" (W., 2002, p. 747). These descriptions from people who live with schizophrenia, along with brain scans, convince some researchers that the neural system correlated with the sense of self, especially the right parietal cortex of the brain, is implicated in the etiology of some symptoms of schizophrenia (Spence, 2002).

Neurobiological Theories of Schizophrenia

Perceptions, emotions, and physical sensations are all coordinated in the complex neural circuits of the brain. The mesolimbic section of the brain is thought to be involved in regulating emotions, beliefs, and sensations, although this is poorly understood

(Keltner, 2002). The clinical effects of antipsychotic medications are thought to be due to the competitive blocking of the neurotransmitter dopamine's receptors on nerve cells in the brain (Mycek, et al. 2000). When subsets of dopamine receptors, D2 receptors, are blocked at a minimum of 65% in the mesolimbic section of the brain, positive symptoms of schizophrenia are alleviated (Katzung, 2001; Mycek, et al.).

The theory of an excess of the neurotransmitter dopamine has evolved to describe the etiology of schizophrenia because blocking of dopamine is associated with a decrease in positive symptoms. In his textbook of psychopharmacology, Keltner notes this therapeutic dopamine blocking is not effective for some individuals and is not effective for treating the entire spectrum of schizophrenia's symptoms. Conversely, the negative symptoms of schizophrenia are associated with a relative deficit of dopamine in the mesocortical tract of the brain (Keltner, 2002). There is more involved in the pathology of schizophrenia than the theory of excess dopamine can explain. Increased understanding of the brain chemistry and neural logistics involved in regulating specific human activities has led to wider, more complex theories regarding the etiology of schizophrenia.

Studies seeking to isolate causes and gain a better understanding of the disruption in brain functions related to schizophrenia may lead to improved treatments in the future. N-methyl-D-aspartate (NMDA) receptors, which play a critical role in healthy nerve development and long-term memory consolidation, may be abnormal in schizophrenia and are currently under study (Abi-Saab, D'Souza, Moghaddam, & Krystal, 1998; Jensen, Idiart, & Lisman, 1996). NMDA dysfunction is associated with synaptic runaway, a process involving excess, erroneous nerve connections that leads to faulty memory

processing and cognitive difficulties (Greenstein-Messica, & Ruppin, 1998). These faulty connections are made in nerve networks associated with activity-dependent learning. Sensory experiences are associated with neuronal activity in the brain's neocortex. The neocortex is associated with cognitive functions such as, learning, memory, and perception. Neuronal activity is characterized by the interactions of neurons emitting and processing electric signals via their synaptic connections (Benuskova, 2000). Event or sensory experience induced changes in neuronal interactions have been demonstrated by Hoffman and McNaughton (2002). Gradually these event-related changes in neuronal associations are established in the neocortex through a process of automatic repetition (usually during sleep). Thus, learning and memory consolidation is dependent on this neuronal activity. Neurons form memories through a process of sequentially reinforcing synaptic connections, which shape neuronal networks (Fries, Fernandez, & Jensen, 2003). The inability to process memories and perceptions correctly and order thought processes in a logical manner is consistent with both synaptic runaway and many symptoms of schizophrenia.

Dopamine is thought to enhance the process of synaptic runaway. This may explain why antipsychotic dopamine blocking agents are frequently effective and take weeks to exert their therapeutic effects (Greenstein-Messica, & Ruppin, 1998). Blocking dopamine may allow these activity-dependent learning nerve networks over time to *self-prune* erroneous connections and establish accurate connections. Synaptic runaway may play a very important role in the pathogenesis of schizophrenia (Greenstein-Messica, & Ruppin) and indicates support for models of treatment that include medication, as well as supportive learning environments.

One way to view the results of synaptic runaway on an individual's functioning may be evident in the study of auditory hallucinations. Disrupted or faulty connections between nerve cells are observed in schizophrenia (Simon, 2002). Auditory hallucinations involve activation in the brain of several functional systems which resembles a model of auditory hallucinations as memories of speech interpreted incorrectly (Copolov et al., 2003). Steady state probe topography (SSPT) is a brain mapping technique used to track electrical activity in the brain's cortex. The technique shows significant sensitivity to cognitive activity, and insensitivity to EEG artifact (Silberstein, Burkitt, & Wood, 1993, as cited in Line, Silberstein, Wright, & Copolov, 1998). Mapping the electrical impulses with SSPT, using a rapid (split second) time scale shows that the right temporo/parietal region is involved with the cognitive interpretation of auditory hallucinations (Line et al.).

Interestingly, self-recognition is associated with this cortical region and may help explain how faulty nerve networks process a non-auditory stimulus (a memory of speech) that appears to be self-generated into an auditory perception (Line et al. 1998). The complex relationship of logistics and neurotransmitters in the brain is also associated with a decreased communication network between the right and left sides of the brain in individuals with schizophrenia (Simon, 2002). Irregularities in NMDA molecules, nerve networks, neurotransmitters, and brain structure appear to all play a role in the impairment of mental function and etiology of negative and positive symptoms of schizophrenia. Not surprisingly, these multiple atypical brain insults contribute to the negative and positive symptoms of schizophrenia and to the enormous difficulties of

many individuals with schizophrenia to negotiate daily life with active symptoms (Copolov et al., 2003; Greenstein-Messica, & Ruppin, 1998; Line et al.; Simon).

Efficacy of Pharmacological Interventions

Over 100 clinical trials and numerous studies have demonstrated the efficacy of the use of antipsychotic medications for treatment of the symptoms of schizophrenia (Kane et al., 2004; PORT, 1998; Sechter, Peuskens, Fleurot, Rein, & Lecrubier, 2002). Efficacy in real terms means a reduction or elimination of many symptoms, with a higher efficacy in the reduction of positive symptoms (Kane et al.; Sechter et al.), such as auditory hallucinations, paranoia, and disorganized speech.

There is also significant evidence to suggest that the continued use of antipsychotic medication, after the remission of symptoms, will prevent recurrence of symptoms and reduce the long-term severity of both positive and negative symptoms (Kane et al., 2004; PORT, 1998; Seeman, & Seeman, 2002). Davis and Andriukutis' meta-analysis of antipsychotic treatment shows a relapse rate of 16% with medication, compared to a 60% relapse rate on placebo (1986, as cited in Agarwal et al., 1998). In a study assessing the impact of dose reduction of antipsychotic medication and family treatment during maintenance treatment, 313 participants at five outpatient centers were treated and assessed for 2 years. Both continuous low-dose and targeted treatment for emergent symptoms led to an increased use of rescue medication and relapse (Schooler, Keith, & Severe, 1997). These findings are further confirmation of the value of uninterrupted use of antipsychotic medication in preventing relapse and rehospitalization.

Although medication is not a cure for schizophrenia, it is clearly an important, critical aspect of treatment resulting in a reduction of symptoms for many individuals. In

a 1-year study of drug therapy patterns and treatment costs for 18,090 individuals receiving outpatient care for schizophrenia with Medicaid insurance it was found that, "all antipsychotic drug use patterns, except uninterrupted therapy, were found to be associated with significantly higher total health care costs" (Lyu, McCombs, Johnstone, & Muse, 2001, p. 93). Yearly direct care costs for treatment of relapse in schizophrenia in the United States are estimated at roughly 800 million dollars (Weiden, & Olfson, 1995). The financial costs are striking and are suggestive of the even more striking personal costs associated with relapse for individuals with schizophrenia and their families.

Psychosocial Impact of Relapse

Relapse of active illness in schizophrenia concomitant with exacerbation of symptoms is associated with poor medication compliance for approximately 40% of individuals who relapse (Weiden, & Olfson, 1995). As a group, individuals with schizophrenia who experience multiple relapses and active psychosis have an increased risk of homelessness, victimization, a poorer prognosis, and longer times to remission of symptoms (Pinikahana, Happell, Taylor, & Keks, 2002; Seeman, & Seeman, 2002).

Active psychosis interferes with every aspect of daily living for both the individual with schizophrenia and their families (WHO, 2003). One study stretching across five countries of the European Union (EU) concluded that caregivers are constantly coping with the consequences of this illness. Four emotional factors emerged from this study as common to all caregivers and they are descriptive of the caregiver role. They include: tension, worrying, supervision, and urging. This caregiver worry and tension exists in the context of the many serious legal consequences of schizophrenia for individuals with this illness (van Wijngaarden et al. 2003).

According to Brekke, Prindle, Bay, & Long (2001) individuals with schizophrenia and schizoaffective disorder are said to be at a 65% to 134% higher risk of being the victim of a crime than the general public. This study followed 172 individuals with schizophrenia over a three-year period, and the authors found that, among other factors, decreased social functioning and poor medication adherence are related to police contact, in the form of victimization or arrest. During the study, 38% of the participants with schizophrenia were the victims of crime, of which 91% were violent crimes. This statistic supports Link, Andrews and Cullen's (1992) finding that when psychosis is controlled for, mentally ill individuals have no greater risk for illegal behavior or violence than does the average person. This aspect is important in supporting the urgency for increased medication concordance associated with fewer symptoms of psychosis, and a lower rate of victimization.

Recent publication of treatment guidelines for schizophrenia, developed through systematic review of research-based evidence and expert opinion, support the use of antipsychotic medications for reducing the symptoms, morbidity and mortality associated with schizophrenia. (McEvoy, Scheifler, & Frances, 1999; PORT, 1998). The importance of preventing relapse can be life saving because the general risk for suicide in people with schizophrenia is higher following an acute psychotic episode. It is estimated that between 20% and 50% of patients with schizophrenia attempt suicide (Simon, 2002) and one of every 10 people with schizophrenia eventually commits suicide (NIMH, 1999b).

Poor Concordance Rates

Terminology is an issue of historical and ideological scope directly influencing the foundation for concordance interventions. Use of the terms, *non-compliance* or *non-*

adherence implies a paternalistic approach to health care (Gray, Wykes, & Gournay, 2002), casting the service user in the role of disobedient child. Consequently, it is proposed that use of the word *concordance*, which emphasizes client rights, the need for information, the importance of two-way communication and decision-making, supplant the use of the word *compliance* (Gray, Wykes, & Gournay). The historical compliance model is at odds with a new concordance model and the new ethics of modern mental health care. Development and research is encouraged to base all interventions addressing use of medications and treatment strongly in a concept of concordance. However, much of the literature in this area utilizes the terms of compliance and adherence and provides the foundation for this concordance concept.

The great economic and personal costs associated with poor concordance and relapses have been the subjects of many studies. It is estimated that within two years of beginning antipsychotic medication, 75% of individuals will stop taking them (Weiden, & Olfson, 1995). Cramer and Rosenheck (1998) studied medication compliance rates and determined average compliance with antipsychotic medications to be 58%, antidepressant medications at 65%, and medications for physical disorders at 76%. When individuals fail to take medication as prescribed, either stopping the medicine or taking it sporadically, positive and negative symptoms return, psychosis and difficulty with reality orientation reemerge. Relapse and costly hospitalization is associated with poor concordance and is well supported in the literature (Brekke et al., 2001; Oehl et al., 2000; PORT, 1998).

Poor compliance is described as when medication is not taken according to a prescribed regimen (PORT, 1998); however, measures of the concept of compliance are

inexact, thus making comparisons between interventions difficult. Difficulties in measuring compliance may be one explanation for the inconsistencies in reported non-compliance rates for people with schizophrenia. Compliance assessment strategies range from clinician determination, electronic pill bottle cap monitoring, to user self-report scales, and interviews (Gray, Wykes, & Gournay, 2002).

The World Health Organization proposes that higher rates of treatment adherence across all chronic disease categories would result in economic benefits by reducing health care costs for illness exacerbations and boosting indirect benefits of improved quality of life and increased social contributions (2003). The World Health Organization also emphasizes that the concept of adherence is a multidimensional phenomenon requiring interventions tailored to the particular needs of each patient.

Variables Associated with Poor Concordance

In a study to evaluate possible factors contributing to what they termed medication non-compliance in schizophrenia, Agarwal et al. (1998) surveyed 78 patients with schizophrenia using standardized instruments to measure insight and subjective response to medication; their families were administered a structured, *Knowledge About Schizophrenia* interview. Results indicated that people with an episodic course of schizophrenia, with onset of illness at 26 years of age and no side effects were 130 times more likely to be non-compliant than compliant. Sixty-six percent of this sample under the age of thirty was non-compliant with prescribed medication regimens (Agarwal et al.).

Hudson et al. (2004) completed a pilot study examining barriers to medication adherence involving 153 patients with schizophrenia receiving inpatient and outpatient

services at three Veterans Administration Medical Centers in the U.S. Nurse coordinators at all three sites conducted a clinical interview lasting 20 to 60 minutes, focused on evaluating barriers to medication adherence (Hudson et al., 2004). The most commonly reported barriers were stigma, adverse drug reactions, memory problems, and lack of social support. Strategies to address each of these variables would include: (a) social change to decrease stigma of mental illness, and increase community supports; (b) improved practitioner-patient relationships; and (c) individualized, cognitively based interventions to address practical issues. While this study focused on barriers to treatment, other studies endeavored to identify factors that contribute to concordance.

Agarwal et al. (1998) identified several factors exerting a positive influence on medication compliance for individuals with schizophrenia. Insight, which is defined as the ability to recognize symptoms that arise from mental illness (David, 1990), was associated with better concordance. This investigation also found an association between positive attitude and knowledge about medication and increased levels of compliance (Agarwal et al.). Oehl et al. (2000) determined treatment related issues such as physician-patient relationship, expectations of the medication, and simple versus complicated regimens to be important factors in their review of the scientific literature.

Idiosyncratic issues of concordance were addressed in Awad, Voruganti, Heslegrave, & Hogan's (1996) study of the subjective experience of antipsychotic treatment. The authors noted that it is necessary "to accept the assumption that how patients feel and function can contribute to a large degree to their compliance with medications" (p. 57). Discerning relevant variables from the vast amount of literature on concordance in schizophrenia repeatedly leads to the concept: decision making about

treatment concordance is multifaceted. In a review of the literature covering 27 studies addressing treatment concordance, Gray, Wykes, and Gournay (2002) differentiated 13 factors that emerged as influencing concordance.

Factors linked with service users being *less likely* to take medication as prescribed include:

1) Presence of side effects.
2) Negative beliefs about treatment.
3) Poor symptom control.
4) Complex medication regimen.
5) Substance Abuse.
6) Impaired judgment.
7) Poor worker-service user relationship.
8) Poor communication

Factors linked with service users being *more likely* to take medications as prescribed include:

1) Acceptance of illness.
2) A perception of severity or susceptibility
3) Level of support.
4) Family stability.
5) Positive therapeutic alliance.
6) Route of administration. (Gray, Wykes, & Gournay, 2003, p. 2).

Hughes et al. (2002) indirectly addressed these factors in a longitudinal study involving 62 patients, determining that clinical treatment of cognitive impairment is an

important aspect influencing treatment concordance. The authors recommended that cognitive impairments be considered and treated separately from other symptoms targeted with antipsychotic medications (Hughes et al.). Cognitive impairment seems to directly affect medication concordance, when considering its profound influence on judgment, relationships, complexity of medication regimens, beliefs, and communication. (Gray, Rofial, Allen, Newy, & Gournay, 2003). Interventions that address these components will address the many variables associated with concordance and will be grounded in evidence-based concepts.

Interventions to Enhance Concordance

All interventions implemented in an effort to increase medication concordance meet with varying degrees of success. Sensky et al. (2000) found in a study of cognitive-behavioral therapy (CBT) for treatment of persistent symptoms in schizophrenia, that negative symptoms could be significantly reduced after an intervention of CBT. Importantly, the efficacy of this *talk therapy* intervention on the reduction of negative symptoms persisted for 9 months (Sensky et al.).

In a study targeting education as a means to enhance what they termed medication compliance, Macpherson, Jerrom, & Hughes (1996) found that education alone led to increased insight, but no change in compliance. The educational intervention under study was structured, individualized and comprised of three educational sessions that resulted in durable gains in insight. The authors found in this study involving 64 patients, that education could engage individuals and improve acceptance and integration of the illness (Macpherson et al.). This study, although aimed at an important variable associated with

non-compliance, supports the concept that there is a need to address variables other than education and insight concurrently.

In a meta-analysis of interventions to reduce treatment non-adherence, Nosé, Barbui, Gray, & Tansella (2003) systematically reviewed 23 studies involving over 3,500 subjects for evidence of effective community-based interventions. Literature from 1980 through 1998 was evaluated, ranging in concept from educational programs to telephone prompts. The subgroup analysis revealed that all categories of interventions were effective in lowering non-adherence rates. The authors concluded that while generalizing was not recommended and no intervention emerged as predictive of a positive treatment effect; there is strong, scientific evidence that community interventions can effectively influence treatment adherence. (Nosé et al.).

Compliance Therapy, Adherence Therapy

A randomized controlled trial of an intervention of *compliance therapy*, devised by Kemp et al. (1996) involved 74 service users with schizophrenia in the United Kingdom (UK). In this study, compliance therapy is described as involving cognitive behavioral techniques and motivational interviewing with a more active therapeutic stance. The intervention led to sustained improvements in compliance rates at a six month follow-up. Important outcomes of this study at the 18-month follow-up included a significant decrease in the number of relapses, an increase in insight, compliance, and global functioning, for the intervention group compared to the control group. Importantly, Kemp et al. notes that an expected concomitant reduction in positive symptoms did not occur. One clinical implication cited in the 1996 study was to examine the possibility of teaching the technique to a range of health professionals (Kemp et al., 1996).

Summarizing a research review of numerous interventions, Gray, David et al., (2003) concluded that effective interventions focusing on concordance would consist of five evidence-based elements.

1. Consistent use of a collaborative approach to working with service users.
2. Giving service users information about their illness and treatment.
3. Encouragement of tailoring medication regimens to suit the user.
4. Consistent use of motivational interviewing and cognitive behavioural techniques.
5. Careful assessment of service users' beliefs and experience of treatment with antipsychotic medication (p. 2).

These five critical elements were incorporated into a medication management-training package that was delivered to community mental health nurses (CMHN) in the U.K. A randomized controlled trial (RCT) was conducted to assess the effects of the medication management package on the CMHN's skills and on the clients' clinical outcomes. This trial demonstrated: (a) training effectiveness, (b) user satisfaction of both clients and clinicians, (c) improvement in attitudes towards treatment, (d) increased medication compliance and (e) a reduction of symptoms for clients in the medication management group, as compared to the treatment as usual group. Variable measures included (a) severity of symptoms in schizophrenia using the *Positive and Negative Syndrome Scale* (PANSS) and (b) changes in attitude toward medication and (c) treatment using the *Hogan, Drug Attitude Inventory* (Hogan, Awad, & Eastwood, 1983). Clinician-ratings of compliance were also used to assess compliance, change in insight and side effects (Gray, Wykes, Edmonds, Dickson, Leese, & Gournay, 2002).

Following this study, Gray, Gournay, and David (on behalf of the European Quatro research group) developed a training manual to further implement Quatro Adherence Therapy. Quatro Adherence Therapy is a brief, structured medication management therapy for users of psychiatric services with schizophrenia. Adherence therapy is characterized by its use of motivational interviewing and cognitive behavioral therapy techniques to focus on involving service users with schizophrenia and schizoaffective disorders in treatment decisions, and discussing their concerns (Gray, David et al., 2003). Completion of QAT is associated with an increase in treatment concordance, and a reduction of symptomatology for service users. This individual therapy focuses on the needs, concerns, fears, values, goals and experiences of the individual with the aim of encouraging people to take their medications. There is an urgent need to integrate these practices throughout the mental health care system (Gray, Wykes, & Gournay, 2002; Kemp et al., 1996).

One recent study stands in contrast to the success of the Quatro Research Group's efforts. O'Donnell et al.'s (2003) study sought to establish the efficacy of compliance therapy among patients with schizophrenia. Fifty-six patients admitted to an inpatient psychiatric unit with psychosis were randomized to receive compliance therapy or non-specific counseling. The main outcome measures were: compliance with drug therapy at one year, attitudes towards medication, insight, symptomatology, overall functioning, quality of life at one year, and occupancy of psychiatric hospital beds for two years. The authors note outcomes for the study indicated that compliance therapy imparted no advantage over non-specific therapy for any of the main outcome measures. One important limitation of the study was the small sample size, which was insufficient to

detect statistical significance. Importantly, this study did not report how fidelity to compliance therapy was monitored or if a determination was made that compliance therapy was provided in accordance with established protocol.

The European Commission is currently funding a four-country randomized controlled trial to study the effectiveness and costs of adherence therapy for people with schizophrenia (European Union, Action Line: Quality of Life-2000). This major undertaking called "Quatro" is currently in progress in London, England; Verona, Italy; Leipzig, Germany; and Amsterdam, Netherlands (Gray, David et al., 2003). The Quatro research group represents a collaborating effort of European researchers coordinated by King's College London to investigate and develop treatment interventions for schizophrenia (D. Robson, personal communication May 30, 2004). Effective management of schizophrenia appears to incorporate a user-centered evaluation of pharmacological interventions; uncomplicated information and the use of both motivational interviewing and cognitive behavioral techniques to help service users make educated decisions about their treatment. There is evidence that routinely incorporating these concepts into the fundamentals of mental health care improves service users' mental health (Gray, & Odunlade, 2002).

Gaps in the Research Literature

There appears to be very little research in the United States of interventions designed to improve concordance for people with schizophrenia. An electronic search of *ClinicalTrials.gov,* an internet database that provides information about federally and privately supported clinical research in the U.S., reveals 65 studies currently registered for treatment of schizophrenia (National Institute of Health, 2003). Of these 65 studies,

one specifically addresses medication adherence. This study, which has not yet begun, will evaluate the effectiveness of a practical, pharmacy-based intervention for improving adherence among clients with schizophrenia.

The Surgeon General's report on mental health addressed pronounced gaps in the mental health knowledge base and defined an urgent need for, evidence which supports strategies for mental health promotion and illness prevention. The report concluded further that an abundance of new medications and treatments for mental disorders challenge the scientific community to develop new methods to deliver health care services (NIMH, 1999a, p. 21).

> Final recommendations from this report include the following admonition: *Ensure Delivery of State-of-the-Art Treatments*: A wide variety of effective, community-based services, carefully refined through years of research, exist for even the most severe mental illnesses yet are not being translated into community settings. Numerous explanations for the gap between what is known from research and what is practiced beg innovative strategies to bridge [the gap] it (NIMH, p. 22).

Finally, previous studies of QAT have been completed with CMHNs as therapists. To, date no studies have been done using mental health therapists of other disciplines such as, clinical social work, marriage and family therapists and licensed mental health counselors.

Summary

Literature regarding the significant impact of schizophrenia on life processes spans the concepts of neurobiological theories, global burden, intrinsic worth, and human

nature. It is clear from a review of the literature that serious economic and personal burdens for individuals with this illness and their families can be positively impacted. Beginning with pharmacological interventions in the 1950s, treatments for severe mental illness have increasingly relied on the methods of scientific inquiry for improvements in efficacy.

The variables contributing to treatment outcomes for people with schizophrenia have been studied, and used as the basis for developing new therapeutic interventions. Medications, when taken as prescribed, effectively reduce the symptoms of schizophrenia for many individuals and lead to better outcomes in life functioning. Yet, making decisions to take or not take medication as it is prescribed "seems to be entrenched in human nature and perhaps should be viewed as *normal* behavior" (Gray, David et al., 2003, p. 2). Describing medication-taking behavior as abnormal is demeaning and possibly furthers the negative stigma for those with metal illness. Especially with regard to the very similar rates of poor treatment concordance seen in virtually all chronic illnesses (Gray, David et al.). Based in a concordance framework, decision making about taking medications revolves around numerous variables with an overriding influence of ambivalence.

Results of recent studies of an intervention for adherence therapy indicate that a process of collaboration, information sharing, value exploration, and review leads to improved outcomes for people with schizophrenia. Based on the theories of motivational interviewing and cognitive behavioral therapy, it is reasonable to believe that through the QAT intervention, a cognitive shift takes place, helping individuals modify their medication taking decisions. Improved treatments for schizophrenia need to be developed

through research to determine the effectiveness of interventions and increase understanding of the outcomes of interventions on the illness. The literature review supports the need for research that demonstrates the influence of QAT and its methods on changes in symptomatology and concordance with medication regimens.

Chapter III

Methodology

Introduction

This pilot study was conducted as partial requirement toward the degree of Master of Science in Nursing. In this chapter, the overall plan of the pilot study is detailed; the study design, site, participants, and procedures are described. Further, an explanation of the intervention, training, and monitoring of the pilot study is provided. Finally, a discussion and description of the data collection involved in measuring study variables and the procedures for protection of human subjects are included.

Pilot Study Design

A randomized, experimental pilot study design was developed to test if there was a difference in the severity of symptomatology of schizophrenia or medication concordance for individual participants who participated in an intervention of QAT. The intervention was added to the service user's usual treatment.

Site

Archways Behavioral Health Care Center (Archways) in Fort Lauderdale, Florida is a not-for-profit community mental health center (CMHC) and is the only site at which the research was conducted. This agency has a stated mission (see Appendix B for copy of Archway's Mission Statement) to "provide quality comprehensive behavioral health care to individuals and families who are in need of improving their quality of life" (Archway's Mission Statement, 1995). The agency, a member of Florida Council for Community Mental Health, has been in operation for over twenty years, and is a provider of services for Broward County Community Mental Health Services Division

(BCCMHSD). The State Department of Children and Families, Alcohol, Drug Abuse and Mental Health Program, through its contracts with BCCMHSD, is the main provider of mental health services in Broward County and maintains contracts with local providers for services.

Archways' mental health services include community mental health day treatment, several levels of residential community living services, case management, medication management, employment placement, individual counseling, and psychiatric evaluation services. The therapists involved in this pilot study are on staff at Archways, and provide ongoing therapy to clients at Archways. Archways provides a range of mental health services to approximately 425 service users living in Broward County, Florida.

The Chief Executive Officer (CEO) of Archways and the Board of Directors of Archways agreed to participate in the pilot study by offering service users the opportunity to participate in the intervention under study and documented this decision with a letter of support and agreement (see Appendix C for copy of the CEO's letter of support and agreement). The principal investigator received formal approval for this pilot study from the Florida International University, Institutional Review Board (IRB), on March 25, 2004 (see Appendix D for copy of IRB confirmation of approval to conduct research). Case managers, advanced registered nurse practitioners, and psychiatrists practicing at this site were informed and educated with regard to the aims of this pilot study and the implications for their practice, prior to its start.

To conduct this pilot study, the Chief Executive Officer of Archways directed the principal investigator to accept active volunteer status. This allowed the principal

investigator access to participants' records and the agency database in accordance with agency confidentiality protocol (see Appendix E for copy of Volunteer Confidentiality Agreement). The principal investigator was an employee of Archways for 8-years and is currently in a clinical preceptorship with a treating psychiatrist at this agency. The agency plans to implement the intervention of QAT on a regular basis after the completion of the pilot study.

Sample

One hundred thirty adult, male and female participants, with a current diagnosis of schizophrenia or schizoaffective disorder who were receiving psychiatric case management services from Archways, were approached for inclusion in the pilot study. The sample recruited was 24 participants, 10 in the experimental (QAT) group, and 14 in the comparison, treatment-as-usual (TAU) group, for this pilot study. Participants' ages ranged from 21 to 61, with 79% male and 21% female. The population ages ranged from 18 to 61, with 65% male and 35% female service users.

To achieve a power level of .80, 120 participants, with approximately 60 per group were needed. Because the resources available for the pilot study limited the total to 24 service users, the pilot study is obviously underpowered. However, completion of this pilot study will enable an estimate of effect sizes in our replication of the technique in South Florida, and thereby set the empirical basis for the funding of a larger study in South Florida.

Eligibility Criteria

Inclusion criteria for participants:

1. Current recipient of services from Archways Behavioral Health Care Center.
2. Diagnosis of schizophrenia or schizoaffective disorder utilizing the current DSM-IV-TR criteria.
3. Recommendation from mental health care provider for participants' inclusion in pilot study.
4. Male or female adult (over 18 years of age) willing to participate in pilot study and able to give informed consent.
5. Currently prescribed medication for treatment of schizophrenia or schizoaffective disorder.
6. Able to read and understand English language.

Exclusion criteria for participants:

1. Co-morbid Axis I diagnosis of moderate or severe learning disabilities or organic brain disorders.
2. Co-morbid Axis I diagnosis of substance abuse/dependence disorder, unless specified in remission.
3. Inpatient status at start of the pilot study.
4. Suicidal or homicidal ideation assessed at start of pilot study.
5. Children under the age of 18 are excluded from the pilot study.

Procedures

Clinician training. Dr. Richard Gray, RN, PhD, and Deborah Robson, RN, BSc, developers of the QAT program in the United Kingdom (U.K.), conducted clinician training. Individuals who received this training include: the QAT pilot study therapists, the principal investigator, the principal investigator's major professor, and the on-site research assistant, who assisted with randomization and on-site coordination/logistics. Training was conducted at Archways' conference room in accordance with the manualized training program, from February 23 through February 25, 2004, and covered the techniques and principles of QAT. The training was offered at no cost to the participants.

The QAT pilot study therapists currently provide individual counseling at Archways. One therapist has been employed by this agency for over nine years and is a licensed clinical social worker. Another therapist has been employed by this agency for four years and is a master's prepared, licensed mental health counselor. The third therapist has been employed by the agency for two and one half years and is a master's prepared registered marriage and family therapy intern, who recently completed two years of required supervision and is eligible to sit for licensure.

Recruitment. The referral source for recruitment of participants was Archways Behavioral Health Care Center in Fort Lauderdale, Florida. Participants were current clients receiving outpatient psychiatric healthcare services at the time of this pilot study. The principal investigator identified potential participants by virtue of their DSM-IV, Axis I diagnosis accessed through Archways' database. Addresses for potential participants were then extracted from this database. A letter inviting participation in QAT

therapy as part of a research project was mailed to all eligible participants (see Appendix F for copy of the invitation to participate letter). A postcard reply form was included with the letter requesting a response (see Appendix G for copy of postcard reply).

Potential participants were instructed via the invitation letter to drop off the postcard reply form, after having indicated on the reply card either, (a) interest in being contacted or (b) no interest in the study. A closed box was positioned in an easily accessible location behind the desk in the reception area of Archways for receipt of the reply cards. During the week following the mailing of the invitation letter, the principal investigator and the onsite research assistant made in person, follow-up contact at the site to both the potential participants who returned the reply card indicating interest and the non-responders. The principal investigator and onsite research assistant approached potential participants, personally at the clinic site through arrangements made with their case manager or day treatment advisors (see Appendix H for scripting of the follow-up contact).

During the second week following the mailing of the invitation, the principal investigator remained onsite for several hours, on several days to be available for approach from potential participants. Concurrently, during this second week, Archways' residential director and the day-treatment supervisor notified potential participants of the principal investigator's availability. Potential participants then met with the principal investigator at the clinic site. Once participants agreed to participate, informed consent was obtained (see Appendix I for copy of Informed Consent) and appointments were scheduled for baseline assessments.

All participants received scripted verbal instructions and understanding was confirmed before participants' completion of the self-administered instruments. The principal investigator and the designated offsite research assistant completed the baseline SCI-PANSS assessments for all pilot study participants who signed informed consent. At the same interview, each study participant completed the PETiT, a self-scored scale. Both the principal investigator and the offsite research assistant were blind to the comparison or experimental status of the participant.

The onsite research assistant using random table assignment assigned the twenty-six participants who signed an informed consent into either the TAU group of 14 participants, who continued to receive treatment as usual or the QAT group of 12 participants who received the intervention. The onsite research assistant, who alone knew the participants' names and associated identification numbers, and completed this procedure, assigned each participant an ordinal pilot study identification number. Then, the onsite research assistant used the JavaScript random number generator program, *Research Randomizer* (Houle, 1997-2003) available at http://www.randomizer. org/ to produce customized sets of random numbers. Each participant was then assigned to either the QAT or TAU group. The current version of *Research Randomizer, v3.0random table*, uses the *Math.random* method within the JavaScript programming language to generate its random numbers (Houle). This program generates random number tables by use of a complex algorithm seeded by the computer's clock (Houle).

Once random assignment was completed, participants in both study groups were notified of their status. The onsite research assistant notified participants assigned to the TAU group of their status. Comparison participants were reminded to not discuss their

study status with either the principal investigator or the offsite research assistant. Either the onsite research assistant contacted participants assigned to the QAT group or their pilot study therapist and individual appointments were scheduled among the three therapists. QAT therapists contacted experimental participants directly in order to schedule appointments. Experimental participants then participated in 1 – 2 sessions of QAT per week. The onsite research assistant maintained contact with the TAU group of participants through casual contact during her working hours at Archways. The onsite research assistant works full time at Archways in the day treatment program. In the course of a typical working day, she has casual contact with most day treatment clients, which included comparison and experimental participants.

Data collection.

Data were collected at baseline, before the introduction of the intervention, and at follow-up, after completion of the intervention. At baseline, demographic information for all participants was extracted from the medical chart to include: gender, age, date of birth, ethnicity, years of education, number of psychiatric hospitalizations, and residential situation (see Appendix J for Demographics Information Collection Form). Demographic information was collected to establish a basis for comparison between the TAU and QAT groups and to analyze for significance of group differences.

Measures

Two major instruments, the *Structured Clinical Interview Positive and negative syndrome scale* (SCI-PANSS) and the *Personal Evaluation of Transitions in Treatment* (PETiT), were completed at baseline and follow-up. These two instruments were used to measure the dependent variables in this pilot study, severity of symptomatology and

medication concordance respectively. Further, the *Schedule for the Assessment of Insight – Expanded* (SAI-E), and the *Liverpool University Neuroleptic Side-Effect Rating Scale* (LUNSERS) were used to monitor participants' participation in the intervention and to provide QAT therapists with a formal means of obtaining information pertinent to the participants' experiences with psychiatric medications

Positive and Negative Symptom Syndrome Scale (PANSS). The PANSS is a scale measuring the positive and negative symptom syndromes experienced by individuals with schizophrenia (Kay, Opler, & Lindenmayer, 1989). A Structured Clinical Interview component can be used with the PANSS, called the SCI-PANSS that provides interviewers with increased consistency. The publishers and authors of this instrument report that the SCI component, a series of questions, increases inter-rater reliability and optimizes the scale's objectivity and standardization (Kay, Opler, & Fiszbein, with Ramirez, & White, 2000) (see Appendix K for selected examples of SCI-PANSS).

The PANSS is a standardized measure of the presence of symptoms in schizophrenia. It consists of 30-symptom items that are rated on a 7-point Likert scale, with 1 being equal to the absence of a symptom and 7 being equal to extreme interference of a symptom. Kay et al. (1989) reports the PANSS yields four syndrome scores (*positive, negative, composite and general psychopathology*) and five cluster scores (*anergia, thought disturbance, activation, paranoid belligerence and depression*).

Higher scores on PANSS subscales reflect a greater severity of symptomatology. The range of possible scores for the PANSS positive and negative subscales is from 7 – 49. The PANSS positive subscale is comprised of scores for the presence and severity of seven symptom identifiers: delusions, conceptual disorganization, hallucinatory behavior,

excitement, grandiosity, hostility and suspiciousness/persecution. The PANSS negative subscale is also comprised of scores for the presence and severity of seven symptom identifiers: blunted affect, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, difficulty in abstract thinking, lack of spontaneity, stereotyped thinking and flow of conversation. The range of possible scores for the PANSS general psychopathology subscale is from 16 – 112. The PANSS general psychopathology subscale is comprised of 16 symptom identifiers: somatic concerns, anxiety, guilt feelings, tension, mannerisms and posturing, depression, motor retardation, uncooperativeness, unusual thought content, disorientation, poor attention, disturbance of volition, lack of judgment and insight, poor impulse control, preoccupation, and active social avoidance (Kay, & Fiszbein, with Ramirez, & White, 2000).

Scores in the initial standardization studies indicate a moderately high internal reliability with Cronbach's alpha coefficients ranging from, $\alpha = 0.73$ to $\alpha = 0.83$ with $p < .001$ (Kay et al., 2000). Studies have demonstrated confirmation of this instrument's good construct validity for mutually exclusive symptom dimensions (Kay et al.). The SCI-PANSS is used clinically and has been used in numerous studies to evaluate the severity of symptomatology in schizophrenia and its relationship with an intervention to reduce symptomatology (Gray, Robson, & Bressington, 2002; Gray, Wykes, Edmonds et al. 2002; Hughes et al., 2002; Rector, Seeman, & Segal, 2002). Additionally, the PANSS or SCI-PANSS is routinely used in clinical trials of neuroleptic medications to evaluate symptom reduction related to the use of medications (Oehl et al., 2000; PORT 1998).

Personal Evaluation of Transitions in Treatment Scale. The PETiT was developed to assess the subjective evaluation of an individual's experience with treatment

for schizophrenia (Voruganti, & Awad, 2002). This instrument is a 30-item, self-rated, scale with each item receiving a rating scale of (a) always, (b) sometimes, and (never). These scales are converted to scores with 0 = negative response, 1 = sometimes, and 2 = a positive response. The scale labels *always* and *never* and their corresponding values vary according to the wording of the question. Comparatively higher scores indicate a higher satisfaction with treatment and medication compliance. The score considers subjective aspects of psychosocial functioning and quality of life including medication compliance specific questions (Voruganti, & Awad). The scale is perceived as user-friendly by subjects and can be completed in approximately 3 – 8 minutes. Voruganti, and Awad reported high internal consistency, with a Chronbach's alpha $\alpha = 0.96$ and good split-half reliability (see Appendix L for copy of PETiT).

At the suggestion of Dr. Richard Gray, this tool was recommended to capture the participants' medication concordance based on the item composition (R. Gray, personal communication December 12, 2003). Voruganti and Awad indicate that this scale should be very useful in intervention research for individuals with schizophrenia (2002). Further Voruganti and Awad suggest in the scales instructions for use, that the last six items of the scale can be used as a subscale to assess medication concordance. PETiT was recently developed and validated in 2002 and as a result no other published studies were found that used this measure for research outcomes. Several researchers have requested to use this scale; so further information regarding the usefulness of this scale should be forthcoming in the literature (Kathryn McColl, personal communication January 26, 2004).

Schedule for Assessment of Insight. The SAI-E is a measurement tool completed by the clinician formulated to assess an individual's level of insight in to diagnosis, awareness and understanding of symptoms (David, 1990). Components of this instrument measure treatment compliance, awareness of illness and ability to re-label psychotic symptoms correctly (Kemp, & David 1995). Research regarding the scale reveals a Cronbach's alpha, $\alpha = 0.92$ (Sanz, Constable, Lopez-Ibor, Kemp, & David, 1998). SAI-E is useful in assessing relevant treatment and patient related variables with regard to the subject's abilities, willingness, and understanding of mental illness and treatment (Kemp, & Lambert, 1995). This scale was used to provide QAT therapists with a consistent and formal procedure for assessing participants' insight, and no outcome data will be analyzed from this scale (see Appendix M for copy of the SAI-E).

Liverpool University Neuroleptic Side-Effect Rating Scale. (LUNSERS). This instrument is a self-rated, 41-item scale, which measures the frequency of medication side effects (Day, Wood, Dewey, & Bentall, 1995). Day, et al. reports the test-retest reliability of the LUNSERS is satisfactory ($r = 0.811$, and $p < 0.001$) (1995). For this scale, service users self rated their experiences choosing from a continuum of 5 responses ranging from *Not at all* to *Very much*. The QAT pilot study therapists used this assessment tool for evaluating presence and impact of side effects. The LUNSERS covers known psychological, neurological, autonomic, hormonal and miscellaneous side effects (Morrison et al., 2000). In addition, this scale contains 10-red herring items, which assist researchers in identifying individuals who might tend to either over-estimate or have cognitive difficulties, impeding their ability to recognize side effects (Morrison et al.).

Studies of the effects of a CBT intervention (Sensky et al., 2000), a medication management intervention by Gray, Robson, & Bressington, (2002) and a study of an education intervention (Macpherson et al., 1996) each used the SAI-E and the LUNSERS to evaluate outcomes and relationships between the variables of side effects and insight in their interventional studies (see Appendix N for copy of the LUNSERS). After the baseline data was collected, the QAT intervention was introduced to the experimental participants.

Explanation of Intervention

Quatro Adherence therapy is a structured pragmatic intervention based broadly on the techniques of motivational interviewing and cognitive behavioral therapy (Gray, Gournay, David et al., 2001, p. 13). The process of this intervention, involves the therapist working to develop discrepancy and importance as two key concepts in resolving ambivalence (Gray, Gournay, David et al.).

Before the start of therapy, therapists considered the physical environment, privacy, shared access with participants to notes taken and style of dress (Gray, David, Gournay et al., 2001). The physical environment was private and comfortable for both therapist and participant and style of dress was casual and modest. Furniture was arranged so that both therapist and participant had access to a common writing surface. Adjustments were made to encourage rapport building.

Goals, Principles and Overriding Themes

Therapeutic guidelines required the therapist to follow participant responses carefully (Gray, Gournay, David et al., 2001). Participants were made aware that the therapist would be listening carefully in order to develop an understanding of the

participant's viewpoint. Attentive listening on the part of the QAT therapist was crucial to picking up the threads of positive statements in the client's narrative.

The therapy had three phases, followed by an evaluation, and usually spans eight individual sessions for completion. Quatro Adherence Therapy embraces social learning theory, which explains that as social beings, humans talk themselves into what they believe. Peplau's theory of the nurse-patient relationship also stresses that conscientious listening on the part of the nurse allows the patient to develop a narrative within which changes in self-view can develop. QAT pilot study therapists in at least two ways applied this theory, (a) clients were specifically asked to describe the good things about medication and treatment, and (b) clients were asked to elaborate when they verbalized positive change statements (Gray, David et al., 2003). There were several key principles overriding each session. These principles require the therapist to:

1) Take an active therapeutic stance during the course of therapy.
2) Emphasize personal choice and responsibility.
3) Facilitate the building of self-esteem in the client.
4) Encourage identify and support self-efficacy for the client.
5) Maintain a flexible, neutral and safe environment.

These principles were applied in therapy by the use of specific counseling techniques required of the therapist. These techniques were learned by the therapist through formal education in a master's program of study and refined through years of clinical supervision.

Required counseling techniques include:

1) Collaborative agenda setting
2) Feedback and understanding
3) Reflective listening
4) Collaboration
5) Pacing and efficient use of time
6) Developing discrepancy
7) Dealing with resistance

Each session began with a *concern check* and *agenda setting*. This was important for immediate concerns or problems of the participants to be addressed at the start of each session. This allowed both therapist and participant to focus on the goals of adherence therapy for the remainder of each session.

Fidelity to these therapeutic techniques was critical to maintaining the integrity of the intervention, as progress was made through each phase of therapy. The initial phase termed, *engagement phase,* was typically completed in the first session. The second, *assessment* phase was completed in one to two sessions and guided by an assessment form. The third phase consisted of five to six sessions, comprising the *therapeutic* phase. After the completion of the third phase an evaluation was conducted, and concluded, usually in one session.

Quatro Adherence Therapy Interventions

In the initial session, therapists engaged in conversation with the participant, establishing rapport. This was done through a focused discussion regarding the participant's views of taking medication. Acceptance of participant views, genuine

interest, feedback of understanding and a conversational style were crucial to the engagement phase. Expectations and clarification of the process were provided to the participant at each session. The assessment phase was structured according to an assessment form. This form was completed as a collaborative effort and the participant was given a copy of the summary at the completion of the assessment phase. Focus in the assessment phase was on eliciting participant's views about medication and thoughts about current and previous treatment. Although engagement was considered complete after the initial session, a need for a return to engagement strategies was assessed as therapy progressed.

Information gathered in the assessment phase provided a basis for discussion during the therapeutic phase. The therapeutic phase was managed with the use of discreet interventions, of which five were mandatory, and six were discretionary. Each intervention was designed to address importance, confidence or both of these concepts as they related to the participant's medication/treatment adherence (Gray, David, Gournay et al., 2001). These discreet interventions or exercises were delineated in the QAT training session; several employed simple pencil-and-paper forms to assist in clarification and fidelity to the therapeutic process.

At the completion of the therapeutic phase, a last session was scheduled to conduct an evaluation. The evaluation phase, one session, was essentially a repeat of the assessment phase conducted in an informal, conversational, and collaborative manner (Gray, David et al., 2003). The goal was to review the course of the illness and consider the progress made throughout therapy. It is especially helpful to clarify how ambivalence may have been resolved over the course of therapy.

Mandatory interventions. These interventions are required to be delivered within the course of the therapeutic phase of QAT. All descriptions of mandatory interventions were adapted from, *Adherence Therapy Manual, Version IV*, (Gray, David et al., 2003).

1) *Sorting Out Practical Issues*: This intervention addressed issues related to obtaining medication or influencing the participants' forgetting to take medication. Practical solutions were generated for simple problems.

2) *Looking Back*: This intervention explored previous treatment experiences and strategies that were helpful as well as those that were not helpful. Repeated failures may diminish self-efficacy, so emphasis in this exercise was on positive and helpful experiences. Therapists made detailed notes with the client and worked logically through the experiences. Emphasis was made for any links between stopping medication and relapse. Negative experiences were not ignored.

3) *Exploring Ambivalence*: This exercise explored the variety of beliefs and uncertainties about the importance of medication. Emphasis was on assisting participant to explore their personal reasons for taking or not taking medication. Dialogue was focused on the *good* and *not so good* things about medication. Therapist provided structure, listening and summarizing. Therapists did not argue whether to stop or to take medications, nor did they tell clients the advantages or costs of taking or not taking medications.

4) *Discussing Beliefs and Concerns*: Summary of clients' beliefs about illness and treatment should have emerged by the time this intervention was introduced. Beliefs were explored one by one, asking the client to talk about

evidence both for and against each belief. Clients were asked about different thoughts and encouraged to think about evidence. Therapists summarized regularly.

5) *Looking Forward:* In this exercise, focus was on maintenance of change. Identifying goals or targets that the participant identified and would like to achieve. Potential barriers were addressed. A problem solving approach was used to identify broad and specific goals. Therapists used this opportunity to talk about the importance of maintaining health in order to achieve self-identified goals. Therapists helped build confidence with summarizing positive examples.

Discretionary interventions. These interventions are deployed at the discretion of the QAT therapist based on their assessment of the client's needs during the therapeutic phase of QAT. Each discrete intervention addresses a specific issue that may be relevant to an individual client's situation. All descriptions of discretionary interventions were adapted from, *Adherence Therapy Manual, Version IV* (Gray, David et al., 2003).

1) *Examining Negative Treatment Experiences*: Clients with unpleasant memories of being restrained or given an intra-muscular injection of medication were invited to share and have these experiences acknowledged. Clients were also encouraged to be more involved and take control of treatment decisions.

2) *Identifying the Less Obvious Benefits of Medication:* If clients failed to see a link between medication and symptom reduction, less obvious benefits were explored carefully. Time was spent exploring alternative benefits such as

fewer fights, getting on better with family, and staying out of the hospital. Offers to spend time talking about less obvious effects of taking medication were made. Everyday things that are easier to do or how other people react or what other people may say about them when the client is taking medication were explored. Clients were not told how much better they are when on medication.

3) *Target Symptoms*: The therapist assisted the client to identify which symptoms or feelings they would like to target. Some clients say they feel more relaxed or can think better. The clients' own words and symptoms were rated on a severity scale over time and used to monitor change in target symptoms. Monitoring may help provide a link between medication and benefits, but this was for the client to describe and monitor, not the therapist.

4) *Normalizing Rationales*: Some clients tend to think of medication as a *cure*, like antibiotics, time-limited and not needed once they *feel better*. Clients were helped to reframe the illness as one that requires maintenance treatment. The vulnerability-stress model was explained in detail. The therapist helped the client to look back over experiences of treatment and make the link between increased susceptibility to stress. Only if the client accepted rationale were analogies made to other illnesses. Emphasis was made that everybody has potential to get ill.

5) *How Things Would Be Different If...*: Therapists asked the client to think hypothetically about stopping medication and then to think hypothetically about continuing to take medication. The aim was to further explore the

importance of taking medication. Therapist emphasis was on how things would be different if……

6) *Medication Problem Solving*: This exercise addressed problems clients have with medication. Side effects, such as weight gain might have been discussed. A problem solving strategy was used to address the problems. A specific problem was chosen and agreed on as a target to achieve. Broad steps needed to achieve the goal were outlined. Client decided on the details of what the practical and realistic tasks necessary to achieve were, then progress was reviewed. Achievable, realistic goals were chosen.

Offsite Monitoring

Monitoring of the intervention for fidelity involved recorded audiotapes of ten randomly selected therapy sessions. All potential sessions were identified and assigned an ordinal identification number. The process for selection of random sessions for taping was the same process utilized for participant assignment as described earlier. Participants were informed of the taping and had the opportunity to refuse the audio taping of the session. Refusal to participate in audio taping of a session did not affect the participants' involvement in the pilot study. A signed release was obtained from the participant and therapist upon consent (see Appendix O for a copy of the Media Consent/Release Form for audiotape).

One copy of each of the original audiotapes was made. The copies were sent to Dr. Richard Gray, RN, PhD and Deborah Robson, RN, BSc for them to determine this pilot study's fidelity with established standards. This assessment was conducted using the *Therapist Fidelity Monitoring Protocol* (Gray, & Robson, 2002) (see Appendix P for

copy of *Therapist Fidelity Monitoring Protocol*), a recognized fidelity-monitoring tool already in use in the U.K. to measure fidelity with training standards. This procedure will allow future analysis and comparison of therapeutic standards between the U.K. and this South Florida pilot study.

Onsite Monitoring

The principal investigator's major professor, who also completed the adherence therapy training, provided regular onsite supervision to the adherence therapists. She is an Advanced Practice Nurse, and Licensed Marriage and Family Therapist with 20 years of experience providing psychotherapy and case supervision, and 15 years experience providing inpatient psychiatric services.

Quatro Adherence Therapy Program Satisfaction Questionnaire (QPSQ) (Ford, & Anderson, 2004). The principal investigator and major professor developed this form in order to gather information regarding user satisfaction with both the intervention and the experience as a study participant. Information from this survey was analyzed to determine how study participants perceived the intervention. Feedback regarding the pilot study from participants is potentially useful to modify future delivery and research of this intervention (see Appendix Q for copy of the QPSQ).

At the completion of the intervention, the onsite research assistant and the QAT pilot study therapists organized scheduling of appointments with both the QAT group participants and the TAU group participants for the follow-up assessments. The principal investigator and off site research assistant completed all follow-up assessments. The TAU group was scheduled to receive QAT after the follow-up assessments were completed.

Data Analysis

Statistical analysis included univariate *t*-tests to examine the effect of the intervention on the dependent variables of severity of symptomatology, measured by the SCI-PANSS, and medication concordance, measured by PETiT. Mean baseline and change scores allowed for comparison between groups. Mean and change scores were then compared by group using *independent sample t-tests.* Additionally, follow up data for all subscales were compared separately for each group *using paired sample t-tests* to determine significant within group differences.

A MANOVA analysis examined change over time for each dependent variable. Statistical analysis examined significance of differences between baseline and follow-up measures of the dependent variables. Results of the statistical analysis of the SCI-PANSS, and PETiT data and descriptive statistics (means, standard deviation and skew) of the demographic data, are presented in the results section of this thesis. Test results were considered significant for $p < .05$. Comparison of demographic variables for significant differences between the experimental (QAT) and comparison (TAU) groups was conducted using independent samples and paired sample *t*-tests (Polit, & Hungler, 1999), as well as Chi Square and crosstabulations to determine significance of variance at baseline between the two groups.

Protection of Participants

This pilot study examined the differences between baseline and follow-up measurements of concordance and severity of symptomatology scores. All individuals who participated in the conduct of this pilot study have completed the required IRB

training (see Appendix R for Human Participation Protections Certification for all study participants).

Participants were expected to benefit from participation in this pilot study by receiving individual counseling aimed at increasing their knowledge and awareness of their diagnosed illness and medication regimen. A 20% improvement in psychopathology or mean change score of .45 measured by the SCI-PANSS would represent meaningful improvement (Cramer, Rosenheck, Henderson, Thomas, & Charney, 2001). If as anticipated, this intervention was found to be associated with positive results for the pilot study participants, Archways plans to offer QAT to other individuals at the study site.

QAT is designed to minimize discomfort and therapist "scripting" addresses emergent concerns or problems both before and after the completion of therapy sessions. Therefore, other potential problems elicited from participants are not avoided or disregarded in order to meet pilot study requirements. QAT therapists noted that no emergent problems required addressing. Psychiatric and case management staff were available through regular Archways policy, either in person or by phone, to address any emergent crises. Therapists accommodated scheduling needs of participants as much as possible.

The researcher was available at all times by cell phone to answer procedural questions regarding the intervention. In addition, Dr. Gray and Ms. Robson were available via email to respond to specific questions and provided co-clinical supervision on one occasion with Dr. Anderson via telephone conference call.

Alternative Treatments

All participants were free to consider and pursue alternative treatment, but none was offered beyond the eight-session intervention of the QAT program. This pilot study was designed to provide an additional intervention to the regimen of services the participant was already receiving. Usual and customary treatment was provided to all participants during the pilot study.

Pilot Study Costs and Compensation

Participants did not incur any costs related to participation in the pilot study. All participants had established access to Archways for collateral mental health services. There was no compensation for pilot study participants; however, light refreshments were available at therapy sessions and at interactions involving completion of pilot study assessments. At the completion of follow-up measurements, all participants in the pilot study were invited to attend an informal meeting where light refreshments were served and discussion was encouraged.

Informed Consent

All potential participants who responded to the invitation to participate in the pilot study were given a copy of the informed consent form and asked if they required assistance with reading the form. Two participants requested assistance with reading the form and subsequently the informed consent was read aloud to them. The principal investigator engaged participants in conversation and encouraged them to ask questions to ascertain participants' understanding of study risks, benefits, time expenditures, expectations of participation and compensation. Participants were informed that the goal of the pilot study was to determine if an intervention of counseling was helpful to

individuals with schizophrenia. Participants were questioned using open-ended questions such as, "What do you think the counseling is for?" and "What do you think this pilot study involves?" The principle investigator was assured of the participants understanding and verbal consent through answers provided by the participants. After understanding was confirmed verbally, written informed consent was obtained through the participant's signature on the consent form, signature of witness and photocopy provided to the participant. Eight participants refused to keep a copy of the informed consent. These participants were advised they could obtain one at any time through the principal investigator or by requesting a copy from their case manager at Archways. Original consents for all pilot study participants will be kept in a locked fireproof box at the principal investigator's home for a minimum of three years following completion of the pilot study. Copies of the signed informed consent forms were also placed in the participant's chart maintained by Archways' Medical Records Department.

All pilot study participants are adults over the age of 18 and signed their own adult consent forms. One consent document, written in English, was developed for this pilot study; all QAT therapists, the research assistants, the principal investigator and pilot study participants are English speakers. No waiver of written consent was sought. The consent was prepared at a fifth-grade reading level, using Microsoft software Flesch-Kincaid assessment, which is consistent with both IRB requirements and the studies regarding literacy and universal ease of understanding (Fisher, 1999), as well as awareness of participants reading differences.

Confidentiality of Data

As data was collected, the principal investigator, both research assistants and each therapist maintained confidentiality of participants' participation by safeguarding data from casual observers and refraining from discussion about the pilot study except when in regular study progress meeting. All therapists also signed an informed consent form (see Appendix S for copy of the Therapist Informed Consent Form).

Removing participants' names from the data collection forms and identifying each form with participants, pilot study identification number only maintained confidentiality of written data. Data collection forms maintained on site were kept in a locked portable file box.

The principal investigator maintained at her residence pilot study-generated data including, audiotape and paper documents on file in a locked, fireproof box throughout the course of the pilot study and will maintain confidentiality and security of the data for three years following completion of the pilot study analysis. For the duration of the pilot study, documents generated on site from the pilot study remained in a locked cabinet in the medical records department at Archways, or in a locked fireproof box at the residence of the researcher. Transportation of data from the pilot study site to the principal investigator's home was made via locked file box in principal investigator's possession.

Chapter IV

Results

Introduction

The purpose of this pilot study was to examine the effects of the QAT intervention on service users' symptomatology and medication concordance scores. Quantitative data obtained from PANSS scores were used as a measure of severity of symptomatology and the PETiT, a self-report scale, was used as a measure of medication concordance. Results of this pilot study are discussed in this chapter, including demographic characteristics, descriptive statistics, and the results of the quantitative data analysis. Quantitative and qualitative data obtained from the QAT program satisfaction questionnaire (QPSQ) completed by experimental participants at the end of the intervention is also presented. The experimental, Quatro adherence therapy group (QAT), and the comparison, treatment as usual group (TAU), baseline and follow-up mean scores were compared using *t*-tests to analyze the differences in scores for symptomatology severity and medication concordance. A repeated measures ANOVA was also done to document the interaction effects of *time X time* and *time X condition* for both the QAT and TAU groups. The baseline assessments were completed and scored before the introduction of QAT and the follow-up assessments, at the completion of the intervention.

A randomized, experimental pilot study design was used to examine if there was a difference in the severity of symptomatology of schizophrenia or medication concordance for individual participants who participated in an intervention of QAT. Archways, a local community mental health center, was the only site where the research was conducted.

Participants were recipients of services from Archways with a diagnosis of schizophrenia or schizoaffective disorder.

QAT is a "structured pragmatic intervention based broadly on the techniques of motivational interviewing and cognitive behavioral therapy" (Gray, Gournay et al., 2001, p. 13). The therapist and participant form a therapeutic relationship denoting the interpersonal process, which develops in the nurse-patient relationship (NPR) described by Peplau (1952). As part of the QAT process, aspects of the participants' mental health, illness and medication concordance are addressed. The process of this intervention involves the therapist working to develop discrepancy and importance with the participant as a means of resolving ambivalence towards medication taking behaviors and treatment of mental illness. The major professor provided regular onsite supervision to the adherence therapists.

Sample Data Results

Twenty-five participants were enrolled in the pilot study after signing the informed consent. Randomization of participants was based on 26 participants due to the error of two participants erroneously reporting enrollment to the onsite research assistant. Subsequently two participants were dropped from the QAT group, one due to failure to sign informed consent and the other due to incorrect diagnosis. These two participants, randomized to the QAT group, received the intervention based on their requests to participate in therapy. However, they were excluded from the data collection process. As a result, for purposes of this pilot study, the QAT group consisted of ten participants and the TAU group consisted of fourteen participants. One comparison participant was dropped from the pilot study due to hospitalization for exacerbation of symptoms of

schizophrenia. Subsequently 10 experimental participants and 13 comparison participants were available for follow-up assessments. No participants left the pilot study voluntarily, which is unusual for studies of mental health interventions. However, the small n and stable nature of the participants' relationship with Archways was likely influential in maintaining the cohort.

Demographic Data

The frequency and percentage distribution of the participants by demographic factors were computed at baseline to describe the sample characteristics (Polit, & Hungler, 1999) and are found in Table 1. Demographic data were obtained through a chart review of participants' medical records. The pilot study sample was predominantly male (78.3 %) and white non-Hispanic (65.2%). The mean age of the sample (n = 23) was 42.9 years old and most (69.6%) lived in the community. Hospitalizations for psychiatric care were somewhat varied, 52% of the sample had between 1 and 10 hospitalizations and 26% had between 11 and 30 hospitalizations. Considering education, 60% of the pilot study sample completed high school and 40% had less than a high school degree or its equivalency.

Crosstabulation and Chi Square tests were conducted to compare baseline categorical variables of diagnosis, sex, residence, race and years of education for significant differences in the proportions of these variables across both groups (Polit, & Hungler, 1999). The nonparametric test, Mann-Whitney U test (Polit, & Hungler), was used for comparison of differences between the two groups on the variables of number of hospitalizations and years of education. There were no significant differences between the comparison, (TAU) and experimental (QAT) groups with respect to descriptive

variables of diagnosis, sex, age, type of residence, number of hospitalizations, and years of education, $p > .05$. Results of the t-test analysis of age revealed no significant difference between the QAT and TAU groups. Mean age for the QAT group was 39.4 with SD of 13.01. Mean age for the TAU group was 46.1 with SD of 10.08.

Table 1

Distribution of Demographic Variables by Group

Variable	QAT		TAU	
	n	%	n	%
Sex				
Male	8	80.0	10	6.9
Female	2	20.0	3	3.1
Ethnicity				
White non-Hispanic	7	70.0	8	1.5
Black non-Hispanic	2	20.0	4	0.8
Hispanic	1	10.0	1	.7
Housing				
Community residence	6	60.0	10	6.9
Residential facility	4	40.0	3	3.1

Table 1 continues.

Table 1 (continued)

Variable	QAT		TAU	
	n	%	n	%
Hospitalizations				
0	1	10.0	3	23.1
1 to 10	5	50.0	7	53.8
11 to 20	2	20.0	0	0.0
21 to 30	2	20.0	2	15.4
31 or more	0	0.0	1	7.7
Years of Education				
Grammar / Middle School	0	0.0	1	7.7
Some years High School	3	30.0	5	38.5
High school / Equivalency diploma	5	50.0	6	46.2
Some college	1	10.0	1	7.7
Completed college	1	10.0	0	0.0
Diagnosis				
Schizophrenia	5	50.0	7	53.8
Schizoaffective Disorder	5	50.0	6	46.2

Interestingly, one experimental participant terminated services with Archways, during the pilot study: however, this participant completed QAT and returned to complete follow-up assessments. Participant commitment to the pilot study and scheduling may have been facilitated because of the small number of participants in the pilot study,

frequent casual contact with pilot study participants and the onsite coordinating of logistics by the onsite research assistant, who is an employee of the pilot study agency.

Research Question 1: Results

> Research question 1: *Is there a difference in the severity of symptomatology for service users with schizophrenia or schizoaffective disorder after participation in the QAT intervention?*

The *Positive and Negative Syndrome Scale* (PANSS) measured the positive and negative symptom syndromes and general psychopathology experienced by individuals with schizophrenia and schizoaffective disorder to address the dependent variable of severity of symptomatology (Kay, Opler, & Lindenmayer, 1989). The scale was administered using the structured clinical interview component. A decrease in PANSS scores by 20% would indicate a clinically significant improvement in symptomatolgy. Consistent with other published studies, for comparison of the QAT and TAU groups, this pilot study used three PANSS subscales: positive, negative, and general psychopathology.

Total subscale raw scores are converted to T-scores and percentile scores, which are ascribed a comparative categorical description ranging from *very much below average* to *very much above average* in relation to the normative group of 240 medicated schizophrenics. Percentile scores for each subscale are based on the normal distribution curves (Kay et al., with Ramirez et al., 2000) found in the normative group.

Baseline data, Positive and Negative Syndrome Scale. Baseline mean symptom subscale scores were computed for the PANSS subscales to allow for baseline statistical comparison and results are reflected in Table 2. For the PANSS, the experimental (QAT) and the comparison (TAU) groups' mean positive and negative symptoms did not differ

significantly at baseline. There was significant difference between the groups on the mean negative symptoms, $p < .01$ (Table 2). Mean score for the QAT group negative subscale was 17.00 whereas the mean for the TAU group negative subscale was 22.38, at baseline. PANSS manual interpretive guidelines allow comparison of this cohort at baseline with the PANSS normative sample regarding severity of symptom syndrome (Kay et al., with Ramirez et al., 2000). The sample scores were compared to the *T*-scores and the percentile scoring of the normative group with participants' scores ranging from 21st to 50th percentile. Compared to the normative group scores, the QAT group's positive and general subscale scores are in the average range and their negative subscale score falls in the slightly below average range. The scores reflected in Table 2 indicate, the TAU group had a higher severity of positive, negative and general symptoms when compared to the QAT group measured at baseline. However, when compared to the normative group scores, the TAU group's positive, negative and general subscale scores are in the average range.

Table 2

PANSS Subscales Baseline by Group

Group	PANSS Subscale	n	Mean	SD	t
QAT	Positive	*10*	*17.90*	*5.34*	
					0.28
TAU	Positive	*13*	*18.54*	*5.50*	
QAT	Negative	*10*	***17.00***	*4.16*	
					**2.68
TAU	Negative	*13*	***22.38***	*5.20*	

Table 2 continues. ** $p < .01$

Table 2 (continued)

Group	PANSS Subscale	n	Mean	SD	t
QAT	General	*10*	*39.70*	*8.26*	0.17
TAU	General	*13*	*40.30*	*8.42*	

Follow-up data, Positive and Negative Syndrome Scale. Descriptive statistics were computed for the PANSS follow-up scores to allow for comparison. Change scores for both the QAT and TAU groups were computed between the baseline and follow up data for the PANSS subscales (Positive, Negative and General Psychopathology).

Table 3 shows statistics computed for the QAT group PANSS subscales from baseline to follow-up. No significant differences were found for any of the three subscales from baseline to follow up, $p > .05$. Mean scores for the QAT group, decreased for each subscale indicating some decrease in severity of symptomatology. However, there is a relatively high variability of scores as indicated by the large standard deviation (SD). This large SD may be reflective of a heterogeneous group. In comparison to the PANSS normative group, the QAT group's positive, negative, and general subscale scores at follow up, each fall into the *slightly below average* group. This represents a decrease in descriptive terms for both the positive and general subscales from baseline scores in the average range. It is critical to note that the positive symptoms for the QAT group decreased 22% from baseline to follow-up, which indicates a clinically significant improvement in symptomatology.

Table 3

PANSS Subscales for QAT Group at Follow-up (n=10)

PANSS Subscale	Baseline		Follow-up		
	Mean	SD	Mean	SD	*t*
Positive Subscale	17.9	5.34	14.9	8.01	1.56
Negative Subscale	17.0	4.16	16.0	6.39	0.65
General Psychopathology	39.7	8.26	33.5	17.79	1.16

Table 4 shows statistics computed for the TAU group PANSS subscales from baseline to follow-up. No significant differences were found for any of the three subscales from baseline to follow up, $p > .05$. Mean scores for the TAU group, decreased for the positive and general psychopathology subscale indicating some decrease in severity of symptomatology. Mean scores remained the same for the negative subscale. There is a relatively high variability of scores as indicated by the large standard deviation (SD). In comparison to the PANSS normative group interpretive guidelines, the TAU group's positive subscale score fell in the slightly below average range, but not at a clinically significant level and the negative and general subscale scores remained in the average range at follow-up.

Table 4

PANSS Subscales for TAU Group at Follow-up (n=13)

PANSS Subscale	Baseline		Follow up		
	Mean	SD	Mean	SD	*t*
Positive Subscale	18.5	5.50	14.8	5.17	1.98
Negative Subscale	22.38	5.20	22.38	7.63	0.00
General Psychopathology	40.3	8.42	35.4	9.88	1.75

The two groups were compared to one another from baseline to follow-up to determine significance of the intervention for the PANSS subscales. Table 5 shows mean decreases for the PANSS subscales by group. For both the QAT and TAU groups there were no significant differences (see Table5) in mean change scores from baseline to follow-up. For all three PANSS subscales, $p > .05$, the intervention was not associated with a statistically significant decrease in severity of symptomatology.

Table 5

PANSS Subscales Mean Change from Baseline to Follow-up by Group

Group	PANSS Subscale	n	Mean	SD	*t*
QAT	Positive Subscale	10	3.0	6.07	0.28
TAU	Positive Subscale	13	3.8	6.87	

Table 5 continues.

Table 5 (continued)

Group	PANSS Subscale	n	Mean	SD	t
QAT	Negative Subscale	10	1.0	6.67	0.28
TAU	Negative Subscale	13	0.0	9.64	
QAT	General Psychopathology	10	6.2	16.96	0.23
TAU	General Psychopathology	13	4.9	10.13	

Finally, in order to document the effects of time and time X condition interactions, a repeated measures Anova analysis was run for baseline to follow-up data. For both the QAT and TAU groups for the PANSS positive subscales there was a significant difference over time ($F = 6.055$; $p = .023$) and no significance for time X group interaction. For both the QAT and the TAU groups for the PANSS negative and general psychopathology subscales there was no significance for time X group or over time interaction, $p > .05$. Lack of significant findings for time X condition interaction suggests that the groups did not change differently from one another over time on the measurement of severity of symptomatology.

Research Question 2: Results

Research question 2: *Is there a difference in medication concordance for service users with schizophrenia or schizoaffective disorder after participation in the QAT intervention?*

The PETiT scale measured the participants' self-evaluation of treatment to address the dependent variable of medication concordance. The scale considers a number of

subjective aspects of psychosocial functioning, quality of life, medication taking behaviors and effectiveness of treatment (Voruganti & Awad, 2002). Total scores range from 0 – 60. Higher scores indicate higher medication concordance.

Baseline data, Personal Evaluation of Transitions in Treatment. Baseline means scores were computed for the PETiT to allow for baseline statistical comparison. The PETiT baseline scores for the experimental, QAT, group revealed a mean of 40.10 with a SD of 9.24 and for the comparison, TAU, group a mean of 40.07 with SD of 10.29. There were no significant differences in the total scores for both groups on the PETiT measure at baseline, $t\ (21) = .01, p < .99$.

Follow up data. Descriptive statistics were computed for both groups on the PETiT follow-up scores to allow for comparison. Additionally, mean change scores for both the QAT and TAU groups were computed from baseline to follow-up and analysis was conducted in order to compare the two groups.

Table 6 shows descriptive statistics computed for the QAT group on PETiT at follow-up. No significant differences were found from baseline to follow up, $p > .05$. Mean PETiT total change scores for the QAT group show some decrease indicating a decrease in medication concordance.

Table 6

PETiT for QAT Group at Follow-Up (n=10)

PETiT Total	Mean	SD	t
Baseline	40.1	9.24	1.26
Follow-up	37.3	8.87	

Descriptive statistics computed for the TAU group at follow up are reflected in Table 7. No significant differences were found from baseline to follow up, $p > .05$. Mean PETiT total change scores for the TAU group show some increase, indicating an increase in medication concordance.

Table 7

PETiT for TAU Group at Follow-up (n=13)

PETiT Total	Mean	SD	t
Baseline	40.1	10.29	.58
Follow-up	41.6	8.63	

Paired and Independent Samples t-tests were computed for the PETiT mean change scores from baseline to follow-up for both QAT and TAU groups to determine significance in change of mean scores for medication concordance. Table 8 shows the group means statistical comparison for the PETiT at follow up. Results of the comparison of means change scores for PETiT, for both the QAT and TAU groups, reveal no significance, $p > .05$.

Table 8

PETiT Mean Change from Baseline to Follow-Up by Group

Group	n	Mean	SD	t
QAT	10	-2.8	7.02	1.20
TAU	13	+1.5	9.59	

Finally, in order to document the effects of time, and time X condition interaction, a repeated measures Anova analysis was calculated for baseline to follow-up data. For

both the QAT and TAU groups for the PETiT scales there was no significant difference over time, or for time X group interaction. $p < .05$. Lack of significant findings for time – condition interaction suggests that the groups did not change differently from one another over time on the measurement of medication concordance.

QAT Program Satisfaction Questionnaire (QPSQ) Data

Follow-up data collected after the conclusion of the intervention to evaluate service user's satisfaction with the program involved QAT group participants completing the QPSQ. The satisfaction levels of two additional participants who participated in the QAT intervention but were not included in the pilot study for analysis of intervention effect were included in the analysis. These participants were included to capture all valid experiences and to prevent rejection of possible negative experience. The QPSQ was developed by the principal investigator and the major professor, in order to assess the experimental participant's level of satisfaction for both the QAT intervention and the study experience. The instrument consists of 11-items self-rated by QAT group participants on a Likert-type scale where a score of 1 = Strongly Disagree, 2 = Disagree, 3 = Not Sure, 4 = Agree, and 5 = Strongly Agree.

Frequencies and percentages were computed for the QPSQ scores in order to quantify the data. A descriptive analysis was also conducted with a comparison of range, mean and standard deviation for the QPSQ scores. Eight of the 10 positively worded statements were scored as either *agree* or *strongly* agree by 100% of the QAT participants. These scores indicate that all QAT participants report a high level of satisfaction with the intervention, a subjective feeling of having a better understanding of how to treat their mental illness, a positive experience of participating in the pilot study,

and would recommend the counseling to a friend. Although 66% of the QAT participants *agree* or *strongly agree* that they understand more about how their medication affects them, 33% of the participants are *not sure* if they understand more about how their medication affects them. Regarding the statement: I learned about managing my mental health, 83% either *agreed* or *strongly agreed* and 17% were *not sure* if they had learned. Table 9 reflects the results of the descriptive analysis conducted for QPSQ scores.

Table 9

Means, Standard deviation and Ranges for QAT Program Satisfaction Questionnaire Scores (n=12)

Statement	Min.	Max.	Mean	SD
I learned about managing my mental illness	3	5	4.25	.754
I had a chance to ask questions	4	5	4.33	.492
I learned about my treatment	4	5	4.42	.515
I didn't learn anything new about my treatment	1	2	1.33	.492
I understand more about how medication affects me	3	5	4.08	.900
My counselor was helpful	4	5	4.58	.515
I enjoyed being a part of the study	4	5	4.67	.492
People in the study treated me with respect	4	5	4.67	.492
I am satisfied with this counseling study	4	5	4.42	.515
I would recommend this type of counseling to a friend	4	5	4.50	.522
I have a better understanding of how to take care of my mental illness	4	5	4.58	.515

On the QPSQ form, following the 11-item scale, two open-ended prompts were posed with blank lines for write-in answers. The statements were: 1) *The best things about this counseling study are*; and 2) *A list of the things I wish had been different in this counseling study*. Every participant commented on at least one of the two prompts. Responses were grouped for similarities for analysis. The participants' responses to the prompt statement concerning the best things about the counseling centered on their being able to express feelings, ask questions, get answers and address problems. Three participants responded to the prompt statement about what they wish had been different. They responded by writing that the QAT program should include: *more information about medication, more time with the therapist and having the nurse practitioner or psychiatrist work, hand-in-hand*, in a manner similar to the counseling.

QAT Therapists' Fidelity to Protocol

Debbie Robson, QAT therapist and trainer at King's College London and Dr. Richard Gray, research fellow, King's College London, evaluated seven random counseling session audiotapes for fidelity to QAT protocol. The tapes were evaluated according to the *Therapist Fidelity Monitoring Protocol* (Gray, & Robson, 2002). This tool provides a score of the session ranging from 0 – 24, based on the therapists' implementation of QAT interventions and the therapeutic techniques of cognitive behavioral therapy and motivational interviewing. Scores from the seven audio-tapes were: 23, 20, 19, 19, 18, 16, 13, and 12. Dr. Richard Gray's assessment is that QUATRO adherence therapy was delivered with a high degree of fidelity.

Summary

A randomized, experimental pilot study design was developed to test if there was a difference in the severity of symptomatology of schizophrenia or medication concordance for individual participants who participated in an intervention of QAT. The sample included 23 participants for this pilot study. The results of all statistical analyses presented in this chapter indicated there was no significant difference between the QAT and TAU groups on measures of severity of symptomatology and medication concordance from baseline to follow-up after the completion of the intervention. The lack of statistical significance between groups in follow-up data for the samples indicates the intervention of QAT may not have influenced service users' symptomatology and medication concordance. However, it is important to note, that for the QAT group there was a clinically significant reduction in the severity of positive symptoms of schizophrenia.

In contrast to the quantitative analysis, the subjective program evaluation data collected from all experimental participants, together with the two additional participants who participated in the QAT intervention, was encouraging with regard to QAT and the study experience. The qualitative data tend to support the concept that QAT involves the development of a therapeutic interpersonal process between the client and the QAT therapist.

Chapter V

Discussion

Introduction

Results of the pilot study and its purpose are discussed in this chapter with consideration of factors that may have influenced the outcomes. Findings of this pilot study are compared with the literature review. Limitations of the pilot study, implications for further study, and recommendations are also discussed. This pilot study found that the measurements of severity of symptomatology and medication concordance did not vary significantly from baseline to follow-up after the introduction of the QAT intervention with the experimental group of service users with schizophrenia or schizoaffective disorder. However, this pilot study established the feasibility of a larger scale study. The qualitative data suggest the interpersonal relationship was viewed as a positive experience related to service users' understanding of their current illness situation. Results of the qualitative data are also discussed. Finally, the significance of this study and implications for the nursing profession are reviewed.

Pilot Study Purpose: Research Questions

The purpose of this pilot study was to examine the effect of the addition of an intervention of QAT to service users' usual treatment at a local community mental health center on the dependent variables of severity of symptomatology and medication concordance. The pilot study provided a previously tested intervention. The first research question posed in this pilot study was to examine the effects of an intervention of QAT on the service users' symptomatology using PANSS to measure the severity of symptomatology. Statistical analysis revealed there was no significant difference in

participants' symptomatology mean subscale scores or mean subscale change scores when comparing baseline to follow-up. There was a clinically significant reduction in the severity of positive symptoms for the experimental group.

This pilot study failed to replicate a number of studies completed over the past several years, which revealed significant difference in symptomatology scores using the PANSS resulting in a decrease in severity of symptomatology. Reasons why this study failed to produce significant results may be due to the small sample size. According to Rosenthal, Rosnow, and Rubin (2000, p. 5), a "small sample size may lead to failure to detect a true effect, in which case …this line of investigation should continue with a larger sample size. Additionally, outliers in a sample can influence the means in a manner rendering it "not reflective of the sample," thus skewing the data (Polit, & Hungler, 1999, p. 463). However, the clinically significant reduction in severity of positive symptomatology for this small sample indicates that the QAT program may produce significant results with a larger sample.

The second research question posed examining the effect of an intervention of QAT on service users' medication concordance scores using the PETiT, a self-report scale. Statistical analysis revealed there was no significant difference in participants' medication concordance mean scores or mean change scores when comparing baseline to follow-up. There are several reasons why the PETiT scale may have failed to show a significant difference in medication concordance. The scale measures more constructs than medication concordance. It may be that the 24-items on this scale related to psychosocial functioning distracted from the 6-item medication concordance scale. However, this should be with some caution since an increase in medication concordance

for many individuals is linked with an increase in satisfaction with psychosocial functioning and this scale targets the areas of psychosocial functioning targeted for improvement by treatment (Voruganti, & Award, 2002). The link between medication concordance and satisfaction with psychosocial functioning may also be mitigated by the presence of side effects. Instructions for the use of this scale suggest that the last six statements can be used as a subscale for medication compliance. However, no use of the separate subscales has been substantiated.

Follow-up data were collected between one week and one day of the participants' completion of therapy. It may be that sufficient time had not elapsed for the participants to incorporate possible new behaviors of medication taking decisions in order to report them. Although not substantiated as a subscale, the medication concordance section of the PETiT, has a range of scores from 0 – 6. An evaluation of the medication compliance section of the PETiT reveals a QAT group mean change score of .30 and SD of 1.41and for the TAU group, a mean change score of -.80 and SD of 2.44. The mean change scores of less than one point on a six-point scale and the comparatively large SD indicate that the means may not be reflective of the group.

Comparing the results of this pilot study to other published study results illustrates a number of similarities, which are strengths of the study. This pilot study identified a sample of individuals with schizophrenia and schizoaffective disorder, which was statistically similar at baseline. This pilot study also utilized the SCI-PANSS, a well-known tool to measure the severity of symptomatology in schizophrenia and schizoaffective disorder, to optimize data collection and provide a basis for comparison

with other similar studies utilizing the same instrument to detect change in symptomatology.

Formal, manualized training and standardized QAT intervention forms were used to provide therapy for the study participants similarly to other published studies. In this pilot study, however, Dr. Richard Gray has made a determination that QAT was provided in accordance with the fidelity monitoring protocol used in the U.K. It is significant to note that the abbreviated training lasting 24-hours over three-days, prepared the therapists to implement QAT. The combined educational preparation and training of the therapists and onsite supervision permitted QAT to be delivered for the first time by non-nurse providers in the U.S.A. Lastly, this study showed results of clinically significant results of a 22% reduction in the severity of symptomatology, which compares favorably with larger studies of this intervention. These encouraging comparisons are in contrast to a large number of differences between this pilot study and the larger randomized controlled trials (RCT) of QAT previously completed.

The differences between this pilot study and other RTCs of QAT are numerous. It may be that the lack of statistical significance for this pilot study in contrast to larger RCTs with significant positive outcomes is related to the small number of study participants involved. A considerably larger number of participants, 120, were needed to achieve a power level of .80, with the ability to compute statistical significance. The small n of this pilot made statistical significance unlikely. In addition, this pilot study stands in contrast to other studies of QAT, with its use of mental health counselors and a licensed clinical social worker in lieu of community mental health nurses to provide the intervention. In the U.S., there is not a large population of community mental health

nurses who are generally available to provide this intervention. Anecdotal evidence arising during the QAT therapist supervision sessions and noted on the service users' evaluation on the satisfaction survey, suggests that the psychopharmacology preparation of the QAT therapists may have been insufficient to meet some of the demands of the intervention.

In preparation for study participation, QAT pilot study therapists received a 4-hour psychopharmacology presentation given by the principal investigator. This presentation was based on Dr. Richard Gray's psychopharmacology overview utilized in the medication management training in the UK. However, the formal educational preparation of CMHN's and QAT therapists differ greatly with regard to the pharmacology component. Nursing education requires physiology and pharmacology in contrast to the educational preparation of licensed clinical social workers and licensed mental health counselors in the U.S.A. QAT therapists regularly attend informal pharmaceutical presentations regarding psychotropic medications, but do not receive a similar in-depth psychopharmacology component as compared to the nursing education process.

One other contrast between this study and Gray, Wykes et al.'s (2003) study of QAT is the number of contacts and exposure over time to health care professionals trained in QAT and medication management services. In Gray, Wykes et al.'s study mental health service users completed QAT and received the equivalent of what in the U.S. would be ongoing case management services, from CMHN's trained in medication management for a longer period of time than was available for this pilot study. Time between baseline and follow-up measurements in Gray, Wykes et al.'s study was 26

weeks, allowing for considerably more contact over time. Time from baseline to follow up in this pilot study was 8 weeks.

Theoretical Framework

Evidence from the satisfaction survey suggests that, as proposed, QAT therapists were able to provide a therapeutic relationship similar to the nurse-patient relationship described by Peplau. The theoretical model of Hildegard Peplau, guiding this pilot study, proposed that the NPR involves a significant, therapeutic, interpersonal process that "helps a patient to identify problematic elements in his current situation and to discover and understand something about what is happening to him during his illness" (1952, p. xiv). In this pilot study, the collaborative relationship between the QAT therapist and participant represented the NPR. The qualitative data suggest support for the concept that the relationships established in the QAT therapist-participant dyad was descriptive of the NPR.

Many responses on the QPSQ, although limited in analytical application, can be compared favorably with facets of Peplau's theory of the NPR. The following statements in italics regarding best things about QAT, obtained from prompts on the QPSQ, provide evidence of clients identifying what Peplau refers to as, problematic elements, such as: *allowed me to express my feelings and concern* and *I was able to talk about my problem.* The development of a therapeutic interpersonal process during QAT is also supported by participant statements on the QPSQ best things about QAT prompt, such as, *worked hand-in-hand, warm empathetic caring, trust, and felt safe expressing my feelings without fear*. These prompted participant self-reported responses support the likely presence of a significant therapeutic interpersonal process developed through QAT, between

participants and QAT therapists. Peplau (1997) depicts the nurse employing health teaching and enhancing learning for the patient during the working phase of the NPR. Two participant's responses to the best things about QAT prompt include: *ask questions and get answers* and *learn about medications* correspond with Peplau's depiction of enhanced health learning and are based in the participants' QAT experience.

The interpersonal process or collaborative relationship was proposed as the vehicle for resolution of ambivalence to problematic elements in the individual's situation and integration of the present experience with other life experiences. This concept of Peplau's was evidenced in one participant's concept of the best things about QAT prompt, *although it drudge up unpleasant memories, it was worth it.* This participant's response also coincides with Peplau's view of self as a process "gradually examining and changing the contents of the self-system by checking self views against reality" (Peplau, 1989c, p. 209), and is consistent with examining and changing the contents of the self-view. Peplau reflects that, "insights, changed perceptions of one's situation and new views of self generated within a client cannot be observed and may or may not be told to the nurse" (Peplau, 1988, p. 11). It may be that what Peplau views as the product of the nurse-patient relationship were measured by this evaluation of the QAT experience.

Limitations

The pilot study design, results and processes suggest a number of limitations. Several emerging factors during this pilot study had the potential to influence data collection, and removed rater blinding as a controlled variable. Limitations of this pilot study include the following:

1) The small sample size of this pilot study might have influenced the results of no significant findings.

2) The possibility of outliers in a sample this size may have skewed the data and led to a statistical analysis not representing the sample variables well.

3) During follow-up assessment interviews, approximately 6 of the 10 experimental participants revealed their status to the raters, effectively un-blinding the study.

4) Discussion between raters subsequent to scoring revealed significant differences in participant's rapport and self-disclosure between raters existed and may have skewed the data. It is believed this factor was dependent on the length and nature of past professional relationships between raters and specific clients.

5) Time constraints resulted in the follow-up assessments being conducted 8-weeks after the beginning of the intervention. In specific participant situations, this period essentially narrowed to approximately 6-weeks due to participants beginning therapy sessions behind schedule.

Additional Interpretation

Although there were numerous limitations to this pilot study, there were also some affirmative outcomes. These outcomes are anecdotal in nature and were brought to the attention of the principal investigator through informal discussion between participants in the QAT and TAU groups and staff at Archways at the completion of the study. Following the conclusion of data collection, the principal investigator participated in informal conversations with Archway's staff who expressed noticing positive

improvements in participants involved in QAT and questioning the principal investigator when the TAU group participants would be starting QAT. Discussion revealed that TAU participants had repeatedly questioned Archways staff about the start date, because they had *heard from* the QAT group participants that QAT was *great*. Archway's staff described the improvements of QAT participants as: initiating discussion a *bit more* frequently than prior to the start of QAT. Initiating conversation for these participants indicates a decrease in the severity of the negative symptom of social withdrawal. Further, through the study, staff at Archways became aware that several study participants were able to benefit from therapy and will be continuing in therapy. This data is viewed with great caution considering the positive professional relationships developed over several years between Archways' staff and the principal investigator and the desire of the staff to provide positive feedback.

Archways plans to implement the intervention on an on-going basis, following the conclusion of this pilot study. This will increase the occasions for concordance. The mental health center will continue follow-up of the participants informally, analyzing any further benefits of the intervention, through the usual and customary provision of services to, and evaluation of treatment response for the QAT group participants of this pilot study. The informal continuation of the pilot study at this site will provide the agency and service users increased opportunities for concordance, hopefully leading to decreased severity of symptomatology, and providing a resource for relapse prevention and health promotion through QAT's focus of increasing concordance.

Implications

This pilot study is significant to advanced nursing practice for several reasons, despite the lack of significant results. Many people with schizophrenia live with distressing symptoms that disrupt their thoughts, emotions, and ability to function independently, and place them at a high risk for suicide (Simon, 2002). Many master's prepared psychiatric nurse practitioners are in the position of monitoring and altering drug therapies and initiating appropriate therapies for individuals with schizophrenia (Florida Department of Health, 2003). Research suggests that medication combined with psychosocial interventions for people with schizophrenia make a significant impact on health outcomes and assist some individuals to recover a relatively higher level of social functioning (McCann, 2001).

Investigating medication concordance interventions is critical to improved healthcare outcomes for individuals living with the illness of schizophrenia. This pilot study contributes the beginnings of research in the U.S. for QAT, an evidence-based program of care delivery for people with schizophrenia that promotes concordance. This study contributed to the promotion and discussion of symptomatology of schizophrenia interventions and medication concordance at Archways. The nursing professions' promotion of mind, body and spirit-focused health care was enhanced by promoting the concept of medication concordance and nurse-patient therapeutic intervention in health care relationships as a standard of care. The nursing profession's goals are promoted because presenting the concept of medication concordance encourages discussion of the client's worldview, respect for individual's receiving care, autonomy and the value of the client's perspective and experience in the therapeutic relationship.

Although this pilot study did not replicate the outcomes of previous studies of QAT, training in assimilating the techniques of motivational interviewing and the spirit of concordance was provided to study therapists. This pilot study exposed Archways' staff to the use of a collaborative approach in providing health care, which has been shown to be consistent with improved health care outcomes (Gray, Wykes, et al., 2002, Healey, et al., 1998). This pilot study made available, to participating service users information about their illness and treatment and discussed tailoring regimens to the needs of the service user. This is consistent with the ethics of nursing practice and informed consent to treatment. Importantly, a thoughtful assessment of service users' beliefs, experiences concerns, fears, goals, and values was provided to the QAT participants. This is consistent with the nursing professions' promotion of ethical care (ANA, 2001), which is responsive to the worldviews of the service users, to whom health care services are provided.

Results in this pilot study suggest that a larger scale RCT is needed to produce statistically significant results. This study also demonstrated that it is feasible to deliver QAT in the U.S.A. at a community mental health center with mental health service providers other than nurses. This therapy is a Medicaid-covered form of short-term individual therapy, which can be provided to individuals for whom therapy has been recommended. This pilot study contributed to the provision of effective management of schizophrenia at this community mental health center, because it offered a user-centered evaluation of pharmacological interventions, uncomplicated information, and the use of both motivational interviewing and cognitive behavioral techniques to help service users make educated decisions about their treatment. There is evidence that routinely

incorporating these concepts into the fundamentals of mental health care improves service users' mental health (Gray, & Odunlade, 2002).

Further research is needed on a larger scale to determine which service users are most likely to benefit from this intervention and whether or not the results of the UK studies can be replicated in the US. Funding and training of individuals to provide QAT is an issue that must be addressed as well. The training provided to QAT therapists for this pilot study was an abbreviated, 3-day form of what in the UK is usually a 10-day training program for CMHNs. The QAT therapists, who were master's prepared counselors with prior training in interpersonal therapeutic techniques, were seen by the trainers to be at an advantage in acquiring QAT's specific blend of MI and CBT active listening skills in comparison with the CHMNs attending training in the U. K. Conversely, the QAT therapists were at a disadvantage in the realm of medication education and psychopharmacology when compared to the CMHNs in the U. K. These issues can be addressed with targeted interventions for trainee groups. Based on the positive qualitative data, the lack of a large enough sample to produce statistically significant results and timing issues of data collection, further study on a larger scale aimed at replicating the results of the QAT studies in the UK is implicated.

Implications for further study include a discussion of outcome measurements. The PETiT was developed to measure service users' subjective response to treatment. The items reflect many concepts that are of importance to service users' recovery and psychosocial functioning, many of which are responsive to medication. The total scale was used in this pilot study and there is a recommendation by the authors to consider using the medication adherence subscale (Voruganti, & Award, 2002), although

statistical evaluation was not available in the literature for this subscale. Further studies may consider obtaining the DAI (Hogan, Awad & Eastwood, 1983), which was used in previous studies as a scale predictive of drug compliance or the PETiT subscale for medication compliance. Further study may also first consider the development of a tool to measure a subjective level of concordance using the components of concordance specified in the literature.

Summary

In this final chapter, the purpose and findings of the pilot study and its results were discussed with consideration of several factors that may have influenced outcome. Findings were discussed with regard to limitations of the pilot study, implications for further study, and for the nursing profession. Recommendations were presented in consideration of the pilot study outcomes and research. The qualitative data suggested the interpersonal relationship developed through the intervention of QAT was a helpful influence on service users' understanding of their current illness situation. The health care community has increasingly relied on the methods of scientific inquiry to produce improvements in treatment available for service users with severe and enduring mental illness. Future research regarding the promotion of concordance in provider - health care recipient relationships has the potential to positively influence many variables that contribute to health care outcomes and develop new evidence-based standards of care that are responsive to the multicultural needs of health care service users.

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Appendix A. Dr. Gray's Letter of Consent.

Institute of Psychiatry

at The Maudsley

Head of the Section of Psychiatric Nursing
Professor of Psychiatric Nursing
Professor Kevin Gournay BA
FRCPsych (Hon) PhD DPsychol RN
k.gournay@iop.kcl.ac.uk

Section Secretary
Mrs Melita Carpenter
Tel 020 7848 0139
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KING'S College LONDON

University of London

Stephanie Hall Ford
609 Southwest 19th Street
Fort Lauderdale
Florida 33315-2049
USA

11th January 2004

Dear Stephanie,

Re: A randomised controlled trial of adherence therapy

I was very excited to receive your request to undertake a trial of adherence therapy in the USA. I am happy to give consent for you to use the adherence therapy approach for the purpose of the trial. I am also happy for you to make use of the adherence therapy training package for the purpose of the trial.

I would be grateful if the source of the material is appropriately acknowledged in any resulting publications.

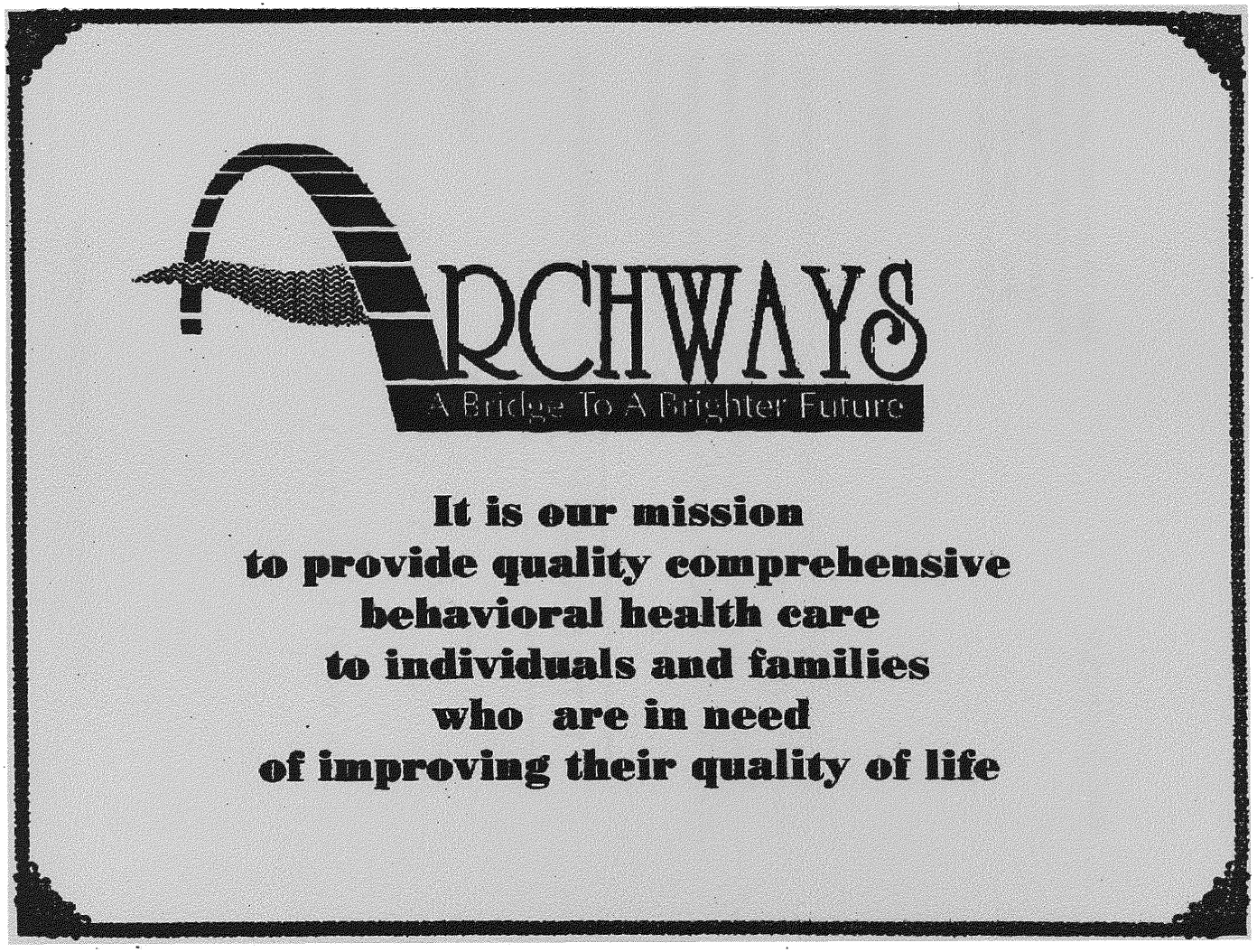
If you wish to make further use of either the manual of training package following the completion of the trial I would be grateful if you could contact us again for our consent.

I very much look forward to working with you on this exciting project.

With very best wishes,

Dr Richard Gray RN PhD
Medical Research Council Fellow in Health Services Research

Appendix B. Archway's Mission Statement.


ARCHWAYS
A Bridge To A Brighter Future
It is our mission
to provide quality comprehensive
behavioral health care
to individuals and families
who are in need
of improving their quality of life

Appendix C. Archways CEO's Letter of Support and Agreement.

ARCHWAYS
A Bridge To A Brighter Future
PROGRAMS ACCREDITED BY CARF

(954) 763-2030
FAX (954) 763-9847
SUN COM 451-5600
919 N.E. 13th Street • Fort Lauderdale, FL 33304

Stephanie Hall Ford, RN, BSN
Florida International University,
Graduate School of Nursing
609 Southwest 19th Street
Fort Lauderdale, Florida 33315

September 25, 2003

Dear Stephanie,

I am pleased to inform you that your request to conduct research regarding the implementation and evaluation of Adherence Therapy for individuals with mental illness here at Archways, Inc. has been approved. I understand that the staff training and provision of the intervention under study, will take place on site and I am happy to provide suitable amenities.

My staff and I look forward to working with you on this study.

Regards,

Andrea Katz, LCSW, BCD
Chief Executive Officer

Providing Quality Behavioral Healthcare Since 1983

Appendix D. IRB Confirmation of Approval to Conduct Research.

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

Division of Sponsored Research & Training
Office of Research Compliance, MARC 430

MEMORANDUM

To:	Stephanie Hall Ford
CC:	Kathryn Hoehn Anderson
From:	Niurca E. Márquez-Castro, Administrator Institutional Review Board
Date:	March 25, 2004
Proposal Title:	Examining The Difference in Community Mental Health Service Users' Symptomology, and Concordance with Medication Regimens After Completion of QUATRO Adherence Therapy.
	Approval # 031704-01

The Institutional Review Board of Florida International University has approved your study for the use of human subjects. Your annual report will be due March 2005. As a requirement of IRB approval you are required to:

1) Provide immediate written notification to the IRB of:
   - Any additions to, or changes in the procedures involving human subjects,
   - Every serious or unusual or unanticipated adverse event as well as problems with the rights or welfare of the human subjects. Confirmation of receipt of serious AE reports must be made with the IRB office.
2) Utilize copies of the date stamped consent document(s) for the recruitment of subjects and receive annual renewal of consent documents.
3) **Receive annual review and re-approval.**

Special Conditions: three consent forms and one invitation letter approved for use.

Please note your approval number is indicated above. For further information, you may contact the IRB Coordinator by email at irbiacuc@fiu.edu or visit the DSRT – Human Subject web site at www.dsrt.fiu.edu.

Appendix E. Volunteer Confidentiality Agreement

ARCHWAYS
FORT LAUDERDALE, FLORIDA

CONFIDENTIALITY STATEMENT

I, STEPHANIE H FORD, hereby acknowledge that the legal and ethical obligations imposed upon me as a volunteer at Archways have been fully explained to me. I understand that the effective maintenance of confidentiality of a member's clinical program facilities. I further understand that failure on my part to preserve the patient's right to confidentiality may result in personal liability.

11/3/03
DATE

Stephanie H Ford
VOLUNTEER SIGNATURE

WITNESS: Shirita Brooks

Appendix F. Invitation to Participate Letter.

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

IRB Approved
Date: 03/25/04
No.: 031704-01

Dear_____,

You are being invited to be in a research study. The study is to find out if 8 weeks of a new kind of individual counseling is helpful to people. If you decide to be in the study, the services you get from Archways will not be affected in any way.

The investigator of the study is Stephanie Ford. The same Stephanie Ford who used to work in Intake at Archways. I (Stephanie) am a student now at Florida International University, in the Graduate School of Nursing. The study includes adults who go to Archways for mental health care.

Individuals who agree to be in the study will each have their own counseling sessions. The counselors are Marie Fairchild or Jeanne Ansourian at Archways. You will start the counseling in either March or June 2004. This is a new kind of counseling program developed in England. This counseling helps individuals gain a better understanding of themselves and their mental health.

The counseling meetings are for one hour, one time each week. The program lasts for eight weeks. You will make appointments with your counselor for times that are good for you. The counseling involves talking about things that you like and don't like. Things like medicine, emotional problems, hospitals, and your life. You will be asked about your hopes and goals for the future. Talking about how you make plans and reach goals in your life is part of the counseling too.

It is hoped that this new type of counseling will help you. If you want to be in the study, you will have two interviews. The interviews are about mental health symptoms you may have. The interviews take about one hour. One interview is in March or April and the second interview in June.

You will also fill out a form that has questions about what you think about medications you take. You can ask questions about the form if you want help. The form has questions and a list of answers. You answer the questions by making a circle around the answer you pick. You will be asked to fill out this form in March and then again in June.

Your name will not be on any of the documents about you. All information will be labeled with a code number, not your name. After the study, we will look at all the information we collect. We hope to find out how the counseling either helped or did not help. I (Stephanie) will give a talk at Archways about what we find out after the study is over. You are invited to the talk to hear about it.

There is no cost to be in the study. We think you will like the counseling meetings. By being in the study, you will help us see if this new kind of counseling is a help to you.

There will be refreshments like coffee, water and juice and a few snacks at the meetings and the counseling sessions.

NEXT PAGE PLEASE!

School of Nursing
College of Health and Urban Affairs
Biscayne Bay Campus 3000 N.E. 151st Street • North Miami, FL 33181 • Tel: (305) 919-5915 • Fax: (305) 919-5395

In this envelope, you will find a card that has boxes to mark. When you mark an X in one of the boxes, it will show me what you want to do about being in the study. If you decide not to be in the study, it is okay and the services you get from Archways will not be affected in any way.

Please mark an X as your answer in one of the boxes on the card in this envelope.

Next, please take this card with you the next time you go to Archways. Then put the card in the box by the receptionist at Archways. She will show you where the box is, if you don't see it!

If you mark the box: YES, INTERESTED, I will get in touch with you and talk to you about being in the study. I will either call you on the phone or see you when you are at Archways. If you want to, you can still decide no after talking with me.

If you mark the box: NO, NOT INTERESTED, that's okay and I will not get in touch with you. Thanks for reading the letter and thinking about it.

If you do not put the card in the box, then I will not get a card from you. If I don't get a card from you, then I will get in touch with you to see if you are interested.

You can also leave a message for me with the receptionist at Archways! If you have a question for me, tell the person at the reception desk and they will call me with your message. I will be happy to answer any questions you have about the study.

If you have further questions and want to talk to someone at Florida International University about this study, please contact Dr. Kathy Anderson at 1-305-919-5376. If you still have questions and need to talk further, you can call Dr. Bernard Gerstman. He is the Chairperson of the Florida International University, Institutional Review Board. His phone number is 1-305-348-3115 or 1-305-348-2494.

Thank you for considering being in the study.

Regards,

Stephanie Ford

APPROVED

Appendix G. Postcard Reply.

APPROVED

RESPONSE POSTCARD
ABOUT THE STUDY
OF A NEW KIND OF COUNSELING.

TO: STEPHANIE FORD

FROM:_____,
Print your name on the above line

FILL OUT THE CARD BY MARKING A BOX BELOW.

☐ **YES, INTERESTED!**
PLEASE GET IN TOUCH WITH ME!
I WANT TO HEAR MORE ABOUT THIS!

☐ **NO, NOT INTERESTED!**
THANKS, BUT DON'T CALL ME!
MAYBE SOME OTHER TIME,
I KNOW THIS IS OKAY TOO!

PLACE CARD IN BOX BEHIND RECEPTION DESK
AT ARCHWAYS

(response postcard enclosure)

Appendix H. Scripting of the Follow-Up Contact.

FOLLOW UP CONTACT SCRIPT

I am Stephanie Ford. I sent you an invitation and you sent me the card back saying you are interested. Do you have any questions for me?

Would you like to talk about signing a form saying that you want to be in the study?

OR

I am Stephanie Ford. I sent you an invitation, but didn't get a card from you.

The invitation letter you got was about being in a research study. The study is to find out if a new kind of individual counseling is helpful to clients of Archways.

I am a student now at Florida International University, in the Graduate School of Nursing. The study is being done here at Archways.

Archways clients who want to be in the study will have their own counseling. The counselors are Marie Fairchild or Jeanne Ansourian at Archways. This is a new kind of counseling program developed in England. This counseling helps individuals understand themselves better.

If you decide to be in the study, the services that you receive now from Archways will not be affected in any way.

I hope that this new type of counseling will help you. If you want to be in the study, there will be two interviews. The interviews last about one hour and are about mental health symptoms you may have. One interview is in March and, the second interview will be in June.

You will also be asked to fill out a form about medicine you take. The form has questions and lists of answers. You will be asked to fill out the form in March and then again in June.

Your name will not be on any of the information about you. All information will be labeled with a number, not your name. After the study, we are going to look at all the information we collect. We hope to see how the counseling either helped or did not help. I will give a talk at Archways about what we find out after the study is over that you are invited to.

The counseling meetings are for about one hour, one time each week. The program lasts for eight weeks. You will be able to make appointments with your counselor for times that are good for you. The counseling involves talking about things that you like and don't like. Things like medicine, emotional issues, hospitals, and your life. You will be asked about your hopes and goals for the future. Talking about how you make plans is part of the counseling too.

There is no monetary cost to be in the study. Being in the study, will help us see if this new kind of counseling is a help to you. There will be refreshments like coffee, water and juice and a few snacks at the meetings and the counseling. Jean and Marie will have a refrigerator set up for this.

You will only be in the study, and have this counseling if this is something you want to do. If sign up for the study but later want to quit being in the study, you can just let your counselor or case manager know. The treatment you

receive now will not be affected in any way if you decide not to be in the study. No one would be upset if you decided to quit. It is your choice.

If you don't want to be in the study you can tell me now or if you want, you can think about it more and leave a message for me at the receptionist desk sometime today please.

If you have further questions and want to talk to someone at Florida International University about this study, please contact Dr. Kathy Anderson at 1-305-919-5376. If you still have questions and need to talk further, you can call Dr. Bernard Gerstman. He is the Chairperson of the Florida International University, Institutional Review Board. His phone number is 1-305-348-3115 or 1-305-348-2494.

I can leave these numbers for you if you want to make calls. You can ask your case manager for help making the calls.

Would you like to talk about signing a form that says you want to be in the study?

If **no** then → Thanks for talking to me, please leave a message for me sometime later today. If I don't get a message, I will know that you are not interested right now. Is that okay.

If **yes** then → Take a look at this form with me and lets read through it. I want to make sure you understand the form and what your part is in the study.

Questions will be answered and information will be clarified before asking subject to sign consent.

Appendix I. Informed Consent.

FIU
FLORIDA INTERNATIONAL UNIVERSITY
Miami's public research university

IRB Approved
Date: 3/25/04
No.: 03-1104-01

SUBJECT CONSENT TO BE IN A RESEARCH STUDY
Title: To find out if a new kind of individual counseling helps people feel better about themselves.

You are being asked to be a subject in a research study. The purpose of the study is to see if a new kind of counseling is helpful to adults who receive mental health care.

The principal investigator of the study is Stephanie Ford. She is a graduate student at Florida International University (FIU) in the School of Nursing. The study will include adults who go to Archways for mental health care. Being a part of this study will not affect the health care or any services that you get from Archways.

Individuals in the study will have 8 weeks of individual counseling. Half of the individuals in the study will receive the counseling from March to June. The other half will receive the counseling from June to August. The counselors are Marie Fairchild and Jeanne Ansourian, here at Archways.

If you decide to be in the study, you will also have two interviews. One interview is in March or April and the other is in June. The interviews are about mental health symptoms you may have. The interviews take about one hour and will be scheduled with you.

The counseling sessions are for one hour, one time each week. The program lasts for eight weeks. You will make appointments with your counselor for times that are good for you. The counseling involves talking about things that you like and don't like. Things like medicine, emotional problems, hospitals, and your life. You will be asked about your hopes and goals for the future. Talking about how you make plans is part of the counseling too.

You will also fill out a form that has questions about what you think about the medications you take. You can ask questions about the form if you want help. The form has questions and a list of answers. You answer the questions by making a circle around the answer you pick. You will be asked to fill out this form in March and then again in June.

The form that you fill out and the notes that we write will not be labeled with your name. You and your counselor will keep any notes you make. We will also get information from your records at Archways. Information about: what type of place you live, your age, your sex, your race, years of school and how many times you have been in the hospital. All of the information about you will be labeled with a code number.

We think participating in this study will be helpful to you. You can ask any questions you want, any time you want to. There is no monetary cost to be in the study. The services you get now from Archways will not be affected in any way. We think you will like the counseling meetings. We also think the form you will fill out is easy and won't cause you stress.

School of Nursing
College of Health and Urban Affairs
Biscayne Bay Campus 3000 N.E. 151st Street • North Miami, FL 33181 • Tel: (305) 919-5915 • Fax: (305) 919-5395

By being in the study, you will help us find out if this counseling is a help to you. There will be coffee, water, juice, and a few snacks at the meetings and counseling. At the end of the study, we will have a meeting for everyone in the study.

At this last meeting the principal investigator, Stephanie Ford will talk about the results of the study. We will also have refreshment then.

You can decide later, after you sign this form, that you want to quit being in the study. If you do, you can tell your counselor or your case manager. If you quit the study, **it will not affect the health care or any services that you get from Archways.** Also, you can still come to the last meeting to hear about the study. It is okay and no one will be upset if you decide to quit.

We might ask you if we can make a voice tape recording of one of your counseling sessions. A researcher named Dr. Richard Gray will listen to the tape recording to find out how the counselor may have helped you. **The tape will not have your name on it.**

If you agree to tape record a session both you and your counselor will sign a form saying it is okay to tape record the session. You can refuse this. If you don't want to have a session taped, it is okay. We only want to tape record a counseling session, if you give permission.

If you have further questions and want to talk to someone at Florida International University about this study, please contact Dr. Kathy Anderson at 1-305-919-5376. If you still have questions and need to talk further, you can call Dr. Bernard Gerstman. He is the Chairperson of the Florida International University, Institutional Review Board. His phone number is 1-305-348-3115 or 1-305-348-2494.

By signing your name below on this form, you are saying that all of your questions have been answered in a way you like. Also, that you understand what your responsibilities are in the study. Your signature on this form also means that you have an understanding of your rights and that you would like to be in the study.

Signature of Participant	Printed Name	Date

I have explained the research procedure and subject rights. I have answered all questions asked by the participant. I have offered the participant named above a copy of this informed consent form.

Signature of Witness	Printed Name	Date

APPROVED

Appendix J. Demographics Information Collection Form.

DEMOGRAPHIC DATA COLLECTION FORM FOR QAT STUDY

SUBJECT STUDY ID NUMBER _____.

1. DIAGNOSIS:

Axis I :

2. SEX:

3. RACE:

4. AGE:

5. DATE OF BIRTH:

6. TYPE OF RESIDENCE:

7. NUMBER OF HOSPITALIZATIONS:

8. YEARS OF EDUCATION:

9. MEDICATION REGIMEN:

Appendix K. Selected examples of *Structured Clinical Interview-Positive and Negative Syndrome Scale* and Copyright Agreement.

Examples of Structured Clinical Interview – Positive and negative Syndrome Scale

Data on Anxiety (G2)

1. Have you been feeling worried or nervous in the past week?

   IF YES, skip to question 3. IF NO, continue.

2. Would you say you are calm and usually relaxed?

   IF YES, skip to question 8. IF NO, continue.

3. What's been making you feel nervous (worried, not calm, no relaxed)?
4. Just how nervous (worried, etc.) have you been feeling?
5. Have you been shaking at times or has your heart been racing?
6. Do you get in a state of panic?
7. Has you sleep, eating or participation in activities been affected?

Data on Depression (G6)

102. How has your mood been in the past week: mostly good, mostly bad?

     IF "MOSTLY BAD," skip to question 104. IF "MOSTLY GOOD," continue.

103. Have there been times in the past week when you were feeling sad or unhappy?
104. Is there something in particular that is making you sad?
105. How often do you feel sad?
106. Just how sad have you been feeling?
107. Have you been crying lately?
108. Has you mood in any way affected your sleep?
109. Has it affected your appetite?
110. Do you participate less in activities on account of your mood?
111. Have you had any thoughts of harming yourself?

     IF NO, skip to question 114. IF YES, continue.

112. Any thoughts about ending your life?
113. Have you attempted suicide?

Example of Rating Scale Criteria for Depression (G6) on PANSS

Depression

There are feelings of sadness, discouragement, helplessness, and pessimism.
Basis for rating – verbal report of depressed mood during interview and its observed influence on patient's attitude and behavior as reported from primary care workers or family.

Score	Rating	Criteria
1	Absent	The question does not apply.
2	Minimal	Questionable pathology, the patient may be at the upper extreme of normal limits.
3	Mild	The patient expresses some sadness or discouragement when questioned, but there is no evidence of depression in the patient's general attitude or demeanor.
4	Moderate	The patient has distinct feelings of sadness or hopelessness, which may be spontaneously divulged, but his or her depressed mood has no impact on his or her behavior or social functioning, and he or she can usually be cheered up.
5	Moderate Severe	The patient's mood is distinctly depressed ands associated with obvious sadness, pessimism, loss of social interest, psychomotor retardation, and some interference in his or her appetite and sleep. The patient cannot be easily cheered up.
6	Severe	The patient's mood is markedly depressed mood is associated with feelings of misery, hopelessness, worthlessness, and occasional crying. There is also major interference with his or her appetite and/or sleep as well as normal motor and social function, possible signs of self-neglect.
7	Extreme	Depressive feelings seriously interfere with most major functions. These manifestations include frequent crying, pronounced somatic symptoms, impaired concentration, psychomotor retardation, social disinterest, self-neglect, possible depressive or nihilistic delusions and/or possible suicidal thoughts or actions.

MHS
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www.mhs.com
Publishers and Developers of Professional Assessment Materials

SENT ELECTRONICALLY

July 26, 2004

Florida International University
11200 S.W. 8th Street
Miami, FL 33199

Attention: Stephanie Ford

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17. Faxed and photostatic copies of this Agreement shall be considered valid legal documents.

MULTI-HEALTH SYSTEMS INC.:

Lori Purchase
Authorized Signing Representative

7-28-04
Date

The Licensee hereby agrees to the above terms and conditions on this 27 day of July 2004.

STEPHANIE FORD:

By: Stephanie H Ford
Authorized Signing Representative

Name: Stephanie H. Ford
(Print)

Title: RN
(Print)

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Date: July 27, 2004

STEPHANIE FORD:
By: Stephanie H Ford
Print Name: Stephanie H Ford
Title: RN
Address: 609 SW 19th Street
Ft. laud., FL 33315

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Appendix L. *Personal Evaluation of Transitions in Treatment* and Permission to Use Letter.

St. Joseph's Healthcare
Hamilton

It is an honour to serve our community.

January 30, 2004

SENT VIA EMAIL AND POST

Ms. Stephanie Ford
609 South West 19th Street
Fort Lauderdale, Florida
USA 33315-2049

Dear Ms. Ford:

RE: PERSONAL EVALUATION OF TRANSITIONS IN TREATMENT (PETiT)

Please be advised that I have forwarded the PETiT instrument, instructions and scoring key to you via email. You are welcome to use the PETiT in your Thesis.

Best of luck in your future endeavours.

Sincerely,

K. McColl

Kathryn McColl (Ms.) for
L. Voruganti, M.D.

LV:km

Encls.

Centre for Mountain Health Services
Member, St. Joseph's Health Care System
Affiliated with the Faculty of Health Sciences, McMaster University

100 West 5th, Box 585, Hamilton, Ontario, Canada L8N 3K7
Phone: 905.388.2511 Fax: 905.381.5601

PERSONAL EVALUATION OF TRANSITIONS IN TREATMENT (PETiT)

Instructions for Users

INTRODUCTION

PETiT is a short, self-administered rating scale designed to capture subjective aspects of quality of life of psychiatric patients over a relatively shorter time frame, i.e. one to six months time. It is useful to arrive at a cross sectional profile of the subjective aspects of quality of life, and also to capture the changes over time.

GENERAL DESCRIPTION

The scale has 30 items: the first 24 items tap into various subjective aspects of psycho-social functioning and quality of life, and the last six questions address the issue of treatment adherence (compliance). These two parts could be used separately as dictated by the needs of an individual product.

SCOPE OF VIEWS

The scale is primarily designed to assess the impact of antipsychotic medications during schizophrenia treatment; however, it could be used in assessing people with other psychiatric disorders who are receiving either pharmacological or psycho-social interventions, or no treatment at all. Since the scale is meant to be a self-administered instrument, it is important to establish that the subject understands English and is relatively stable in terms of adequate consultation and comprehension. Subjects who are extremely disturbed with clinically thought disorder, distractibility, agitation or potentially excessive behaviour are not suitable to complete the scale.

PROCESS OF ADMINISTRATION

Subjects should receive adequate introduction and instructions, prior to administration to the scale. Subjects should be explained the purpose and the context of its use, and should be warned about the time frame of the self-appraisal. The interviewer or supervisor must be available during the period of administration, which is likely to be about 3 to 5 minutes. This will help the supervisor to observe the subject's behaviour during the completion and ensure the validity of the answers. Besides the supervisor may help to clarify any doubts the subject may have about individual items. However, the supervisor should not try to interpret the meaning of the statements or suggest the answers.

After the subject completes the questionnaire, the supervisor should make sure that all the items are checked. The supervisor/interviewer should also note the date and the required identification data at the bottom of the scale.

SCORING INSTRUCTIONS

The scoring key is enclosed. Each item could receive a score of 0, 1, or 2. Ratings from the individual items are summed to come up with a total score. Total score for the last six items (the treatment adherence subscale) could be completed separately, as per the needs of the investigators. If the subjects fail to answer any of the items, the validity is likely to be seriously jeopardized.

APPLICATIONS

PETiT could be used during routine clinical practice or for the purposes of clinical research. The scale is sensitive enough to capture clinically meaningful differences between one month and twelve months.

PERSONAL EVALUATION OF TRANSITIONS IN TREATMENT

PETiT

We are interested in how you have been feeling and doing during the **past ONE week.** Read each of the following statements. Choose the best answer that indicates your feelings, and circle that option.

Please circle: **Often** if you frequently feel or act in the way described in the sentence,
Sometimes if you only feel or act that way occasionally, or
Never if you had not felt or acted that way during the past week.

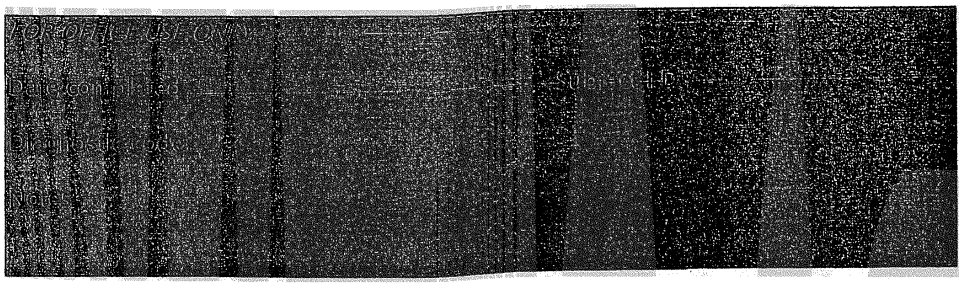
1. I am satisfied with my life	*Often*	*Sometimes*	*Never*
2. I am worried about what is happening to my health	*Often*	*Sometimes*	*Never*
3. I feel dull and sluggish	*Often*	*Sometimes*	*Never*
4. I believe that other people aren't comfortable around me	*Often*	*Sometimes*	*Never*
5. I feel too tired to do things that I should do	*Often*	*Sometimes*	*Never*
6. I find it hard to come up new ideas	*Often*	*Sometimes*	*Never*
7. I am unable to trust people	*Often*	*Sometimes*	*Never*
8. My mind is sharp and clear	*Often*	*Sometimes*	*Never*
9. I am able to concentrate on reading or television	*Often*	*Sometimes*	*Never*
10. I am unhappy	*Often*	*Sometimes*	*Never*
11. I have family or friends who really understand me	*Often*	*Sometimes*	*Never*
12. My sex drive is weak	*Often*	*Sometimes*	*Never*
13. I am able to communicate better with people	*Often*	*Sometimes*	*Never*
14. Chores such as cleaning, washing and shopping are too much for me	*Often*	*Sometimes*	*Never*
15. I am able to remember things easily	*Often*	*Sometimes*	*Never*
16. I feel ready to work either as a volunteer or for pay	*Often*	*Sometimes*	*Never*
17. I feel good about myself	*Often*	*Sometimes*	*Never*
18. My future seems gloomy	*Often*	*Sometimes*	*Never*

19. I avoid meeting new people	*Often*	*Sometimes*	*Never*
20. I feel weird and strange	*Often*	*Sometimes*	*Never*
21. I can cope with the daily hassles of life	*Often*	*Sometimes*	*Never*
22. I dislike the way I look	*Often*	*Sometimes*	*Never*
23. I am not sleeping well	*Often*	*Sometimes*	*Never*
24. I am able to do things as well as other people	*Often*	*Sometimes*	*Never*

Finally, we would like to ask you some questions about your medication. Again please indicate your response by circling the answer that best shows what you have been feeling and doing.

25. I forget to take my medication	*Often*	*Sometimes*	*Never*
26. My medication is helping me	*Often*	*Sometimes*	*Never*
27. I dislike my current medication	*Often*	*Sometimes*	*Never*
28. Friends and family believe that my current medication is good for me.	*Often*	*Sometimes*	*Never*
29. Taking medication is unpleasant	*Often*	*Sometimes*	*Never*
30. I feel that the good things about taking medication outweigh the bad	*Often*	*Sometimes*	*Never*

Thank you for your time.



Appendix M. Permission to use Schedule for the Assessment of Insight – Expanded.

Institute of Psychiatry

at The Maudsley

Section of Neuropsychiatry
Division of Psychological Medicine

Anthony S David
Professor of Cognitive Neuropsychiatry

Box 068
De Crespigny Park
Denmark Hill
London SE5 8AF
Tel +44 (0)20 7848 0138
Fax +44 (0)20 7848 0572
a.david@iop.kcl.ac.uk
www.iop.kcl.ac.uk

KING'S College LONDON

University of London

11th January 2004

Stephanie Hall Ford
609 Southwest 19th Street
Fort Lauderdale
Florida 33315-2049
USA

Dear Stephanie,

Re: A randomised controlled trial of adherence therapy

Thank you for your request to use the Compliance Scale and Schedule for the Assessment of Insight (SAI-E). I am happy to give consent for you to use these scales in your trial.

I would be grateful if the scales are appropriately acknowledged in any resulting publications.

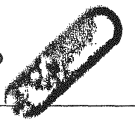
If you wish to make further use of the scales following the completion of the trial I would be grateful if you could contact me again for my consent.

With very best wishes.

Yours sincerely,

Anthony S David, MD FRCP, FRCPsych
Professor of Cognitive Neuropsychiatry

Appendix N. *Liverpool University Neuroleptic Side-Effect Rating Scale.*

Lungers 

Name: _____

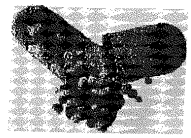
Assessment No:._____ Assessment Date: _____

Please indicate how much you have experienced each of the following symptoms in **the last month** by ticking the appropriate boxes.

	Not At All	Very Little	A Little	Quite a Lot	Very Much
1.Rash	☐	☐	☐	☐	☐
2.Difficulty staying awake during the day	☐	☐	☐	☐	☐
3.Runny nose	☐	☐	☐	☐	☐
4.increased dreaming	☐	☐	☐	☐	☐
5.Headaches	☐	☐	☐	☐	☐
6.Dry mouth	☐	☐	☐	☐	☐
7.Swollen or tender chest	☐	☐	☐	☐	☐
8.Chilblains	☐	☐	☐	☐	☐
9.Difficulty in concentrating	☐	☐	☐	☐	☐
10.Constipation	☐	☐	☐	☐	☐
11.Hair loss	☐	☐	☐	☐	☐
12.Urine darker than usual	☐	☐	☐	☐	☐
13.Period problems	☐	☐	☐	☐	☐
14.Tension	☐	☐	☐	☐	☐
15.Dizziness	☐	☐	☐	☐	☐
16.Feeling sick	☐	☐	☐	☐	☐

	Not At All	Very Little	A Little	Quite a Lot	Very Much
17.Increased sex drive	☐	☐	☐	☐	☐
18.Tiredness	☐	☐	☐	☐	☐
19.Muscle stiffness	☐	☐	☐	☐	☐
20.Palpitations	☐	☐	☐	☐	☐
21.Difficulty remembering things	☐	☐	☐	☐	☐
22.Losing weight	☐	☐	☐	☐	☐
23.Lack of emaotions	☐	☐	☐	☐	☐
24.Difficulty achieving climax	☐	☐	☐	☐	☐
25.Weak fingernails	☐	☐	☐	☐	☐
26.Depression	☐	☐	☐	☐	☐
27.Increased sweating	☐	☐	☐	☐	☐
28.Mouth ulcers	☐	☐	☐	☐	☐
29.Slowing of movments	☐	☐	☐	☐	☐
30.Greasy skin	☐	☐	☐	☐	☐
31.Sleeping too much	☐	☐	☐	☐	☐
32.Difficulty passing water	☐	☐	☐	☐	☐
33.Flushing of face	☐	☐	☐	☐	☐
34.Muscle spasms	☐	☐	☐	☐	☐
35.Sensitivity to sun	☐	☐	☐	☐	☐
36.Diarrhoea	☐	☐	☐	☐	☐
37.Over-wet drooling mouth	☐	☐	☐	☐	☐
38.Blurred vision	☐	☐	☐	☐	☐

	Not At All	Very Little	A Little	Quite a Lot	Very Much
39.Putting on weight	☐	☐	☐	☐	☐
40.Restlessness	☐	☐	☐	☐	☐
41.Difficulty getting to sleep	☐	☐	☐	☐	☐
42.Neck muscles aching	☐	☐	☐	☐	☐
43.Shakiness	☐	☐	☐	☐	☐
44.Pins and needles	☐	☐	☐	☐	☐
45.Painful joints	☐	☐	☐	☐	☐
46.Reduced sex drive	☐	☐	☐	☐	☐
47.New or unusual skin marks	☐	☐	☐	☐	☐
48.Parts of body moving of own accord. *For example foot moving up and down.*	☐	☐	☐	☐	☐
49.Itchy skin	☐	☐	☐	☐	☐
50.Periods less frequent	☐	☐	☐	☐	☐
51.Passing a lot of water	☐	☐	☐	☐	☐

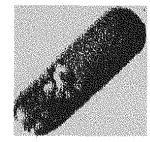
Lurkers 

Side Effect Prevalence in a sample of 50 schizophrenic patients

Prevalence of side-effects in a sample of 50 schizophrenic patients, distress associated with side-effects in those patients who report them (0 = Not at all; 1 = Very little; 2 = A little; 3= Quite a lot; 4 = very much) and percentage of patients experiencing side-effects who attribute them to medication.

Side Effect	Prevalence (%)	Distress	+ve Attribution
Tiredness	78	2.353	54
Dry mouth	74	1.400	54
Diff. remembering	70	1.970	29
Tension	68	2.552	15
Depression	68	2.533	27
Restlesness	66	2.000	46
Blurred vision	66	1.893	27
Diff. concentrating	66	2.280	30
Increased dreaming	66	1.500	21
Diff. getting to sleep	64	2.250	28
Passing a lot of water	58	1.556	28
Shakiness	56	1.950	54
Sensitivity to sun	56	1.538	68
Dyskinesia	54	1.692	52
Muscle stiffness	54	2.217	37
Pins and needles	54	2.136	18
Headaches	54	2.136	22
Incresed sweating	52	1.454	23
Putting on weight	50	2.450	64
Slowing of movements	50	1.609	52
Diff, staying awake	48	1.889	54
Lack of emotions	48	2.333	50
Dizziness	48	1.577	38
Period problems	48	2.750	56
Sleeping to much	46	1.500	70
Constipation	44	1.300	23
Palpitations	40	1.812	30
Feeling sick	38	1.765	37
Muscle spasm	36	1.933	44
Reduced sex drive	34	1.461	41
Periods less frequent	33	1.125	57
Increased sex drive	32	1.231	6
Loosing weight	28	1.312	21
Rash	24	1.133	42
Itchy skin	22	1.850	45
Diff. achieving climax	20	2.250	40
Diarrhoea	20	2.333	20
Drooling mouth	20	2.429	70
Skin marks	18	1.375	45
Diff. passing water	16	2.500	37
Gynaecomastia	8	1.714	50

Lurkers



Side Effect Scoring by Group

Extrapyramidal side effects
19.Muscle stiffness
29.Slowing of movements
34.Muscle spasms
40.Restlessness
43.Shakiness
48.Moving body parts
37.Over-wet or drooling mouth
Possible score range 0-28

Other autonomic side effects
15.Dizziness
16.Feeling sick
20.Palpitations
27.Increased sweating
36.Diarrhoea
Possible score range 0-20

Psychic side effects
2.Diff. staying awake during the day
4.Increased dreamin
9.Diff. concentrating
14.Tension
18.Tiredness
21.Diff. in remembering things
23.Lack of emotions
26.Depression
31.Sleeping too much
41.Difficulty getting to sleep
Possible score range 0-40

Miscellaneous side effects
5.Headaches
22.Losing weight
39.Putting on weight
44.Pins and needles
Possible score range 0-16

Anticholinergic side effects
6.Dry mouth
10.Constipation
32.Difficulty passing water
38.Blurred vision
51.Passing a lot of water
Possible score range 0-20

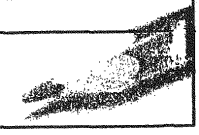
Allergic reactions
1.Rash
35.Sensitivity to sun
47.New or unusual skin marks
49.Itchy skin
Possible score range 0-16

Hormonal side effects
7.Swollen or tender chest
13.Period problems *female only
17.Increased sex drive
24.Dificulty in achieving climax
46.reduced sex drive
50.Periods less frequent *female only
Possible score range (males) 0-16
Possible score range (females) 0-24

Red herrings
3.Runny nose
8.Chilblains
11.Hair loss
12.Urine darker than usual
25.Weak fingernails
28.Mouth ulcers
30.Greasy skin
33.Flushing of face
42.Neck muscles aching
45.Painful joints
Possible score range 0-40

Range for total scores

Females:Score excluding red herring items = 0 - 164
Males:Score excluding red herring items = 0 - 156
Females:Score including red herring items = 0 - 204
Males:Score including red herring items = 0 - 196



Appendix O. Media Consent/Release Form for audiotape.

IRB Approved
Date: 3/25/04
No.: 03-04-21

MEDIA CONSENT FORM

Media Consent & Release

Permission is hereby given to Stephanie Ford, a Florida International University graduate student, her agents, and persons or entities hired or authorized by her, to make, or have made, voice recordings and to use such voice recordings without compensation as authorized by Stephanie Ford for **educational and instructional purposes only** related to the QAUTRO Adherence Therapy study and program fidelity monitoring protocol.

I also understand that the original recording will be safeguarded in a secure, locked cabinet to maintain my confidentiality and no identifying information will be attached to the voice recording tape. Therefore, I agree to indemnify and hold harmless from any claims Stephanie Ford, her agents, and persons or entities hired or authorized by her.

I understand the original audiotapes will be held in a locked, fireproof box at the graduate student's residence for three years and then destroyed.

The undersigned hereby agrees to the terms and conditions of this Agreement. If subject is a minor (under 18 years of age), parent/guardian signature must be included.

Name: _____

Signature: _____

Witness Name: _____

Witness Signature: _____

Appendix P. *Therapist Fidelity Monitoring Protocol.*

QUATRO
Adherence Therapy

Fidelity monitoring protocol

Richard Gray
FMPv14602

QUATRO
Adherence Therapy

ADHERENCE THERAPY SCALE

(Gray and Robson 2002 adapted from the cognitive therapy scale Vallis et al., 1986)

Therapist name: _____

Centre: _____

Patient trial code: _____

Date of session: _____

Session number: _____

Rater name: _____

Date of Rating: _____

Directions: For each item, assess the therapist on a scale from 0 to 3, and record the rating in the space provided. Descriptions are given for each item.

1. Collaborative agenda setting

Score	Rating	Anchor points
0	☐	The therapist did not set an agenda
1	☐	The therapist set an agenda that was vague or incomplete
2	☐	The therapist worked with the patient to set a mutually satisfactory agenda that included specific areas for discussion.
3	☐	The therapist worked with the patient to set an appropriate agenda with specific and relevant areas for discussion suitable for the time available. Established priorities and then followed this agenda.

2. Feedback and understanding

Score	Rating	Anchor points
0	☐	The therapist did not ask for feedback to determine the patient's understanding of, or response to, the session.
1	☐	The therapist elicited some feedback from the patient, but did not ask enough questions to be sure the patient understood the therapist's line of reasoning during the session or to ascertain whether the patient was satisfied with the session
2	☐	The therapist asked enough questions to be sure that the patient understood the therapist's line of reasoning throughout the session and to determine the patient's reactions to the session. The therapist adjusted his/her behaviour in response to the feedback, when appropriate.
3	☐	The therapist was especially adept at eliciting and responding to feedback throughout the session (e.g. elicited reactions to session, regularly checked for understanding, helped summarize main points at end of session).

3. Reflective listening

Score	Rating	Anchor points
0	☐	The therapist repeatedly failed to reflect back what the patient explicitly said and thus consistently missed the point. Poor empathic skills.
1	☐	The therapist was usually able to reflect or paraphrase what the patient explicitly said, but repeatedly failed to respond to more subtle communication. Limited ability to listen and empathise.
2	☐	The therapist generally seemed to grasp the patient's "internal reality" as reflected by both what the patient explicitly said and what the patient communicated in more subtle ways. Good ability to listen, reflect and empathise
3	☐	The therapist seemed to understand the patient's "internal reality" thoroughly and was adept at communicating this understanding through appropriate responses to the patient (e.g. the tones of the therapist's response conveyed an empathic understanding of the patient's "message")

4. Collaboration

Score	Rating	Anchor points
0	☐	The therapist did not work in a collaboratively way with the patient.
1	☐	The therapist attempted to collaborate with the patient, but had difficulty establishing rapport.
2	☐	The therapist was able to collaborate with the patient and establish rapport.
3	☐	Collaboration seemed excellent; the therapist encouraged the patient as much as possible to take an active role during the session (e.g. by offering choices) so they could function as a "team".

5. Pacing and efficient use of time

Score	Rating	Anchor points
0	☐	The therapist made no attempt to structure therapy time. The session seemed aimless.
1	☐	The session had some direction, but the therapist had significant problems with structuring or pacing (e.g., too little structure, inflexible about structure, too slowly paced, too rapidly paced).
2	☐	The therapist was reasonably successful at using time efficiently. The therapist maintained appropriate control over flow of discussion and pacing
3	☐	The therapist used time efficiently by tactfully limiting peripheral and unproductive discussion and by pacing the session as rapidly as was appropriate for the patient.

6. Developing discrepancy

Score	Rating	Anchor points
0	☐	The therapist relied primarily on debate, persuasion, or the didactic presentation of information.
1	☐	The therapist relied too heavily on persuasion and debate, rather than developing discrepancy. However, the therapist's style was supportive enough that the patient did not seem to feel attacked or defensive.
2	☐	The therapist, for the most part, helped the patient to see new a perspective through developing discrepancy (e.g., examining evidence, considering alternatives, exploring ambivalence) rather than through debate. Used questioning appropriately.
3	☐	The therapist was especially adept at developing discrepancy during the session. Achieved an excellent balance between skilful questioning and other modes of intervention.

7. Dealing with resistance

Score	Rating	Anchor points
0	☐	The therapist did not use any strategies to work with resistance
1	☐	The therapist made an attempt to work with resistance but tended towards confrontation and argument
2	☐	The therapist, for the most part, used effective strategies to work with resistance (e.g. reflective listening, emphasis on personal choice and control, reassessing readiness, importance and confidence, backing off and coming along side the patient).
3	☐	The therapist was extremely skilled at working with resistance during the session. Made excellent use of a range of strategies.

8. Application of adherence therapy techniques *(Note: For this item, focus on how skilfully the techniques were applied, not on how appropriate they were or whether change actually occurred).*

Score	Rating	Anchor points
0	☐	The therapist did not apply any recognisable adherence therapy techniques.
1	☐	The therapist used adherence therapy techniques, but there were **significant flaws** in the way they were applied.
2	☐	The therapist applied adherence therapy techniques **with moderate skill.**
3	☐	The therapist **very skilfully** and resourcefully employed adherence therapy techniques.

Total score (add items 1-8 together) _____

In your opinion was this patient receiving

☐ Adherence therapy
☐ Health education
☐ Don't know/unsure

Once completed please send a copy to Richard Gray, at the Health Services Research Department, Institute of Psychiatry, De Crespigny Park, London, UK.

Appendix Q. QAT Program Satisfaction Questionnaire.

QAT PROGRAM SATISFACTION QUESTIONNAIRE

Please circle the response that most closely describes how you feel right now.

	5	4	3	2	1
1. I learned more about how I manage my mental health.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
2. I had a chance to ask questions I always wanted to ask.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
3. I learned more about my treatment for mental health.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
4. I didn't learn anything new about my treatment for mental health	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
5. I understand more about how the medication I take affects me	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
6. My counselor was helpful to me.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
7. I enjoyed being a part of the study.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
8. People in the study treated me with respect.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
9. I am satisfied with this counseling study.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
10. I would recommend this type of counseling to a friend.	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
11. I have a better understanding of how to take care of my mental illness	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree

The best things about the counseling study are:

_____.

_____.

_____.

_____.

A list of the things I wish had been different in this counseling study:

_____.

_____.

_____.

_____.

Appendix R. Human Participation Protections Certification for all Study Members

UW Human Subjects Training Certification

Print this page as a record of completing the Human Subjects Protection Training
To print, select Print from the File menu, or hit the printer icon on your toolbar.

This certifies that **KATHRYN ANDERSON** completed the UW computer-based training on human subjects protection on **5/28/2003**.

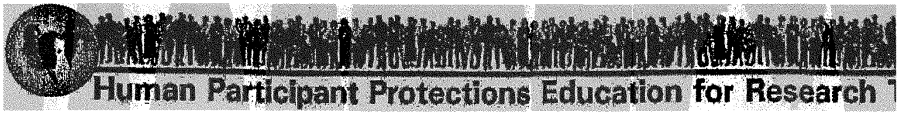
For specific questions on human subjects protection or IRB related policies, check the Protection of Human Subject in Research website or contact one of the following IRB offices:

Health Sciences Center IRB
This IRB reviews all research protocols involving medical interventions or procedures where medical expertise is required for evaluation.
Contact: Nichelle Cobb , Ph.D., Acting Director, 262-1980
Office: Judith Brickbauer, Program Assistant, 263-2362
IRB Chair: Norman Fost, M.D., M.P.H., Professor, Pediatrics, 263-8562

Social and Behavioral Sciences IRB
This IRB reviews social, behavioral, and non-medical health research. It does not have appropriate expertise for review of medical research, but may review research protocols involving minimal risk health-related studies, such as those involving exercise, tape sensors, and single venipuncture, where medical training is not necessary for the evaluation of risk to research subjects.
Contact: Donna Jahnke, Assistant Dean, 263-2320
IRB Chair: Jon Miller, Ph.D., Professor, Communicative Disorders, 262-6461

Education Research IRB
This IRB specializes in education research. It does not have appropriate expertise for review of medical research, but may review research protocols involving minimal risk health-related studies, such as those involving exercise, tape sensors, and finger sensors, where medical training is not necessary for the evaluation of risk to research subjects.
Contact: Kari Walsh , 262-9710
IRB Chair: Allan Cohen, Ph.D., Associate Professor, Educational Psychology, 262-5863

Research and Sponsored Programs Homepage



Completion Certificate

This is to certify that

jean ansourian

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 10/19/2003.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

Completion Certificate

This is to certify that

Patricia Brinson

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 10/25/2003.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

Completion Certificate

This is to certify that

marie fairchild

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 10/27/2003.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

http://cme.cancer.gov/cgi-bin/cms/cts-cert5.pl 10/27/2003

Completion Certificate

This is to certify that

Stephanie Ford

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 10/03/2003.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

http://cme.cancer.gov/cgi-bin/cms/cts-cert5.pl 10/3/2003

Completion Certificate

This is to certify that

Richard Gray

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 02/18/2004.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health

Completion Certificate

This is to certify that

Tara Haley

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 02/09/2004.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

Completion Certificate

This is to certify that

marina oksengorn

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 02/09/2004.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

Completion Certificate

This is to certify that

Debbie Robson

has completed the Human Participants Protection Education for Research Teams online course, sponsored by the National Institutes of Health (NIH), on 03/24/2004.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
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- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health

Appendix S. Therapist Informed Consent Form.

If your client agrees to tape record a session, you and your client will sign a form saying it is okay to tape record the session.

You will receive clinical supervision from Dr. Kathy Anderson on site as arranged by you and you will participate in further supervision with Dr. Richard Gray or Deborah Robson individually as agreed during the training session.

The principle investigator, Stephanie Ford, and research assistant, Patricia Brinson will be blinded to the control or experimental status of all study subjects. You agree to maintain the confidentiality of subject's identity and refrain from discussion of the study and subjects participation in counseling except in private supervision sessions.

Stephanie H. Ford, the principle investigator, is available for any questions at 954.463.0457 or 754.581.2844.

If you have further questions and want to talk to someone at Florida International University about this study, please contact Dr. Kathy Anderson at 1-305-919-5376. If you still have questions and need to talk further, you can call Dr. Bernard Gerstman. He is the Chairperson of the Florida International University, Institutional Review Board. His phone number is 1-305-348-3115 or 1-305-348-2494.

By signing your name below on this form, you are saying that all of your questions have been answered in a way you like and that you understand what your responsibilities are in the study. Your signature on this form also indicates that you have an understanding of your rights and that you would like to participate in this study.

Signature of Participant	Printed Name	Date

I have explained the research procedure and subject rights. I have answered all questions asked by the participant. I have offered the participant named above a copy of this informed consent form.

Signature of Witness	Printed Name	Date

APPROVED