OUTCOME EVALUATION OF AN EARLY PSYCHOSIS PROGRAM USING PRE-POST COMPARISON AND PROPENSITY MATCHING

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OUTCOME EVALUATION OF AN EARLY PSYCHOSIS PROGRAM USING PRE-POST COMPARISON AND PROPENSITY MATCHING

By

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ABSTRACT

Early Psychosis Programs have been developed as a solution to reduce delays and improve outcome for first episode psychotic patients. Evaluations of the programs worldwide have found that the programs help reduce symptoms and hospitalizations and improve quality of life. The purpose of this thesis is to evaluate the overall impact of the Newfoundland and Labrador Early Psychosis Program (NL Program) for its patients. Traditionally, programs are evaluated by pre-post methodology. However, this method may have limitations since it does not use standard control groups and any changes seen in the patients from entry to completion of the program may be due to natural events, such as maturation and changes in hormones, since the patients tend to be fairly young. Therefore, this study will test a novel methodology, propensity matching, as an alternative method to evaluate the NL Program. The patients are matched to a national population from the Canadian Community Health Survey (CCHS) on several clinical and social outcomes to determine how the patients differ from the general population at entry into the NL Program and then after two years, to see if they converge back to the population after completing the NL Program. Propensity matching results are then compared to the pre-post results. Analysis of the data found the propensity matching methodology did produce similar results as the pre-post evaluation approach on social and clinical outcomes such as reducing substance use, depression, hospitalizations and suicide, and improving quality of life and vocational functioning. In conclusion, this study found the NL Program is having a major treatment effect for its patients, and propensity matching may serve as a model in future evaluations in mental health research.

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CHAPTER 1

INTRODUCTION TO THE PROBLEM: OUTCOME EVALUATION OF AN EARLY PSYCHOSIS PROGRAM USING PRE-POST COMPARSION AND PROPENSITY MATCHING

1.1 Statement of the Problem

Psychosis is a medical condition that affects the brain. First episode psychosis refers to the first time an individual experiences psychotic symptoms or psychotic episode. Approximately three percent of all Canadians will experience a psychotic episode in their lifetime (Mheccu, 2000). It usually occurs in late adolescence–early adulthood. Symptoms of early psychosis include hallucinations, delusions, bizarre behaviours, and mood changes (Mheccu, 2000). Research has found that psychosis is a treatable medical condition, but recovery varies from person to person (EPPIC Statewide Services, 2000b).

Several studies have shown that a delay in treatment and prolonged duration of psychosis is correlated with poorer clinical outcomes and major health care expenditures, such as increased hospitalizations and expensive medication (McGlashan & Johannessen, 1996). Detecting psychosis at the earliest possible time can reduce symptoms and promote recovery, thereby providing long-term benefits for patients and their families (McGorry & Yung, 2003).

Early psychosis programs have been developed as a solution to reduce delays in treatment and improve outcomes. These programs are designed to provide structured treatment for three years. McGorry et al. in Melbourne, Australia (2000a); Addington et al. in Calgary, Canada (2004a); and Malle et al. (2001) in Ontario, Canada have evaluated their programs and have found that these programs do reduce delays and hospitalizations, improve patients' quality of life and can help reduce medication dosage. Thus, these programs have clinical and economic benefits. The Newfoundland and Labrador Early Psychosis Program (NL Program) was established in 2001 and has not yet been evaluated to determine if this program provides beneficial treatment outcomes.

1.2 Purpose of this Study

The purpose of this study is to evaluate the overall impact of the NL Program for patients.

The difficulty in evaluating a program that is designed specifically for a unique population is determining the best methodology to use for the most accurate results. While a Randomized Clinical Trial (RCT) is recognized as the gold standard in program evaluation, it is not always ethical to randomly assign patients to two groups, i.e. those who will receive treatment and have another who will not receive treatment to determine a treatment effect. There are ethical challenges to conduct a prospective study in which individuals with early psychosis are denied treatment at random for prolonged periods of time in order to assess outcome (McGorry, 2000a). RCTs also have high internal validity since the intervention is done under controlled circumstances with double-blinded

procedures. The difficulty in performing an RCT to evaluate an early psychosis program is that there is evaluator and participant bias that can influence the treatment effects. Recently, Petersen et al. (2005) performed an RCT of integrated versus standard treatment for first-episode psychosis. Patients were randomized into either treatment by computer-generated random lists. Both treatments offered the same anti-psychotic medication and psychotic care provided routinely by the mental health services, but the integrated treatment included more personal contact and follow-up by the multidisciplinary team and more support facilities. Their RCT found the integrated treatment had a significantly better effect on clinical and social outcomes of patients compared with standard treatment (Petersen et al., 2005). This was the first study to perform an RCT design on first psychotic patients using integrated versus standard care.

Other studies have used a methodology of comparing patients to historical control groups. However, this methodological approach also has limitations. Simple comparisons of individuals receiving different treatments are potentially biased in that they do not reveal the effect of treatment per se, and there maybe baseline differences that could be an explanation for the observed differences.

Therefore, most studies to date as outlined in the literature review (Chapter 2), evaluated early psychosis programs by assessing patients at entry into the program and after completion of the program on several outcomes to determine a treatment effect (Addington et al., 2004b; Malla et al., 2001a). However, there may also be a flaw in using pre-post methodology. First, there are no standard control groups being used. An evaluation of a program by comparing the early psychosis group with a control group

would be of value since any differences found between the groups on clinical and social outcomes would suggest a treatment effect of the program. Secondly, the researchers using a pre-post approach implicitly assume any changes in the patients' outcomes from entry to completion of the program are due to the treatment. However, since early psychosis patients tend to be young, the treatment affects maybe due to natural events, such as maturation and changes in hormones.

Another evaluation approach, propensity matching, allows matching of a unique group to a control group on similar variables, such as gender, age and living status, to eliminate baseline differences. Propensity matching is based on a critical assumption that individuals who are matched on the same characteristics can then be sorted into treatment and control groups as if randomly assigned (Ascher-Svanum et al., 2003). Given the assumption of no baseline differences, the groups can then be compared on several clinical and social outcomes, such as employment, substance use and hospitalizations, to determine if the program has helped patients improve from initiation to the end of the three-year program. This study is the first time an early psychosis program will be evaluated using propensity-matching methodology.

The objectives of this study are:

1. To evaluate the impact of the NL Program for patients on a number of clinical and social outcomes.
2. To use propensity matching to match psychosis patients with the general population on demographic variables to eliminate baseline differences since randomization into the program is not feasible.

3. To use a national database, the Canadian Community Health Survey (CCHS), as the general population for comparison with the NL early psychosis patients.
4. To determine how the patients differ from the general population at entry level into the NL Program on clinical and social variables, such as employment and hospitalizations.
5. To determine if patients at the end of the NL Program converge back to the population mean on the same variables.
6. To compare and contrast this new methodology with the traditional pre-post methodology, which evaluates the patients before and after in a program to determine the treatment effect of early psychosis programs.

The Importance of This Research

This research will test a novel methodology on a unique population. If this methodology does prove to be more useful in evaluating unique population programs, then this method may serve as a model for future program evaluations in mental health research. According to McGorry (1998) evaluation allows clinicians to judge the value of an intervention and that outcome data can influence policy makers. Good quality evaluation can help protect innovative services in an environment of scarce resources.

1.3 Structure of the Thesis

Following this introductory chapter, Chapter 2 provides an introduction to psychosis, describing its characteristics, identifying who can develop psychosis, examining what can cause psychosis to occur, describing the different types of psychoses, the characterizing symptoms and the three phases of the disorder. The chapter continues with a literature review of studies completed on early psychosis, such as the effects of delayed treatment (duration of untreated psychosis-DUP), the importance of early intervention, the development of early psychosis programs as a solution and studies that have evaluated the programs and their outcomes. Finally, previous studies using propensity matching will be discussed.

Chapter 3 describes the methodology used to evaluate the NL Early Psychosis Program, using the NL Program and the CCHS databases.

Chapter 4 presents the results obtained using the propensity matching methodology and the pre-post methodology.

Chapter 5 presents a summary and discussion of the results.

Chapter 6 is the concluding chapter that highlights the importance of the research findings, the research limitations and recommendations.

All the references used in this thesis will be placed at the end. The appendices will follow, which includes a letter asking permission of the NL Early Psychosis Coordinators to use the patient database; an Early Psychosis Program approval letter granting permission to use the database; HIC application; HIC approval letter; RPAC

application; RPAC approval letter; and matched questions from the Early Psychosis Program scales and the Canadian Community Health Survey (CCHS).

CHAPTER 2

LITERATURE REVIEW OF EARLY PSYCHOSIS

2.1 What is Psychosis?

Psychosis is a medical condition that affects the brain. It involves loss of contact with reality and is characterized by notable changes in a person's thoughts, beliefs, perceptions and/or behaviours (EPPIC Statewide Services, 2000a). Approximately three percent of all individuals will experience a psychotic episode in their lifetime (Mheccu, 2000). Eighty percent of episodes usually occur in late adolescence or early adulthood (ages 16-30). The median age of first onset of psychosis is 19 years (Mheccu, 2000).

Adolescence is the stage in life where individuals go though a biological process of physical maturation, which closely interacts "with psychological and social tasks of preparation for independence and adult responsibilities" (Goudreau, 2003). Many youth have difficulty adapting and accepting the change and transformations that occur during this time (Goudreau, 2003). Psychosis is a challenging condition to face at any point in life, however its effects can be particularly disruptive during this critical period of development. It can seriously damage a young person's development of identity and interrupt their ability to create and maintain relationships and long-term vocational plans to create a meaningful and productive future (Liberman & Fenton, 2000). Thus, it is a confusing and disturbing process for both the person and their family. The initial

reactions to psychosis can range from bewilderment to denial, anxiety and shock (Kuipers & Raune; 2000).

Research has found that psychosis affects males and females equally. However, studies have found females typically experience a first episode two to three years later than males (Loebel et al., 1992). It can also occur across all cultures and socioeconomic status. McGorry & Killackey (2002) reported that mental health problems account for 75% of the burden of disease in the late adolescent-early adult group.

2.2 What Can Cause Psychosis?

Several theories have been suggested as contributing factors to developing psychosis, but there remains no clear consensus as to the underlying cause (EPPIC Statewide Services, 2000a). Although the exact causes of psychosis remain unknown, evidence supports the fact that psychotic disorders are brain disorders that result from disturbances in brain functioning. The "stress-vulnerability" model is one proposed theory to understand the onset and course of psychosis (Mheccu, 2000). This model suggests that psychotic symptoms can be triggered by interactions between a biological predisposition (genetic and neurodevelopmental factors) and environmental stressors (Mheccu, 2000). In other words, biological factors create vulnerability to experiencing psychotic symptoms, which when coupled with environmental stressors, such as substance abuse, psychotic symptoms often emerge in such vulnerable individuals. Some factors may be more or less significant in one person than in another. Some biological

factors include a positive family history of psychosis and paranoid personality disorders (Mheccu, 2000). For example, the risk of developing psychosis is 1% for the general population compared to 13% for the children who have parents with schizophrenia (Mheccu, 2000). Other causes of psychosis include substance abuse or withdrawal; social changes; psychiatric disorder; prenatal complications; obstetric complications; dopamine dysfunction; neurotransmitters; and/or viruses.

2.3 Types of Psychosis

Individual experiences of psychosis and the type of psychosis diagnosed vary. Diagnosis means "identification of an illness by a person's symptoms and it will depend on the cause of the illness and the duration of the symptoms" (EPPIC Statewide Services, 2000a). There are a number of conditions that can present psychosis such as the following:

- A) Drug-Induced Psychosis: This psychosis occurs from using or withdrawing from alcohol and drugs (EPPIC Statewide Services, 2000a).
- B) Organic Psychosis: Psychotic symptoms appear as a result of a head injury or a physical illness, such as AIDS or a tumor, which disrupts brain functioning (EPPIC Statewide Services, 2000a).
- C) Brief Reactive Psychosis: Psychotic symptoms appear as result of a sudden response to a major stress in the individual's life, such as a death in the family (EPPIC Statewide Services, 2000a).

- D) Delusional Disorder: Psychotic symptoms appear as a result of false beliefs (EPPIC Statewide Services, 2000a).
- E) Schizophrenia: There are changes in a person's behaviour that have continued longer than six months. (EPPIC Statewide Services, 2000a).
- F) Schizophreniform Disorder: There are changes in a person's behaviour that last less than six months (EPPIC Statewide Services, 2000a).
- G) Bipolar (Manic-Depressive) Disorder: This psychotic illness is characterized by psychotic symptoms following the persons' general disturbance in mood, either extreme highs (mania) or lows (depression) (EPPIC Statewide Services, 2000a).
- H) Schizoaffective Disorder: Psychotic symptoms are present that are not distinctive of a mood disorder or schizophrenia. The person has alternating symptoms of both a mood disorder and psychosis (EPPIC Statewide Services, 2000a).
- I) Psychotic Depression: Illness involves severe depression with psychotic symptoms. However, unlike bipolar disorder, there are no periods of mania (EPPIC Statewide Services, 2000a).

2.4 Psychotic Symptoms

Symptoms of psychosis develop gradually over a period of weeks, months or even years. Symptoms vary from person to person and may change over time. The symptoms can be classified into positive, negative and cognitive symptom clusters.

Positive symptoms include hallucinations, delusions, thought disorder, disorganization, and bizarre behaviour (Kuipers & Raune, 2000). Hallucinations are distorted perceptions, such as the individual sees, hears, feels, smells or tastes something that is not actually there. Delusions are fixed false beliefs; such as the belief that their house is being monitored by police (Kuipers & Raune, 2000). Thought disorder symptoms can occur when the individual has jumbled or unusual thought processing, such as thoughts seeming to speed up or slow down (Kuipers & Raune, 2000). They may find it difficult to express themselves (Mheccu, 2000). Disorganization occurs when the individual has difficulty organizing thoughts, speech and/or behaviour. And finally, bizarre behaviour occurs when an individual behaves differently from usual (EPPIC Statewide Services, 2000a). For example, they may become angry without apparent cause, or will stop eating because they are concerned that the food is poisoned (EPPIC Statewide Services, 2000a).

Negative symptoms include emotional unresponsiveness, loss of motivation, poverty of speech and social withdrawal (Mhecuu, 2000). Individuals may display inappropriate emotional display. Loss of motivation is present when an individual has no desire to perform activities, such as homework. Poverty of speech is manifested when it is difficult to understand the language used by the individual. Social withdrawal is characterized by an individual withdrawing from relationships with family and friends.

There are also cognitive symptoms associated with psychotic disorder. Cognitive problems may include problems with verbal, working and spatial memory, and as well as difficulty concentrating and focusing attention (Lieberman & Fenton, 2000).

Other symptoms that are additional early signs of psychosis may include: sleep or appetite disturbances, agitation, anxiety, depression, suicidal thoughts and impaired role functioning, such as not fulfilling the role of a parent (Mhecuu, 2000).

2.5 Three Phases of Psychosis

A psychotic episode can be divided into three phases, with the duration of each phase varying from person to person. The three phases are the prodromal phase, the acute phase and the recovery phase.

The Prodromal Phase is the period during which the individual experiences changes in feelings, thoughts, perceptions and behaviours but they have not experienced clear positive psychotic symptoms such as hallucinations, delusions or thought disorder (Mheccu, 2000). These prodromal signs are vague and hardly noticeable, and do not always precede the acute phase. Some prodromal symptoms include: feelings of vague suspiciousness, depression, anxiety and mood swings; difficulty in concentrating and remembering; feeling somehow different from others; sleep disturbances; appetite changes and loss of energy or motivation (EPPIC Statewide Services 2000c). Family members or friends may notice that the individual's behaviour changes, their studies or work deteriorate, they become more withdrawn, socialize less or they might become less active (EPPIC Statewide Services 2000c). However, these changes could have resulted from psychosocial difficulties, physical or psychiatric disorders (Mheccu, 2000).

Despite extensive research into the interaction between risk factors and attempts to establish developmental pathways of mental disorders, the probability of whether or not a particular group of signs and symptoms predicates the development of the disorder is unknown (Spencer, 1996). The high-risk research still produces a high level of false positives, where individuals who are identified as being at risk due to the presence of particular signs, do not go on to develop a full-blown disorder (Spencer, 1996).

The Acute Phase occurs when the individual experiences clear psychotic symptoms, such as hallucinations, delusions or social withdrawal. In order to declare that a person is experiencing a psychotic episode, the prodromal symptoms have reached a threshold of severity and are persistent. (Lieberman & Fenton, 2000).

The Recovery Phase occurs when an individual has been identified with psychosis and begins treatment. Psychosis is a serious but treatable medical condition, however recovery varies from person to person. Research has found that most people do recover from a first psychotic episode (Mheccu, 2000). However, others will develop recurring episodes of psychosis, but will be relatively well and will continue to lead a productive life, especially if they continue on maintenance medication (Mheccu, 2000). The recovery process is dynamic, with success being a function of a number of interacting factors, such as treatment environment, medication, psychological therapies, families, and social environments, all of which will be discussed below.

2.6 Consequences of Delayed Treatment (Duration of Untreated Psychosis -DUP)

Several studies have shown that there is often a significant delay in treatment for individuals who experience a first episode of psychosis (McGorry & Killackey (2002); McGlashan & Johnannessen (1996); Johnstone, Johnson & MacMillan (1986)). Psychosis often remains untreated for many months and some people live with untreated psychosis for years. Also, when the illness is recognized, there are often other barriers to assessing treatment. Further delays can occur as a result of skill and knowledge gaps among professionals. Canadian statistics, on average, indicate that first episode patients make 2.3 help seeking contacts following the onset of psychosis; most of these are made to emergency services and family physicians (Addington et al., 2002). The duration of untreated psychosis (DUP) is defined as "the time from onset of psychosis to the initiation of adequate treatment" (Larsen et al., 2000). It has been estimated that DUP can be 1-2 years (Kalla et al., 2002). Addington et al. (2002) estimated DUP to be 2-5 years. These findings suggest that many psychotic patients can be living within the society for a considerable period of time with the condition undiagnosed (Kalla et al., 2002). Delays in identifying and treating psychotic cases represent a major public health concern (Kalla et al., 2002).

Studies have shown that delayed treatment and prolonged duration of delays is correlated with poorer outcomes (McGlashan & Johannessen, 1996). Bottlender et al. (2003) performed a study involving patients with schizophrenia to test the hypothesis that DUP prior to first psychiatric admission adversely affects treatment response and short-

term outcome in schizophrenia. Their results found that a longer DUP was associated with lower global functioning and more pronounced psychotic symptoms. They concluded that DUP prior to first admission detrimentally affects long-term outcome. These researchers stress the importance of health service programs for early detection and treatment of patients to reduce DUP and therefore improve patients' outcomes (Bottlender et al., 2003).

Another study by Harrigan et al. (2003) was conducted on first episode subjects to test whether DUP predicted 12-month outcome independently of the effects of potential cofounders, such as age of onset of symptoms, gender, level of education, severity of drug use and diagnosis. The study found that DUP remained a consistent predicator of functional and symptom outcome even after controlling for these potential confounders.

Although the evidence provides supportive, but not conclusive evidence of the adverse effects of DUP, DUP should still be the focus of early intervention strategies. Reducing delays is justified in order to prevent much unnecessary misery and suffering. Undiagnosed and untreated psychosis inflicts a significant burden of suffering and confusion for individuals and their families (Lieberman & Fenton, 2000). Untreated psychosis is accompanied by impairments in functioning that affect the normal processes of development for a young adult (Lieberman & Fenton, 2000). Developmental tasks such as building peer and romantic relationships, achieving independence from family, acquiring independent living skills, and preparing for future endeavors may all be disrupted (Lieberman & Fenton, 2000). McGorry (1998) states that such a prolonged delay in treatment during the critical developmental phases of early adult life could

negatively influence the capacity for psychosocial recovery, even if the biological disturbance could be successfully treated. There is an additional theory that the biological change may itself prove less responsive to treatment if it is present for a long period before the person is treated with anti-psychotic medication (Wyatt, 1991). However, there is skepticism of this argument since there are no contemporary RCTs comparing timely versus delayed intervention (McGorry, 1998).

Untreated psychosis also increases high-risk behaviours, such as violence, with the impending long-lasting consequences for the individual and/or others (Lieberman & Fenton, 2000). DUP also increased rates of relapse (Crow, MacMillan, Johnson, & Johnstone, 1986; Addington et al., 2002). Johnstone et al. (1986) found the rate of relapse was significantly predicted by delay in treatment, with patients who had a delay longer than one year having a greater risk to relapse over the following two years, compared to those with a shorter DUP.

Psychosis accounts for major health care expenditures, such as increased hospitalization and treatment with costly medications. Moscarelli et al. (1991) studied patients three years after treatment and found the cost of treatment for patients with a DUP greater than 6 months was twice the cost of those with DUP less than 6 months. Yung et al. (2002) found similar results of the economic burden of a long DUP.

A summary of the effects of a significant delay in treating psychosis therefore includes disruption of life course, parenting role, family and social relationships and study or employment. It may also increase family strain: financially if a parent has to quit his/her job to become a caregiver of the patient; and emotionally if there are needs

and expectations of other siblings. As well, it could intensify use of drugs and alcohol; increase risk of depression, suicide, criminal activity, hospitalization, economic cost to the community, risk of injury to themselves and could lower self-esteem and self-identify and slow recovery. Therefore, detecting psychosis at the earliest possible time can reduce symptoms and promote recovery, thereby providing long-term benefits for individuals and their families.

2.7 Reasons for Treatment Delays

Several reasons have been proposed to explain why there has been a delay in early treatment of psychosis. DUP maybe confounded by other predictors of outcomes, such as pre-morbid adjustment, family psychiatric history, level of education, homelessness, level of substance use and mode of onset (Harrigan et al., 2003).

Gender can also account for delay in treatment seeking as men have been found to have longer DUP than women (Loebel et al., 1992). This may be due to the fact that families may have a greater tolerance to the disturbed behaviour in male adolescents or that families have a greater difficulty in recognizing psychotic symptoms in males and thus delay seeking help for males. McGorry et al. (1996) also reported that longer DUP was documented among those living alone compared to those living in a family setting.

Socio-cultural factors may also affect treatment. Although the early signs are universal, the influence of the individual, family, social and health service related factors

on treatment seeking behaviour might vary according to different cultural contexts (Larsen et al., 2001).

Lack of insight and understanding about mental illness may also delay treatment. The individuals experiencing psychosis may not perceive themselves as ill. The initial episode of psychosis is often a particularly confusing and traumatic experience for both the individual and their family. The change in the individual's behaviour causes concern and distress because it is difficult to understand what is happening. This lack of awareness and inability to recognize the symptoms of psychosis often leads to delays in seeking help, and therefore leave these illnesses unrecognized and untreated.

Even when help is sought, further delays may occur before the right diagnosis is made because recognition of these disorders can be difficult. This can cause problems in referral pathways or access to psychiatric services (Kalla et al., 2001). There is often a lack of adequate training for community health staff. There can be problems with lack of community resourced services or limited access to these appropriate services. Sometimes, if services are not available, psychotic individuals are often forced to make multiple contacts to find treatment help (Addington et al., 2002).

Initiation of treatment seeking may be negatively affected by fear of being admitted to a psychiatric facility. Etheridge, Yarrow & Peet (2004) found hospital admissions to a general acute psychiatric ward for first episode treatment was inappropriate because of the adverse psychological effects of young people being placed on psychiatric wards with adults.

Individuals may also have a perception that psychosis is a disability that carries with it a "life sentence". They often develop a subsequent anxiety regarding the possibility of developing a disorder. They may also believe in the "wait and see" approach, denying that there is a problem or thinking that it perhaps can get better on its own. Early detection and appropriate treatment offer the best chance for full recovery (EPPIC Statewide Services (2000b).

One of the major impacts of delay and powerful disincentives to treating psychosis is the social fear and stigma associated with mental illness. Individuals do not want to become "labeled" in any negative way and therefore be stigmatized and treated differently by others. Rosenfield (1997) noted negative effects of the stigma attached to mental illness on the psychological well being on the individual.

2.8 What is Early Intervention?

Early intervention is a "process of screening, case identification and the provision of effective and intensive treatment" (Rickwood, 2000). The interventions are not merely the translation of standard treatments developed for later stages of the disorder and for more persistent courses of the disorder (McGorry et al., 1996).

Early intervention can be defined has having 3 components: (1) prepsychotic intervention, (2) early case detection and initial treatment, and (3) optimal management of the first episode and the subsequent "critical period". These are described below.

Prepsychotic intervention is the process of identifying people before they have become acutely ill. Prepsychotic is thus, primary prevention, which consists of

prevention strategies aimed at the total population, such as immunizations (Larsen et al. 2001). However, identifying early psychosis is very difficult, and there are a substantial number of high false positives (Warner, 2001). As well, intervening pharmacologically during this period cannot be justified since it is unethical to introduce this treatment given the high rates of adverse side effects (Bebbington, 2000). McGorry & Killackey (2002) argued that primary prevention is beyond the capacity of our present knowledge.

As described above, the second component-early case detection-which reduces DUP is advantageous to the long-term clinical outcome. Intervention at the onset of psychosis prevents chroncity and thus is a form of secondary prevention (Whitehorn, Lazier, Kopala, 1998). McGorry & Killackey (2002) state that mental health services along with communities, primary care and clinicians should embark upon a range of strategies to reduce delays in treatment onset, such as improved recognition skills among general practitioners though training, and improved access to mental health services. This would substantially reduce DUP and thus, reduce the need for inpatient care and involuntary treatment.

The third component is that optimal treatment in the early phase of psychosis could reduce the length of the illness and thus reduce the prevalence of the disorder (McGorry & Killackey, 2002). Therefore, optimal treatment should have a positive effect over the long-term. Treating young people during this "critical period" is both clinically and cost-effective (McGorry & Killackey, 2002; Malla & Norman, 2002).

The first three years of psychosis (treated and untreated) illness offers an opportunity to prevent, or limit, this potential decline (Birchwood, 2000). Jackson &

Birchwood (1996) state that there are two main reasons why intervening in the first three years may have long-term benefits. First, treating in these early years can predict later outcome. Second, social theorists have stated that establishing or reestablishing a range of valued roles and goals such as employment would be best done as early as possible and cognitive theorists have stated that damage to cognitions also form in the early years.

Early intervention is hardly an unlikely goal and would be non-controversial in other areas of healthcare, where primary prevention remains out of reach, e.g. diabetes, and many cancers (Malla & Norman, 2002). It is a strategy that can provide considerable long-term benefits.

2.9 Benefits of Early Intervention

There are several reasons for early intervention:

- First, it promotes recovery from the first psychotic episode (McGorry & Yung, 2003). Treatment can reduce symptoms. Following a first psychotic episode, the probability of recovery is very high (80%). McGorry & Yung (2003) state a first episode of psychosis should be viewed as a psychiatric emergency and treatment should be made a matter of urgency.
- Second, the longer the time spent in psychosis the greater the risk of long-term morbidity. The onset of psychosis is associated with a range of comorbidity, such as substance use, depression, suicide and social anxiety,

which if successfully addressed, should reduce mortality (McGorry & Yung (2003).

- Thirdly, psychosocial damage can occur in this critical period, such as the substantial impact of onset on self-identity and transitions of family life (McGorry & Yung, 2003). Early intervention may increase the chances of recovery in these areas, thereby improving capacity to maintain self-identity and self-esteem.
- Fourth, early intervention may prevent some biological toxicity from the brain illness. Treatment can slow the process of deterioration. If deterioration does occur early in the course of schizophrenia, earlier application of biological or psychological treatments or both should make a difference in the long-term course and outcome of the disorder than later interventions (McGlashan & Johannessen, 1996).
- Fifth, it has been suggested that strong investment in early intervention will be cost-effective (McGorry & Yung, 2003; Kuipers & Raune, 2000).
- And finally, it has been suggested that early intervention might be beneficial for families and care-givers in reducing depression, stress and distress and therefore, the likelihood of these symptoms recurring in the individuals (Kuipers & Raune, 2000). Providing therapeutic support that emphasizes the importance of improving the quality of relationships can help patients to recover.

In summary, the focus of early intervention is designed to limit damage to personal identity, social networks, and role-functioning and decrease health costs caused by the underlying illness (McGorry et al., 1996).

2.10 Barriers to Early Intervention

McGorry & Killackey (2002) state that despite the early intervention reform, the quality of healthcare for those experiencing psychosis remains unacceptably poor. They state several reasons: there are considerable pessimistic doubts about outcome; psychiatry seemingly has low priority in the healthcare system and as a result is often under funded with poor workforce quality; and the advances made in treatment are not always translated into clinical settings (McGorry & Killackey, 2002).

The main problem in justifying early intervention is that randomized controlled trials of early intervention cannot be done because of ethical restrictions. (Bebbington, 2000). This would be an RCT of early and later intervention. However, there are ethical challenges to deny early treatment for prolonged periods of time that may be of benefit to someone (McGorry, 2000a). Harrigan et al. (2003) examined whether the duration of untreated illness (DUP) had an affect on patients' outcomes. They found that although there was an association between DUP and outcome, they could only provide supportive, but not conclusive evidence since their study was only correlational. The casual link between prolonged DUP and poor outcomes can only be finally established by experimentation. However, some authors argue that since a casual relationship between DUP and outcome has not been established, then DUP cannot conclusively be said to

relate to poorer outcomes (Kuipers et al., 1994; Verdoux, 2001). Verdoux (2001) believes there are other factors delaying treatment seeking that may independently predict poor outcomes. Verdoux argues that it is difficult to say that early intervention programs benefit individuals because these subjects may differ from those who did not take part in the program, for example in terms of illness severity, or in social adjustment and social networks. As well, if it is difficult to predict which subjects presenting psychotic symptoms will develop a full-blown psychotic disorder in subsequent years, then how can it be determined which subject would benefit from early treatment? He also makes the point that only a few randomized controlled trials have been performed on first episode subjects. Verdoux (2001) argues that early intervention using psychotherapy is not equivalent to early anti-psychotic treatment, implying psychotherapy treatment has greater negative consequences compared to those induced by anti-psychotic medication. As well, Verdoux (2001) states that the stigma associated with a mental illness could have a major impact of distress for the subject and family. He concludes that the time has not yet come to be overconfident in the feasibility and benefits of early intervention programs.

However, as stated earlier, several researchers, such as McGorry et al. (1996) and Harrigan et al. (2003), oppose Verdoux's view, stating that early intervention is very beneficial for individuals with psychotic disorders by treating symptoms early and effectively improving functioning. They state that traditional treatment of patients was both crude and insensitive in the way they were delivered to young people during their first contact with psychiatric services. In addition, there were significant gaps in

expertise and resources (McGorry, 1992). The experience of psychosis, pathways to care that involve the police and/or emergency departments and hospitalization on a secure ward are likely to be traumatizing for first time patients and may lead to persisting symptoms of post-traumatic stress disorder (Drury, 2000).

2.11 Early Psychosis Programs

There are an increasingly large number of groups that have now established clinical programs worldwide (Edwards & McGorry, 2002). These early psychosis programs are "a comprehensive individualized treatment plan that uses an interdisciplinary team approach and incorporates the use of low dose anti-psychotic medications with education and psychosocial interventions to promote full recovery from early psychosis" (Canadian Mental Health Association, 2002). The programs provide dedicated support to all first episode cases for the first two or three years following diagnosis (Jackson & Birchwood, 1996). Whitehorn et al. (1998) state that the treatment programs reduce the severity of the illness by detecting cases early and by providing treatment and support, therefore reducing long-term psychiatric disability. It is hoped that early psychosis programs, by providing secondary prevention, will help patients as they attempt to recover and rehabilitate (Whitehorn et al., 1998).

There are four elements of management of first episode patients in a program (McGorry & Killlackey, 2002). The first element is access and engagement of patients. The program should be non-stigmatizing and should identify first episode patients as soon as possible to reduce the length of untreated psychosis (DUP) (Addington et al.,

2002; Kalla et al., 2002). The second element is assessment, which is detecting and diagnosing psychosis (McGorry & Killackey, 2002). The third is acute treatment, which is integrated care using biological, psychosocial, family therapies, and the fourth element is the recovery phase (McGorry & Killackey, 2002). The role of the clinician throughout the process is to identify the early warning signs of psychosis, provide a range of appropriate and timely interventions and coordinate patient care (Mheccu, 2000). Some patients will require hospital admission for treatment or adequate assessment. It is important that transport to hospital and the admission itself are also handled with care to prevent shame and unnecessary distress (Mheccu, 2000). It has been well documented that psychological adaptation and adjustment can be a very difficult and painful period. Patients may be traumatized by being admitted to the hospital and/or the involvement of the police (Mheccu, 2000).

Most early psychosis programs are an integration of biological, psychosocial and structural elements of intervention which includes novel medication strategies, case management, family work, psychoeducation, psychotherapy (individual and group), occupational therapy, recreational therapy, spiritual counseling and substance abuse counseling (McGorry & Killackey, 2002), all of which will be discussed below.

Novel medication strategies involve using low doses of medication to minimize side effects. The ability of these antipsychotic drugs to reduce symptoms and possibly to improve functioning has a major impact in helping patients to participate fully in recovery and rehabilitation activities (Whitehorn et al., 1998).

Case managers are nurses who coordinate care among a variety of treating professionals and create links to other community services, such as social workers and occupational therapy services, as needed, to ensure continuity of care for patients (Mheccu, 2000). They help normalize the patients' environment as quickly as possible, monitor the clinical progress and help them work through recovery. They also provide support to family (Whitehorn et al., 1998).

Family work involves helping families cope, care and understand a loved one with a psychotic illness. Involving family should not be under-emphasized. An educated and committed family is a valuable resource for the patient and the treatment team. By providing the family with information about the illness and the rationale of the program, the family will hopefully be able to understand and support the program, and help play a role in engaging the patient in the therapeutic process. (Drury, 2000; Whitehorn et al., 1998). Jackson & Birchwood (1996) found patients with no family contacts tended to relapse earlier, have poorer outcomes and poorer occupational functioning.

Psychoeducation is a method used to train patients about mental illness while maintaining an ongoing, interactive psychotherapeutic relationship (Mheccu, 2000). It involves personal meaning, mastery and self-esteem. Personal meaning is seeing the psychotic disorder as it is related to other life experiences. Patients are taught that psychosis has added to their life experience and will be a source of future personal information about them, as opposed to erasing the experience from their mind (Jackson & Iqbalt, 2000; Whitehorn et al., 1998). They must also realize that psychosis is something that is potentially controllable and for which they must take some responsibility to

prevent relapses (Jackson & Iqbalt, 2000). Mastery "involves instilling hope for recovery, building stress management and coping skills, learning to recognize possible signs of relapse and how to access necessary resources in the future" (Mheccu, 2000). Self-esteem enhancement includes helping patients overcome stigmizing views (i.e. incompetence) they may have internalized (Mheccu, 2000; Jackson & Birchwood, 1996). Information seeking about psychosis should be encouraged. Staff should provide psychoeducation information and an interactive environment in which that can process the information.

Psychotherapy is provided both individually and in-group settings. Group therapy provides peer support by sharing of experiences; education; problem-solving opportunities for coping skills; and learning to manage through discussion and observation, which help to reduce the patient's sense of isolation and bewilderment and encourage the person to take on an active social role during a time when psychosocial functioning may be low (Mheccu, 2000; Drury, 2000). Albiston, Francey & Harrigan (1998) evaluated the impact of a group-based psychosocial program within The Early Psychosis Prevention and Intervention Centre (EPPIC), a treatment service in Australia. They found the role of group involvement in helping patients to limit the effects of psychosis to be significant. They state that further studies are needed to replicate their findings and to identify those aspects of group interventions that have the greatest impact in promoting recovery and preventing disability in the critical period of psychosis (Albiston et al., 1998).

Occupational therapy offers patients help in recovery by encouraging and helping them complete or continue their education and to integrate them into the workforce. Looking for employment can be frightening and overwhelming for people with psychosis and may require cooperation between mental health, social services and employment agencies to facilitate the pathway and to prevent relapse (Jackson & Birchwood, 1996).

Recreational therapy provides social activities. It has been well documented that social isolation is an occurring factor with psychosis and its effects can be long-term (Jackson & Birchwood, 1996). Therefore, community-oriented care involving assertive outreach can improve quality and quantity of social networks (Jackson & Birchwood, 1996).

Other forms of non-pharmacological interventions include stress management approaches and cognitive therapy. Stress management approaches "help people develop coping strategies and reduce vulnerability to stress-induced relapse" (Mheccu, 2000). It shows patients ways to deal with their stress, recognize potential relapse symptoms and modify the stressor by adjusting their environment or behaviour (Mheccu, 2000). Cognitive therapy is a "structured psychotherapy directed toward solving current problems by modifying distorted thinking and behaviour" (Mheccu, 2000). Cognitive behaviour therapy may be used to treat non-psychotic symptoms such as depression, anxiety, and substance abuse and is increasingly recognized in treating the positive symptoms of psychosis (Mheccu, 2000, p203).

The cognitive aspects of the group work focuses on "individual's beliefs about the origins and maintenance of their psychotic symptoms, assessing the loss and reduced

control associated with developing a psychosis, subjective assessment of risk and benefits of treatment in context of personal goals and values and the negative thoughts and beliefs about stressors and anxiety-provoking situations" (Drury, 2000). The Drury et al. (1996) study used Cognitive Behavioural Therapy (CBT) for one group compared to a group receiving standard care. The CBT group led to 25-50% reduction in recovery time and a 50% reduction in time spent in hospital. However, Haddock et al. (1999) evaluated the effectiveness of individual cognitive-behavioural therapy in early psychosis and found no significant difference between those who received CBT and those who received standard psycohoeducational therapy. Jackson et al. (2001) and Ueland & Rund (2004) found similar results to Haddock et al. (1999).

Gorrell et al. (2004) evaluated an early psychosis service offered to young patients experiencing psychosis with the introduction of specialized early psychosis teams and staff training and compared them to those who received treatment prior to the service being implemented. They used 24 clinical indicators to measure optimal care over a 12 month period. Their results indicated significant improvements in service provision for 10 indicators, such as family involvement, case manager involvement, change in medication regime and psychological aspects of a biopsychosocial approach, suggesting there has been substantial progress in early psychosis programs.

A focus group consisting of first episode patients described their experiences in the Southwark First Onset Psychosis Service (FIRST) in O'Toole et al. (2004) study. Participants identified several key elements that helped them in their recovery, including the 'human' approach which consisted of individualized care, time and attention and

partnerships; being involved in treatment decisions; flexibility of service delivery and appointment times; reduction in psychotic symptoms; increased confidence and independence; and provision of daily structure. This was the first qualitative evaluation of users' experiences. The authors concluded by stating what is considered important by mental health researchers and clinicians might be different from those expressed by patients. Focus groups ensure priority is given to the respondents 'hierarchy of importance' (O'Toole et al., 2004).

Yung et al. (2003) evaluated the management of early psychosis patients at a hospital for general adults and compared them to the published data of EPPIC service that only focuses on treatment for first-episode patients. Subjects were compared on the number of required admissions, average length of stay, DUP, psychotic drug dosage and if police were involved if there was an involuntary admission. The study found police involvement, length of stay and DUP were lower for EPPIC patients. Furthermore, general adult mental health services tended to focus on the needs of the majority of patients (ie. those with chronic schizophrenia). Patients may also be exposed to high levels of potentially traumatizing events such as a closed environment with large numbers of older and chronic patients. As well, staff may not be aware of the needs of this group, who are dealing with a psychotic episode for the first time. Most staff has dealt with patients who are familiar to the system. Thus, early psychosis programs are important in reaching the young person and providing services directed to their needs.

Addington, Leriger & Addington (2004a) undertook a study to determine the change in positive, negative and depressive symptoms in the Calgary Early Psychosis

Program. Subjects were assessed every three months up to the first year. Symptoms were measured using the Positive and Negative Syndrome Scale (PANSS) and the Calgary Depression Rating Scale for Schizophrenia (CDSS). Their study found significant improvements in positive symptoms by three months; depressed symptoms by 12 months and negative symptoms changed little. Thus, early psychosis programs helps individuals improve over time, but their needs to be more emphasis on early detection of negative symptoms since they may be well established prior to entry into treatment.

Mihalopoulos, McGorry & Carter (1999) conducted an evaluation at the EPPIC program in Australia to examine its cost-effectiveness in terms of improving outcomes for young people experiencing psychosis and providing 'value for money'. EPPIC patients were compared to Pre-EPPIC patients on a number of symptomatic and functional outcomes over 1 year as well as a cost-effective appraisal were undertaken. For example, the cost of improvement in psychosocial functioning was measured by the Quality of Life Scale and the resource utilization for each subject. Their study found the EPPIC model to be more cost-effective since it achieved better treatment outcomes and saved resources through the reduction in in-patient bed days. They concluded, that although community based care is expensive, it was approximately half the cost of in-patient utilization that was incurred when community based care was not available. They concluded that reducing the provision of inpatient care without such enhancement of community care would substantially worsen outcomes for patients. Thus, the shift of resources from hospital to community represents an economically viable method of improving patient outcomes. Rappaport (1989) used a similar cost-effectiveness index

(CEI) as a tool to help evaluate mental health programs. Yung et al. (2003) also reported the economic burden of hospitalization, which makes up 50-90% of direct treatment costs.

Thus, early psychosis programs are seemingly cost-effective, reduce symptoms, maximize the chances of full recovery and minimize the likelihood of relapse and comorbidity.

2.12 Current Models of Early Intervention

Australia

The Early Psychosis Prevention and Intervention Centre (EPPIC) was developed in Melbourne, Australia in October, 1992 by a group of clinicians and researchers, to provide early detection and optimum treatment for first psychotic episode patients (Larsen et al., 2001; McGorry, 1996). It has a 24-hour mobile assessment and community treatment team, The Youth Access Team (YAT), which is the first point of contact with EPPIC (Edwards et al., 2000). The Personal Assessment and Crisis Evaluation (PACE) clinic was also established to identify and treat individuals who are thought to be at risk of developing a psychotic disorder (Edwards et al., 2000). EPPIC has outpatient case management and medical treatment for early psychosis patients. The center has a 16-bed inpatient service to help reduce the symptoms (Edwards et al., 2000). In addition to using low dosage of psychotic drugs, the group program provides acute and recovery groups for four themes: vocation, creative expression, recreational, and personal

development (Albiston et al., 1999). There are family sessions to provide support and education about psychosis (Albiston et al., 1999). There is also a focus on suicide prevention. Finally, cognitive oriented psychotherapy for early psychosis (COPE) is offered to help patients understand the illness and its effects on their self-concepts and self-esteem (McGorry, 1996). An evaluation of the EPPIC program was done by comparing EPPIC patients with patients treated prior to the development of the EPPIC program. The non-EPPIC group was considered the control group and had previously been assessed over one year. The EPPIC group was also followed and assessed over one year. Thus, both groups were analyzed using the pre-post methodology and then the EPPIC group was compared to the non-EPPIC group. The overall evaluation found that there were improvements in quality of life, including social and role functioning, for EPPIC patients resulting from them receiving a treatment package combining intensive case management, psychosocial interventions, family support and education, and low-dose medication strategies (McGorry et al., 1996; Edwards et al., 2000; Larsen et al., 2001). These results were strongest for patients with a DUP of 1-6 months, which is a short treatment delay (Larsen et al., 2001). The level of post-traumatic stress, previously associated with hospitalization, was reduced and the length of average stay and drug dosage was reduced (Edwards et al., 2000).

Europe

An Initiative to Reduce the Impact of Schizophrenia (IRIS) was developed in the UK by the West Midlands Early Psychosis Group to pursue positive outcomes for young psychotic patients and their families (Edwards et al., 2000; Macmillan & Shiers, 2000).

IRIS produced a framework of standards of care that had a set of core principles, which included "a youth and user focus; the importance of early and assertive engagement; the embracing of diagnostic uncertainty; treatment to be provided in the least restrictive and stigmatizing setting; an emphasis on social roles and a family-oriented approach" (Macmillan & Shier, 2000).

Larsen et al. (2000), in Norway and Denmark, developed an educational campaign called TIPS to investigate whether early identification of first episode psychosis leads to better long-term outcomes. First episode patients at three different sites were compared, with TIPS being aimed at only one group and the remaining two groups acting as controls (Edwards et al., 2000). The TIPS campaign included public lectures on selective psychiatric topics, newspaper advertisements, information brochures, and movies with panel discussions. All three groups did receive the same care of clinical and psychotherapy treatments. Evaluation occurred at baseline, 3 months and one, two and five years. Their study found that the group at which the information campaigns were aimed (GPs, family, schools and patients themselves) was more successful in helping them detect patients earlier. Melle et al. (2004) published similar results that early detection programs significantly shorten DUP compared to patients in no early detection areas.

Canada – Early psychosis programs have emerged in Canada in the last seven years. Although there are programs developed throughout the Country, this thesis will only discuss four Canadian early psychosis programs.

Whitehorn, Lazier & Kopala (1998) developed a comprehensive program in Nova Scotia that provides support to individuals by identifying their goals and helping them overcome obstacles encountered in returning to school, work and social settings (Whitehorn et al., 1998; Edwards et al., 2000). A psychiatrist sees each patient as often as necessary. In the initial medication adjustments, a psychiatrist sees each patient weekly or biweekly and then less often. They prefer to use "the term 'medical condition' rather than 'illness' since a medical condition is one that is associated with biological alternations and is improved by drug therapy and other treatments" (Whitehorn et al., 1998). They state that recovery of social and occupational functioning requires a longer period of time than symptom reduction. An overall evaluation of the program using pre-post methodology found that most families reported that the patient improved functioning and were able to continue pursuing their education after 2 years, and those over the age 27 have been able to return to some degree of social and occupational independence (Whitehorn et al., 1998).

Early Psychosis Treatment and Prevention Centre in Calgary, Alberta offers comprehensive services to first episode patients for a three-year period (Addington et al., 2002; Addington et al., 2004b; Edwards et al., 2000). The program includes outpatient case management, which involves psychiatrist and case manager assignment who undertake assessment and monitoring functions as well as provide assistance in

contacting agencies for employment or housing. The program includes psychotherapy, psychoeducation, and individual cognitive therapy to help patients adapt to the psychotic illness and the effects on life circumstances (Edwards et al., 2000). Patients are taught skills to manage anger and stress and are provided with substance use and suicidal prevention counseling (Edwards et al., 2000). One of the components of the program is family intervention. There is individual family work with education about psychosis and strategies for coping with the disorder, as well as family group work and communication training. The program also offers education to mental health agencies, family physicians, and school and colleges about psychosis, how to recognize the signs and how to access treatment. An overall evaluation of the program using pre-post methodology found that symptoms were reduced and there was medication adherence to low dose atypical drug therapies. Furthermore, there were improvements in insight and social outcomes and reduction in suicidal thoughts and substance use (Addington et al., 2003; Addington et al., 2004a; Addington et al., 2004b; Edwards et al., 2000).

The Prevention and Early Intervention Program for Psychosis (PEPP) established in 1997 in London, Ontario is a community-oriented, comprehensive, multidisciplinary assessment, treatment and research program (Edwards et al., 2000, Malla et al., 2003; Scholten et al., 2003). The program consists of two essential components: (1) early detection and (2) medical and psychosocial assessment and treatment to reduce DUP (Malla et al., 2003). It utilizes an assertive case management model, whereby the case manager's role includes assessment, treatment and helping the patient with recovery. (Edwards et al., 2000; Malla et al., 2003). "This is achieved through a close partnership

with families, strong therapeutic relationship with the patient, community services, educational institutions and employers to reintegrate the young person to his/her full potential over a 2-year period" (Malla et al., 2003). Some patients are given extended case management for additional one to three years if they are not sufficiently recovered to assume independent functioning (Malla et al., 2003). All patients continue with medical management for at least five years. (Malla et al., 2003). An eight-week group intervention addresses issues of stigma, identity, peer pressure, and substance use as well as provides skills training (Edwards et al., 2000). It also has a 16-bed inpatient unit (Edwards et al., 2000). An overall evaluation of the program, using both pre-post methodology by following the patients over one year and then comparing to a historical control group prior to the establishment of PEPP, found the use of low drug dosage, high retention and remission (75%) rates, and significant improvements for self-rated quality of life and cognition, and DUP and symptoms reduction (Malla et al., 2003).

The Newfoundland and Labrador Early Psychosis Program (NL Program) was established in the Winter 2001. The goals of the NL Program include promoting early recognition of psychosis and reducing DUP; providing optimum, safe and comprehensive assessments, intervention and support for patients and their families; and promoting recovery and preventing relapse. Other goals include promotion of education on psychosis to primary care physicians, mental health professionals and community resources; and continuing research in the area of early psychosis. The NL Program involves three years of comprehensive individualized treatment that includes the following components: psychiatric care, case management, low-dose medication regimes,

family intervention, psychotherapy (individual and group), occupational therapy, recreational therapy, spiritual counselling, substance use counselling and research. Individuals referred to the NL Program are experiencing a psychotic episode for the first time. At initiation to the NL Program, a full assessment of the patient by a psychiatrist is carried out by a structured clinical interview to confirm diagnosis of a psychotic disorder. Following admission to the NL Program, the assigned psychiatrist sees each patient as often as necessary, with weekly or biweekly visitations in the beginning for medication adjustments. The NL Program has not yet been evaluated since the first patients are only now finishing or have completed their third year of treatment.

Evaluations of the programs

Evaluations of the early psychosis programs in Australia and Canada have found that the interventions can help reduce DUP, lower medication dosage, increase medication adherence, reduce hospitalization, improve quality of life, improve insight, foster and maintain family and social support, and reduce the secondary effects of psychosis, such as social and educational disruption and substance abuse (McGorry et al., 1996; Whitehorn et al., 1998; Malla et al., 2003; Addington et al., 2002). Evaluations of some of these outcomes will be discussed further below.

Insight

"Insight can be defined as "a patient's awareness of having a mental disorder, of the social consequences of the disorder, and of the need for treatment" (Mintz, Addington & Addington, 2004). Earlier studies on insight have suggested that 50-80% of patients do not think they have a psychotic illness (Mintz et al., 2004). Mintz, et al. (2004)

conducted a study to determine if insight improved after one year of treatment in their Calgary early psychosis program. They assessed the patients' insight over one year using the PANSS scale, using the lack of judgement and insight variable. They found insight did improve over the one year as positive symptoms improved, especially in the first three months after treatment began. This program offered patients cognitive-behavioural and other psychosocial interventions that may have helped to improve their knowledge and understanding of the illness, and thus may have impacted their level of insight.

Hospitalization

Whitehorn, Richard & Kopala (2004) determined the rates of hospitalization during the first year of treatment for schizophrenia in Nova Scotia. Their study found patients who were initially diagnosed while inpatients had a higher rate of hospitalization in the first year of treatment compared with those initially diagnosed while outpatients. They also found hospitalization rates were higher for those who lived in rural areas. Thus, emphasis should be placed on preventing hospitalization during the first year.

Medication Adherence

A major problem in treating psychosis is non-adherence with medication (Coldham, Addington & Addington, 2002; Bebbington, 2000; Bryden et al., 2003). Coldham et al. (2002) reported that numerous studies have found 40% of patients stopping medication within one year and 75% by two years, thus having a significant impact on the illness, with social and psychological consequences, as well as increasing relapse, hospitalization and poorer outcomes. Coldham et al. (2002) stated that it is important to address the adherence of first episode patients since the younger patients are

more likely to be non-adherent than older patients. The major reason for non-adherence is that the drugs have many adverse side effects (Bebbington, 2000). However, if it is possible to reduce the dosage for effective treatment and therefore, improve the experience of medication, then this increases the likelihood of adherence (Bebbington, 2000). The development of newer antipscyhotic atypical drugs is designed to minimize the side effects (Bebbington, 2000). There is increasing evidence that these novel antipsychotics are recommended over the conventional agents because of their safety profiles and their effects on positive and negative symptoms (Currier, 2000). They are also better tolerated than conventional treatments and therefore increase patient compliance (Bryden, et al., 2003). However, these newer drugs are also very expensive (Bebbington, 2000). A one year study looking at pharmacy refill records of patients treated with typical versus atypical drugs found moderately higher adherence rates in those treated with the atypical drugs (Bryden et al., 2003). Therefore, since these newer drugs increase patient adherence, the higher costs of these drugs are relatively minor compared to the higher costs of hospitalizations.(Bebbington, 2000; Fuller, Shermeck, Secic, Laich, Durken, 2002; Bryden et al., 2003). Fuller et al. (2002) compared the costs between patients taking typical drugs versus atypical drugs. They found that those taking atypical drugs had higher drug costs but lower hospitalization costs and therefore, overall all, their total costs were lower than patients using typical drugs.

Coldham et al. (2002) conducted a study to determine the rates of medication adherence in first episode patients in their early psychosis program in Calgary. They defined "non-adherence as dropping out of the program before one year and/or took

medication erratically or not at all". Inadequate adherence was defined as "taking medication irregularly", and finally, good adherence was defined as "rarely or never missing a dose of medication". Their results found 39% non-adherent, 20% inadequate adherent and 41% good adherent. The non-adherent patients were younger, had an early age of onset, were less likely to have family contact and demonstrated more positive symptoms, more relapses, more substance use, reduced insight and poorer quality of life. They conclude that relationships with family members are important to be maintained as well as interventions for substance use. Bebbington (2002) suggests that the experience of medication can be enhanced in non-pharmacological ways, such as building a trusting mutual relationship with patients and providing them with information in an amount, sequence and manner that makes them feel safe, valued and involved.

Substance Use

Psychiatric comorbidities in psychotic disorders are often under-recognized, under-diagnosed and under-treated. It is, therefore, important for clinicians to recognize and diagnose them early in the course of the psychotic illness and administer appropriate treatment when necessary (Sim et al., 2004). It has been estimated that 60% of individuals suffering from schizophrenia use illicit drugs and alcohol (Addington & Addington, 2001). Those who use the substances say that they help to relieve a variety of unpleasant non-psychotic experiences, and it decreases depression, anxiety and the side effects of antipsychotic medication (Addington & Addington, 2001). Substances are damaging to a psychotic patient because they may increase positive symptoms, and thus, may cause damage to an already compromised brain (Addington & Addington, 2001).

Studies have found a higher prevalence of substance abuse in first episode samples (Hambrecht & Hafner, 1996), and past substance abusers had a significantly younger age of onset than the non-abusers (Van Mastrigt, Addington & Addington, 2004). Van Mastrigt et al. (2004) examined the prevalence and correlates of substance misuse in first episode patients at the time they received their first treatment. The Case Manager Rating Scale for Substance Use Disorder was used to assess the level of substance use over the past year. Their study found substance misuse was higher amongst patients compared to the general population and was significantly higher among males, younger patients and the younger the age of onset (Van Mastrigt et al., 2004). Pencer & Addington (2003) also stated that problems with substance use for psychotic patients include greater severity of symptoms and poorer prognosis, significantly more admissions to hospitals and outpatient visits, higher medication dose and medication nonadherence. Van Mastrigt et al. (2004) concluded that the extent of substance misuse in the first episode group should be addressed as part of an integrated treatment program since it has clinical implications for treatment.

To address the problem of substance abuse among first episode patients, the Calgary Early Psychosis Treatment and Prevention Program offered several substance abuse treatment strategies within the psychosocial treatments offered (Addington & Addington, 2001). As well, a Stopping Substances Group was formed at the end of the first year of treatment to help educate, engage, and support patients with substance use problems. The group discusses issues such as how to resist peer pressure; avoiding risky situations and learning new skills to cope with daily living once they become abstinent

(Addington & Addington, 2001). Addington & Addington (2001) followed patients in their program for one year and found that the specialized substance use treatment program within their treatment facility helped to reduce substance use at one year after entry into the program. Substance use clearly has serious implications for psychosis and must be addressed within treatment programs.

Sorbara, Liraud, Abalan & Verdoux (2003) studied the impact of substance and alcohol misuses on clinical and social outcome over a 2-year follow up after a first hospitalization for psychosis. The patients were assessed at six-month intervals. Clinical outcomes were explored by assessing re-hospitalization and symptom status. Social outcomes were explored by assessing occupational and residential status. They found that although there was no association between drug use and social outcomes, but persistent drug use increased risk for readmission to hospital and thus, poorer clinical outcomes. Their findings suggest therapeutic interventions for substance use (Sorbara et al., 2003).

Pencer & Addington (2003) found no association between substance misuse and cognitive functioning among first episode patients. The possible explanation for the result was that the level of substance use amongst the sample was not high and/or the sample examined was young, and many studies have shown that substance use impairs cognitive functioning only after many years of prolonged and excessive use (Pencer & Addington, 2003). It is possible that the detrimental effects of substance misuse are not yet evident. Thus, they concluded that although there was no association of alcohol misuse and cognitive functioning in their young sample, such as long-term use may lead

to later problems. Thus, long-term substance use must be stopped; and intervening early at first episodes may help the young people to understand the long-term problems that could occurred with continued substance use (Pencer & Addington, 2003).

Suicide & Depression

It has been estimated that 10% of those suffering from schizophrenia commit suicide, and the first year of psychosis has been reported as a particularly high-risk period (Addington et al., 2004b). There are several predictors of suicide, such as fewer positive and negative symptoms, long DUP, and a history of parasuicide (i.e. non-fatal deliberate physical harm, such as self-injury or overdose) (Addington et al., 2004b). Subjects who misused drugs were seven times more likely to engage in suicidal behaviour (Verdoux et al., 2001). Addington et al. (2004b) conducted a study to determine the prevalence of suicidal behaviours prior to and during the first year of treatment in their Calgary early psychosis program. Patients were assessed at the entry into the program and one year later, using measures such as suicide attempts, depression, positive and negative symptoms, social functioning and substance misuse. The program offered treatment in depression and suicidal thinking, psychoeducation, individual case management and family work. They found that after one year of treatment, the likelihood of attempting to commit suicide decreased. They concluded that "specifically designed first episode programs can reduce suicidal behaviour in this high-risk population" (Addington et al.,2004b). Verdoux et al. (2001) also assessed suicidal behaviour in first admitted patients but over a two-year period, and conducted assessments every six months. Their study found similar results to Addington, et al. (2004b). Power et al. (2003) also studied

suicidal behaviour, but within the EPPIC program in Australia. They developed a cognitive therapy called LifeSPAN as a preventive strategy for suicidal patients. In their study, they randomly assigned first episode suicidal patients to standard clinical care or standard care plus LifeSPAN therapy. They report that the patients offered this LifeSPAN therapy showed a reduced risk of suicide as compared to those who were not part of this program (Power et al., 2003).

Depression has been found to play a major part in psychotic illness and a precursor to suicide when associated with hopelessness (Jackson & Iqbalt, 2000). It has been argued that depression after the onset of psychosis may be a reaction to the changes associated with the psychosis itself (Jackson & Iqbalt, 2000). Individuals experience a major change in their personal lifestyles and commonly express feelings of alienation and loss of self-esteem (Jackson & Iqbalt, 2000). Chintalapudi, Kulhara & Avasthi (1993) found depressed subjects tended to have longer DUP, better premorbid adjustment prior to psychosis (i.e. patients psychosocial performance was better prior to the illness) and an excess of stressful life events compared to those patients who did not develop depression with psychosis.

Quality of Life/Social Outcome

Quality of Life is determined by a variety of circumstances such as level of social/community functioning, objective life circumstances and, for those with serious illness, the symptoms related to health status (Norman et al., 2000). People with mental illness are believed to experience lower life satisfaction than the population as whole (Blenkiron & Hammill, 2003). Malla, Norman, McLean & McIntosh (2001b) assessed

the impact of community focused treatment programs on different dimensions of self-reported quality of life of first episode patients. The Wisconsin Quality of Life Scale was used to assess subjective aspects of the patients' level of functioning. The nine domains included: general satisfaction level (e.g. leisure, housing, sexual activity); activities and occupation; psychological well-being (e.g. personal feelings about life); symptoms/outlooks; social relations and support; money; and activities of daily living. The patients were assessed on these domains for one year following treatment and the results showed that the patients had significant improvements in each domain (Malla et al., 2001).

It has been reported that first episode patients have social functioning deficits that are equivalent to those seen in more chronic psychotic patients (Addington, Young & Addington, 2003). These first episode patients often fail to attain age appropriate social and vocational functioning with most remaining unemployed after one and two years of treatment (Addington et al., 2003). Addington et al. (2003) study examined social functioning of first episode patients in EPP over one year, using the Quality of Life Scale. Their study found that after one year there were significant improvements in patient's quality of life. McGorry et al. (1996) and Malla et al. (2001) reported similar results. These findings are encouraging and supportive of early psychological interventions. However, since positive and negative symptoms continue to have an impact on social functioning, it is important that treatment programs undertake measures to reduce these symptoms, such as supportive employment programs to improve employment outcomes (Addington et al., 2003). Addington et al. (2003) also state that since social functioning

may have been declining for many years, improvement may require more time than just one year.

Family

Family members do not choose the caregiver role; however they find that they become carers of first episode patients. When family members take on the role of caregiver, they are likely to suffer increased levels of worry and strain, depression and anxiety (Kuipers & Raune, 2000). They are likely to be emotionally upset and have anxiety about the future (Kuipers & Raune, 2000). They may also suffer from reduced social networks and feel isolated and stigmatized (Kuipers & Raune, 2000). This in turn, can be very stressful for the patient. It has been shown that providing early intervention programs with family aspects can be beneficial in reducing both the symptoms for the patients and the emotional burden of the carers (McGorry et al., 1996; Kuipers & Raune, 2000). Family interventions can also help prevent relapse amongst patients (McGorry, 1996; Kuipers & Raune, 2000). Families provide the supportive setting that can help the patient overcome the psychotic experience (Kuipers & Raune, 2000).

Relapse & Recovery

Prevention of relapse is important for the future well-being of individuals who have experienced psychosis (Scott et al., 2004). Every relapse results in an increased probability of future relapses, as well as the growth of residual symptoms and accompanying social disability (Scott et al., 2004). Studies have shown that relapse is usually preceded by subtle changes in behaviour (Scott et al., 2004). Therefore,

identifying these early warning signs of psychotic relapse can help to reduce the risk of relapse (Scott et al., 2004).

Liberman & Kopelowicz (2005) discuss the importance of setting standard criteria to define recovery so that individual patients can be categorized as either achieving remission (recovery) or not. In this way, early psychosis programs may be evaluated by the number of patients that achieve the criteria for recover at various points in time. For example, a definition of recovery would include independent functioning of patients, such as being productive in work or school, social relations, family life, and recreational activities as well as achieving symptom remission. The individual would be considered recovered if one is able to take care of their personal needs without assistance, such as managing one's own medication, health and money. An operational definition of recovery would help researchers identify the factors that may impede or promote recovery and facilitate research on recovery as a therapeutic goal.

2.13 Propensity Matching Research

As stated in the above sections, Randomized Controlled Trials (RCTs) have ethical challenges when performed on early psychosis patients. However, several studies, such as Ascher-Svanum, Zhu, Stensland & Sterling (2003) and Shenyang, Barth and Gibbons (2004), who are dealing with vulnerable populations, are now using a new evaluation methodology called propensity matching.

Ascher-Svanum et al. (2003) compared the illness severity of schizophrenia patients served at the Veterans Healthcare Administration with that of Non-Veteran

Medicaid patients served at state facilities. The ultimate goal of their study was to understand the treatments currently provided to schizophrenia patients and to determine which treatment options produced the best outcome of care. Previous studies comparing the two groups did not adjust for important patient characteristics, such as age, race and age of illness onset. Their study addressed prior methodological issues by comparing the two groups while matching on patient's gender, age, race, age at illness onset, and study site using propensity score matching. Ascher-Svanum et al. (2003) defined propensity score as the conditional probability of being a Veteran patient (Y) given the covariates of interest (X) of the individual: gender, age, race, age at illness onset, and study site. PS=Pr(Y/X). The Veteran and non-Veteran Medicaid patients were first pooled and the logit score for each patient was calculated using the selected covariates. A Veteran patient was then selected and matched with a non-Veteran Medicaid patient with the closest propensity score. Both patients were then removed from further matching and a new Veteran patient was selected, until all Veteran patients were matched with a non-Veteran Medicaid patients. Once matching was completed, the groups were then compared on baseline symptomatology, functional status, quality of life, substance abuse, work status, violent behaviour, suicidal tendencies, adherence to medication and prior hospitalization using chi-square tests and t-tests. They found that once baseline characteristics were adjusted for, their groups could be compared and their results found similarities between the two groups on many of the clinical outcomes.

Shenyang et al. (2004) examined whether substance abuse treatment reduced the likelihood of re-reports over an 18 month follow-up period using the Alcohol and Other

Drugs (AOD) cases from a treatment program and comparing to cases from the National Survey of Child and Adolescent Well-being (NSCAW). The challenge with their study was selection bias, i.e. how do they address the concern that cases that did not get substance abuse treatment did not need it? To address this problem, they decided to use a propensity matching methodology for program evaluation. They identified variables with likely linkage to substance abuse treatment, such as marital status, education, poverty, employment and age. A propensity score was calculated for each participant, using a computational software STATA-PSMATCH2, and matched to the non-participants with the closest propensity score using the same variables, so that they share almost the same characteristics. Therefore, selection bias may be mitigated in the new sample. Once the participants and non-participants were matched, Shenyang and co-investigators were able to compare the matched cases on what variables predicted the likelihood of the re-report, such as receipt of welfare, active domestic violence, number of children and trouble paying for basic necessities. Their study found once selection bias is controlled through matching, substance abuse services are not associated with the likelihood of re-reports over 18 months. They concluded that when evaluating a program, one can use propensity score matching to match the treatment sample to a carefully selected national sample to assess the impact of the program.

Foster (2003) reviewed the propensity matching approach and illustrated its use in an analysis of dose response, the relationship between the volume of services received, and treatment outcomes. He argues that the benefit of using propensity score matching is that one can control or adjust for all known covariates and therefore, can produce more

precise estimates of program effects. The data for this study was taken from a well-known study of children's mental health services, and the analysis estimated the impact of outpatient therapy based on comparisons of individuals receiving different treatment doses. The comparisons are adjusted for the preexisting observed differences among the groups using the propensity score method. They were compared on sex, age, parental education and previous services used. Once all baselines differences were accounted for, the subjects were compared on dose and outcomes. The analyses of this study using propensity score matching suggested that added services improved treatment outcomes, especially child functioning. Foster (2003) concludes that "propensity score methods represents a promising means for improving comparisons by providing a flexible and convenient way to adjust for preexisting between-group differences", and thus, of potential value to health services researchers, where randomization is difficult or impossible, for them to evaluate treatment programs.

CHAPTER 3

METHODOLOGY

3.1 Early Psychosis Program Setting

The NL Program was developed in 2001 at the Waterford Hospital, St. John's and provides psychiatric treatment services for individuals diagnosed with a first episode of psychosis. The NL Program is currently serving a total provincial population of approximately 500,000. There are 2 psychiatrists, 1 program coordinator, 3 nurse case managers, 1 family worker, 1 pharmacist and a half-time occupational therapist that make-up the interdisciplinary team. The main goal of the NL Program is to provide optimum, safe and comprehensive assessments, intervention and support for patients with a first episode of psychosis and their families for three years.

3.2 NL Early Psychosis Patient Demographics

There are currently 150 active patients in the NL Program. New patients are continually entered into the NL Program as they become detected and diagnosed with first time psychosis. As patients enter the NL Program, they are assigned an identifier number. Seven patients discontinued the NL Program due to transferals, relocated or were non-compliant to the treatment. For this study, timing for analysis allowed only data collected on the first 150 patients to be used.

Table 1 describes the demographic characteristics of the NL early psychosis patients.

Table 1. Demographic Characteristics of NL Early Psychosis Patients

AGE DISTRIBUTION	SEX	MARITAL STATUS	LIVING ARRANGEMENT
15-19: 38 (25%) 20-24: 60 (40%) 25-29: 26 (17%) 30-34: 7 (5%) 35-39: 7 (5%) 40-44: 1 (1%) 45-49: 1 (1%) 50-54: 1 (1%) 55-59: 2 (1%)	Males: 109 (73%) Females: 41 (27%)	Single: 130 (87%) Common-Law: 3 (2%) Married: 12 (8%) Widowed/Divorced: 2 (1%) Not Stated: 3 (2%)	Alone: 26 (17%) With Parents: 92 (61%) With Spouse: 4 (3%) Other: 18 (12%) Not Stated: 10 (7%)

3.3 Data Collection of NL Program

As part of monitoring their treatment in the NL Program, the patients are assessed on several scales to measure their clinical and social outcomes. Some scales measure patients at entry into the NL Program and every three months thereafter until the three-year treatment has been completed. Other scales are used only once, every six months or every year. The data collected for each patient is entered into the Early Psychosis database (here after referred to as the "database"). This database will be used in this study's analyses.

There are fourteen scales used for patient evaluation, all of which will be described below.

a). Diagnosistic Assessment Scale: This scale is used to identify the type of disorder from which the patient suffers. The assigned psychiatrist will use this scale to assess patients at initiation and then at the end of the first year, second year and third year of the program. There are four categories of disorders, psychotic, anxiety, mood and

other disorders, with several subtype disorders under each category to clarify the patients' specific problem, such as obsessive compulsive disorder under the Anxiety disorder category, or major depressive disorder, under the Mood disorder category.

b). Positive and Negative Syndrome Scale (PANSS): This scale is used to measure the presence/absence and severity of the positive and negative symptoms. Patients are assessed at initiation and every three months using this scale. The PANSS is a 30-item semi-structured clinical interview that has demonstrated high internal reliability and construct validity (Kay et al., 1987). It contains 7 items measuring positive symptoms, such as measuring hallucinatory behaviour, 7 items measuring negative symptoms, such as measuring emotional withdrawal, and 16 items measuring general aspects of psychopathology, such as guilt feelings. The 30 items are rated on a 7-point scale from 1= absent to 7= extreme.

c). Montgomery-Asberg Depression Rating Scale (MADRS): This scale is used to measure the severity of patients' depression symptoms (Montgomery & Asberg, 1979). Patients are assessed at initiation and every three months using this scale. MADRS is a 10-item scale that rates patients' levels of depression on a scale of 0 to 6, with higher scores reflecting greater severity of depression. For example, the apparent sadness item, rates the patient from 0= No sadness to 6 = Look miserable all the time.

d). Calgary Depression Scale for Sczhiophrenia: This scale is also used to measure the severity of patients' depression symptoms and suicidal thoughts, since research has shown that there is high levels of depression amongst first episode patients. Patients are assessed at initiation and every three months using this scale. Addington,

Addington & Matricka-Tyndall (1993) developed this scale. It contains 9 items that are rated from absent (0) to severe (3). Some items include, depressed mood, hopelessness, self-depreciation and suicide.

e). Premorbid Adjustment Scale: This scale measures current and premorbid social functioning. This scale is usually done once by a reliable family member or friend who provides the source of information The first twelve items in the scale ask specific questions about the history of the patients' childhood to the age they developed psychosis, such as normal development, head injuries, health problems and stressors in their life that could have contributed to the development of psychosis. The remaining 8 items rate patients' behaviours at certain ages, such as sociability and withdrawal, peer relationships, sexual behaviour and level of occupational and educational activities. The scale was developed by Cannon-Spoor, Potkin & Wyatt (1982).

f). Family History: This scale is done only once, but provides information on the history of psychotic disorders in a family.

g). Quality of Life: This scale assesses the quality of life of patients. They are assessed at initiation and every six months. There are 21 items rated on a 7-point scale, with higher ratings indicating better quality of life. Some items include social activity, time utilization and activities. Heinrichs, Hanlon & Carpenter (1984) developed this scale.

h). Global Assessment Scale (GAS): This scale is a single-item rating scale for evaluation of overall patient functioning during a specified period on a continuum from psychiatric illness to health. The scale value ranges from 1 (hypothetically sickest person)

to 100 (hypothetically healthiest person), divided into 10 equal intervalsFor example, 31-40, is a major impairment in several areas, such as work, family relations, judgment, thinking or mood OR some impairment in reality testing or communication OR single serious suicide attempt. The clinician may feel this range best describes the patient at the time of assessment and gives the patient a rating of 34. Luborsky (1962) developed the GAS.

i). Clinical Global Impression (CGI): This scale is a three-item scale used to assess treatment response in psychiatric patients. The three items are: Severity of Illness; Global Improvement and Efficacy Index. The Severity of Illness item is rated on a seven point scale (1=normal to 7=extremely ill) and requires the clinician to rate the severity of the patient's illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis. Considering total clinical experience, a patient is assessed on severity of mental illness at the time of rating according to: normal (not at all ill); borderline mentally ill; mildly ill; moderately ill; markedly ill; severely ill; or extremely ill. The Global Improvement item is rated on a seven-point scale (1=very much improved to 7=very much worse) and requires the clinician to rate how much the patient's illness has improved or worsened relative to a baseline state. The Efficacy Index is rated on a four-point scale (from 'none' to 'outweighs therapeutic effect'). Patients are assessed at initiation and every three months thereafter.

j). Barnes Akathisia Rating Scale (BAS): This scale measures akathisia, which is a frequent and common adverse effect that can occur as a result of treatment with antipsychotic drugs. Reported prevalence rates vary between 5 and 36.8% (See Miller &

Fleischhacker, 2000). The Barnes Akathisia Rating Scale is a four-item scale used to assess the presence and severity of drug-induced akathisia. It is the most widely used comprehensive rating scale for akathisia, including both objective items (eg observed restlessness) and subjective items (eg patient's awareness of restlessness and related distress), together with a global clinical assessment of akathisia. Global assessment is made on a scale of 0 to 5 with comprehensive definitions of akathisia provided to scale patients of having akathisia: 0=absent; 1=questionable; 2=mild akathisia; 3=moderate akathisia; 4=marked akathisia; 5=severe akathisia. The patients are assessed at entry into the program and every three months using this scale.

k). Young Mania Rating Scale (YMRS): This scale is an 11-item instrument used to assess the severity of mania in patients. The 11 items are: Elevated Mood, Increased Motor Activity Energy, Sexual Interest, Sleep, Irritability, Speech (Rate and Amount), Language - Thought Disorder, Content, Disruptive - Aggressive Behaviour, Appearance and Insight. The patients are rated in each item by a 4-point range, 0= absent to 4= severe. Patients are assessed at entry and every three months. Ratings are based on patient self-reporting, combined with clinician observation. Young, Biggs, Ziegler & Meyer (1978) developed YMRS. YMRS is a reliable and commonly used assessment tool of proven validity, which has been used in clinical practice since 1978.

l). Extrapyramidal Side Effect Rating Scale (ESRS): The scale assesses the extent of damage to the extrapyramidal system and the motor functions that it controls. This scale consists of 12 multipart items, four of which are general neurological assessments and eight of which are specific to the symptoms of Parkinson's disease. The items are

rated on a scale of 0 to 6 of severity of the person. The higher the score, the greater the effect symptoms have on function. Patients are assessed at entry and every three months using this scale. Chouinard et al., (1980) developed the ESRS.

m). UKU Side Effect Rating Scale: This scale was developed to provide a comprehensive side effect rating scale with well-defined items to assess the side effects of psychopharmacological medications. The rating is formed on the basis of an interview with the patient and other relevant information from all available sources. The clinician's observations are given more weight than patient reports. This scale contains 48 items. Rating is independent of whether the symptom is regarded as being drug-induced. The rating is either not assessed, present or not present. If there is a probability of the causal relationship (or lack of it) of each item to the medication in question is indicated in a separate column, which makes it useful for determining subsequent course of action. Lingjaerde et al., (1987) developed this scale. The scale assesses patients at entry and three months thereafter.

n). Case Manager Rating Scale for Substance Use Disorder: This scale rates patient's use of alcohol and other drugs over six month intervals. The rating is based on evidence from self-report, interviews, behavioral observations and/or family reports. The scale used ranges from 0 (no substance use) to 4 (extremely severe substance use). This scale is based on the Drake (1990) scale of diagnosis of Alcohol Use Disorders in Schizophrenia.

3.4 The Study Design

To evaluate the impact of the NL Program, it was decided to compare the NL Program's patients to a national population to determine if the NL Program helps improve patients on several clinical and social outcomes from initiation to the end of the three-year program. Two national population databases were considered as a control group: the National Population Health Survey and the Canadian Community Health Survey. Information about both databases can be found at www.statcan.ca. Each survey was carefully reviewed to determine if they could have similar characteristics to potentially match the NL Program.

The National Population Health Survey (NPHS) collected information related to the health of the Canadian population and related socio-demographic information. There are three cycles of data collection. The first cycle of data collection began in 1994. The data will then be continued to be collected every second year thereafter, for approximately 20 years in total. Three cycles of collection are now completed: NPHS Cycle 1(1994-1995), NPHS Cycle 2 (1996-1997) and NPHS Cycle 3(1998-1999). NPHS Cycle 3 is a longitudinal study, which consists of all respondents chosen in Cycle 1 who had completed at least the general component of the questionnaire in 1994-1995. The questionnaire includes questions related to health status, use of health services, determinants of health, chronic conditions and activity restrictions. This questionnaire did have a mental health section, but it was very limited. Thus, although it was a

longitudinal study, NPHS was not considered a good candidate population to match with the early psychosis patients.

The Canadian Community Health Survey (CCHS) Cycle 1.2, Mental Health and Well-being was designed to address priority mental health determinants, mental health status and mental health system. The topic selection for the content of CCHS was conducted through a process of extensive consultation with regional, provincial and federal representatives and the research community. The selection of mental disorders as well as mental well-being areas were a result of discussions with the Mental Health Expert Group assembled for the survey, as well as the Population Health Advisory Committee. These topic areas matched topic areas addressed at the NL Program, such as Alcohol Dependence and Use, Illicit Drug Use and Dependence, Medication Use, Mental Health Services, Psychological Well-being, Stress, Spiritual Values, Social Phobia and Social Support. Therefore, CCHS provided good data to potentially match the NL Program. However, CCHS is a cross-sectional study, meaning that the study only questioned individuals at one point in time. Therefore, in order to compare the early psychosis patients at initiation and three-years later, two different points in time, two cohorts from the CCHS population would have to be used.

Thus, after carefully reviewing both surveys, it was decided that the CCHS would supply the best population to use as a control group, since there is substantial overlap of characteristics to match with the NL early psychosis patients.

3.5 Benchmarking to an Age-Representative Population

The main purpose of benchmarking is to compare the NL early psychosis patients with the rest of the national population, to identify how different these patients are at the beginning of treatment and then how comparable they are to the population average at the end of the program. Several variables, such as education, employment, substance use, quality of life, depression and functional status will be examined. To compare to a national population average, the CCHS is the best choice since it was completed by a variety of people (36, 984). Therefore, this is a large sample to use for an age-specific and region-specific group.

This study's first aim in using the CCHS is to benchmark the NL patients with the CCHS population of the same age group and from a specific region to compare the groups when the patients entered and then completed the program. This study will use the CCHS population from Atlantic Canada. Since the majority of those who develop early psychosis are between the ages of 15-29, the CCHS population will also be taken from that age range. There are 1461 people surveyed in Atlantic Canada that are between the ages of 15-29.

Since the CCHS was done at only one point in time, a cross-sectional study, it was decided to increase the age range to 15-34 years, the next interval in the age category of the CCHS to assess the population after 2 years. This is considered the best way to measure the CCHS at the second point in time since the NL patients would have increased in age by two years. There are 2073 patients between the ages of 15-34.

Table 2 describes the demographic characteristics of the Atlantic Canada Population.

Table 2. *Demographic Characteristics of CCHS Atlantic Canada Population*

AGE DISTRIBUTION	SEX	MARITAL STATUS	LIVING ARRANGEMENT
15-19: 552 (27%) 20-24: 466 (22%) 25-29: 443 (21%) 30-34: 612 (30%)	Males: 879 (42%) Females: 1194 (58%)	Single: 1169 (56%) Common-Law: 252 (12%) Married: 569 (27%) Widowed/Divorced: 78 (4%) Not Stated: 5 (0.2%)	Alone: 322 (15%) With Parents: 833 (40%) With Spouse: 757 (37%) Other: 146 (7%) Not Stated: 15 (1%)

The second part of this study will use the CCHS population to propensity match the early psychosis patients with the CCHS population who has displayed symptoms of psychosis. From the survey data file, 411 people stated they have psychosis, taken from question 281: Do you have any psychosis? Within the 411 people, 360 people ranged between the ages of 15-59 years. Therefore, these 360 people will serve as the psychotic population. Table 3 describes the demographic characteristics of these 360 people.

Table 3. *Demographic Characteristics of CCHS With Psychosis*

AGE DISTRIBUTION	SEX	MARITAL STATUS	LIVING ARRANGEMENT
15-19: 21 (6%) 20-24: 35 (10%) 25-29: 28 (8%) 30-34: 48 (13%) 35-39: 51 (14%) 40-44: 48 (13%) 45-49: 54 (15%) 50-54: 38 (11%) 54-59: 37 (10%)	Males: 166 (46%) Females: 194 (54%)	Single: 171 (48%) Common-Law: 22 (6%) Married: 80 (22%) Widowed/Divorced: 87(24%)	Alone: 187 (52%) With Parents: 38 (10%) With Spouse: 93 (26%) Other: 42 (12%)

3.6 The Study Procedure

Part One

The first analysis is a pre-post examination of the NL Program. This is done to compare traditional methodology with the later analyses of propensity matching to see which method shows a greater treatment effect. To perform the pre-post, only the early psychosis database will be used. 120 patients were used to perform the pre-post methodology. The results are derived from 120 patients who have been in the program for a period of at least two years. The 120 patients are evaluated at entry into the program, first year, second year and then three years later, to determine a treatment effect on the social and clinical outcomes. However, often there were patients that were not assessed at all three-month intervals. Therefore, if there is no patient assessment data at 12, 24 and 36 months, the mean of the assessment data for months before and after the entry points is used. For example, if there is no entry for the 12-month interval, then the mean of 9 and 15-month entries are used. This increases the number of patients to be assessed. The patients are first assessed on eight scales to see if there are any treatment effects. The scales used in this pre-post approach are Quality of Life, The Case Managers Rating Scale for Substance Use Disorder, The Calgary Depression Scale, YMRS, MADRS, PANSS, BAS, and GAS. Then to further examine program treatment effects, several variables on each of the clinical scales will be assessed such as quality of life, substance use, suicidal tendencies, sleep habits, aggressive behaviour, insight,

hospitalization, education, employment, depression and functional status. All computations will be performed using SPSS-one sample t-tests.

Part Two

In the second part of the analysis, comparisons are made with the CCHS Atlantic population by benchmarking to the same age. The matched individuals are then compared twice, once for the initiation of early psychosis patients into the NL Program to see if they differ from the population at entry, and secondly, at the end of two years into the NL Program for the early psychosis patients to see if they converge back to the population. The end of two years was chosen since most patients have not yet reached program completion (three years). The clinical and social outcomes that is used to compare the individuals are: quality of life, substance use, suicidal tendencies, hospitalization, education, employment, depression and functional status. Some of the variables are similar to those matched in the pre-post. The variables are matched by comparing items on the early psychosis scales with items answered in CCHS. Therefore, only certain variables that are used in the pre-post can be used here since the questions from both databases had to be matched as closely as possible. Data analyses for the comparisons will be performed using SPSS-independent sample t-tests. Convergence at two years is indicated when the t-value is non-significant, i.e. suggesting the patients did not differ from the population after two years of treatment. In some cases, the t-value may be significant at two years, but the t-value at two years may be smaller than at initiation. This suggests that although the treatment effects tend to be small, there is a trend towards convergence.

Below are examples of matched question variables from the early psychosis scales and the CCHS questions. The remaining matched variables can be found in Appendix G. EPP is abbreviation for Early Psychosis Program.

Question 2: Distress related to restlessness: Each scale rated this question as:

EPP (From BAS scale): No distress (0), Mild (1), Moderate (2), Severe (3)

CCHS: All of the time (1), most of the time (2), some of the time(3), little of the time(4), none of the time(5) (disb_10e)

Therefore, the MATCHED QUESTION FOR EPP-CCHS: Distress related to restlessness:

0=No distress (CCHS none of the time 5)
1= Mild (CCHS little of the time (4))
2= Moderate (CCHS some of the time (3))
3= Severe (CCHS all of the time (1) and most of the time (2))

Q14. Drank Alcohol in the last 12 months:

CCHS: Yes (1), No (1), not applicable (6), not stated (9) (alcb_1)

EPP (Case Manager Rating Scale for Substance Use Disorder) Alcohol: None (0), Mild (1), Moderate (2), Severe (3), Extremely Severe (4)

MATCHED QUESTION FOR EPP-CCHS: Alcohol:

1. Yes (EPP 1, 2, 3 and 4)
2. No (EPP 0)

Part Three

The third analysis is propensity matching the NL early psychosis patients with those members of the CCHS population who have psychosis as an alternative method to the pre-post comparison. This study originally envisioned performing propensity matching similar to that described by Ascher-Svanum et al. (2003). For example, the matching would be performed on four variables: age, gender, marital status, and living

circumstance. The propensity score would be defined as the conditional probability of being an early psychosis patient (Y) given the covariates of interest (X) of the individual: age, gender, marital status and living circumstance: PS=Pr(Y/X). Using these selected characteristics, a propensity score would be calculated for each individual in both groups using SPSS. An NL early psychosis patient would then be randomly selected and matched with a CCHS individual with the closest propensity score. Both individuals would then be removed from further matching, and a new patient would be selected until they are all matched. However, the CCHS sample size of 132 people was too small to calculate a propensity score to individually match the CCHS group with the NL early psychosis patients. Propensity matching, as described above, can only be used with a large population. Therefore, this study will perform a difference of differences approach as a propensity matching method.

Difference of differences approach is used to model the treatment effect by estimating the difference between outcome measures at two points in time for both those receiving the treatment and the controls (those not participating in the program) and then comparing the difference between the two groups (Buckley & Shang, 2003). For example, on the outcome variable sleep, if the NL patient was 60% at entry and then 52% at two years and the CCHS was 40% at entry and 37% in two years, it shows that although there is a difference between the groups, the NL patient group is narrowing the gap and converging towards the population. However, this is not showing a program effect. Any differences found here of narrowing the gap may only suggest the NL patients are getting older and therefore, any changes maybe a result of maturation or

hormones. However, going a step further by differencing the differences, that is, differencing the trajectory of the NL patients on these variables, such as taking the difference of the NL patients' trajectory of sleep towards the CCHS population, would identify any NL Program effects. This technique ensures that any variables (i.e. maturation or hormonal effects) not observed, but are correlated with the individuals and the outcome variables, will not bias the treatment effect (Buckley & Shang, 2003). The key assumption of the difference of differences approach is that the analyst assumes that unmeasured factors or changes affect both the participants and the non-participants in similar ways (Buckley & Shang, 2003). This methodology employs the propensity matching technique, whereby there is a small control sample to match.

Therefore, this study will use the difference of differences approach (inference about the difference between two means when there are independent samples). The criteria necessary to perform this type of propensity matching are that (1) the CCHS group had psychosis (answered yes to question 281) and that (2) they were of age-specific relevance (15-29 age range to match at initiation of the program and 15-34 age range to match two years later). The groups will first be compared on how different the NL group is from the CCHS group upon entry into the program and then at two years later. The groups are compared on the same social and clinical variables that are used in Part Two, which included quality of life, substance use, suicidal tendencies, hospitalization, education, employment, depression and functional status. The data will be analyzed using the difference of differences t-tests.

3.7 Ethical Considerations

The rights of the patients participating in this evaluation study are protected to the fullest extent possible. This was accomplished by getting approval on every aspect of this study.

First, a letter was written in January 2005 requesting the Coordinators of the NL Program to give permission to conduct research on the program and to use their database (See Appendix A). Permission was obtained from the Coordinators in January 2005 (See Appendix B).

Second, in January 2005, an ethics application was filled out describing in detail the Study's objectives and the use of a hospital database. This application was forwarded to the Memorial University Faculty of Medicine Human Investigation Committee (HIC) (See Appendix C). In February 2005 ethics approval was granted by HIC to pursue this Study (See Appendix D).

Third, in February 2005, another ethics application describing the Study was sent to Resource Proposal Approval Committee (RPAC) for using the Health Care Corporation of St. John's database (See Appendix E). Permission was granted in March 2005 (See Appendix F). Therefore, full approval was granted to perform this study.

The NL Program database was stored on computer files that were password-protected and accessible only by the principal investigator, the Studies Supervisor and the NL early psychosis program Coordinators. To protect privacy and confidentiality,

numerical identifiers that are associated with individual information were used during analysis. All information is untraceable to any study participant.

CHAPTER 4

RESULTS

4.1 Pre-Post Results on Patient Assessment Scales

120 patients are assessed on multiple clinical scales at entry, first, second and third year into the NL Program using one-sample t-tests. The results for the treatment effects from entry to first year are presented in Table 4. This study found significant improvements in the patients on all the scales ($p \leq 0.01$), except for the BAS scale.

The results for the treatment effects from the first to second year are presented in Table 5. During this time interval, only two scales show significant patient improvements. YMRS scale shows significant treatment improvement for patients at $p \leq 0.01$ and MADRS shows significant treatment improvement for patients at $p \leq 0.05$.

The results for the treatment effects from the second to third year of the NL Program are presented in Table 6. During this time interval, patients show no statistically significant improvements on any of the 8 scales assessed ($p \geq 0.10$).

Table 4. *Pre-Post treatment results for the first year on the patient assessment scales*

SCALE	MEAN (INITIAL)	MEAN (12 MONTHS)	MEAN DIFFERENCE	t-value
PANSS	75.86	47.78	28.1127	11.713 p=0.000***
GAS score (n=90)	42.18	64.97	23.0278	10.933 p=0.000***
Calgary Depression	2.54	0.7324	1.8182	4.227 p=0.000***

MADRS	13.90	5.10	8.9375	5.388 p=0.000***
YMRS	9.12	3.04	5.8000	5.913 p=0.000***
Substance Use	3.67	1.80	1.7600	6.063 p=0.000***
Quality of Life	65.29	79.44	13.7792	3.772 p=0.000***
BAS	0.76	0.47	0.2639	1.368 p=0.175

*p≤0.01*** p≤0.05** p≤0.10**

Table 5. *Pre-Post treatment results between 12-24 months on the patient assessment scales*

SCALE	MEAN (INITIAL)	MEAN (12 MONTHS)	MEAN DIFFERENCE	t-value
PANSS	47.78	46.18	-0.6053	-0.289 p=0.774
GAS score (n=70)	64.97	67.32	2.3429	1.448 p=0.152
Calgary Depression	0.7324	0.800	-0.1316	-0.419 p=0.677
MADRS	5.10	4.05	-1.8636	-2.217 p=0.038**
YMRS	3.04	1.80	2.0556	3.403 p=0.01***
Substance Use	1.80	1.80	0.2444	1.132 p=0.264
Quality of Life	79.44	81.40	2.1000	1.120 p=0.268
BAS	0.47	0.49	-0.1500	-1.062 p=0.295

*p≤0.01*** p≤0.05** p≤0.10**

Table 6. *Pre-Post treatment results between 24-36 months on the patient assessment scales*

SCALE	MEAN (INITIAL)	MEAN (12 MONTHS)	MEAN DIFFERENCE	t-value
PANSS	46.18	47.80	-1.6087	-0.670 p=0.510
GAS score (n=34)	67.32	67.65	1.0147	0.317 p=0.753
Calgary Depression	0.800	0.5667	-0.0833	-0.303 p=0.765
MADRS	4.05	4.93	-0.6250	-1.321 p=0.200
YMRS	1.80	2.63	-0.5000	-0.796 p=0.434
Substance Use	1.80	1.79	-0.3846	-1.631 p=0.115
Quality of Life	81.40	87.83	2.3571	0.858 p=0.399
BAS	0.49	0.53	-0.1739	-0.723 p=0.477

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

4.2 Pre-Post Results on Variables Within The Scales

120 patients are assessed on several scale variables at entry, first, second and third years into the NL Program using one-sample t-tests. Patient data on school and employment rates were only available at entry and at two years. Therefore, these variables are assessed for a two-year range using one-sample t-tests.

The results for the treatment effects on the variables from entry to the first year are presented in Table 7. Over the first year, patients are showing statistical significant improvements at $p \leq 0.01$ on PANSS delusions, conceptual organizations, hallucinatory behaviour, suspiciousness, emotional withdrawal, difficulty in abstract thinking,

stereotyped thinking, anxiety, guilty feelings, depression, unusual thought content, disorientation, poor attention, lack of judgment and insight, disturbance of volition and active social avoidance; CGI scale severity of the illness; The Calgary Depression scale depressed mood; MADRS apparent sadness, reduced sleep, concentration difficulties, pessimistic thoughts and suicidal thoughts; YMRS sleep, irritability, content, disruptive behaviour and insight into the illness; The Case Managers Rating Scale for Substance Use Disorder alcohol, cannibinoids, and hallucinogens use; and Quality of Life Scale on social activity, social withdrawal, sociosexual relations, extent of quality of life, adequacy of quality of life, underemployment, sense of purpose, motivation, time utilization and activities.

Patients are showing significant treatment improvements at $p \leq 0.05$ for PANSS passive/social apathetic withdrawal variable, and The Calgary Depression scale hopelessness and suicide.

There are no significant differences ($p \geq 0.10$) for the following variables: CGI global improvement; The Calgary Depression Scales self-depreciation; MADRS lassitude and inability to feel; YMRS speech; The Case Manager's Rating Scale for Substance Use Disorder cocaine use; ESRS restlessness; and BAS objective, subjective and distress related to restlessness.

Table 7. *Pre-Post treatment results for the first 12 months on several variables within the scales*

VARIABLE	MEAN (INITIAL)	MEAN (12 MONTHS)	MEAN DIFFERENCE	t-value
Delusions (n=88)	4.26	2.00	2.1932	10.225 p=0.000***

Conceptual Disorganization (n=88)	2.72	1.55	1.0966	8.012 p=0.000***
Hallucinatory Behaviour (n=71)	3.11	1.50	1.4648	7.345 p=0.000***
Suspiciousness (n=88)	3.77	1.87	1.8125	10.170 p=0.000***
Emotional withdrawal (n=88)	2.46	1.94	0.5625	3.911 p=0.000***
Passive/Apathetic Social withdrawal (n=88)	2.27	1.95	0.2784	1.993 p=0.049**
Difficulty in abstract thinking (n=88)	3.00	2.56	0.4148	3.077 p=0.003***
Stereotyped Thinking (n=88)	2.25	1.66	0.5114	4.010 p=0.000***
Anxiety (n=88)	2.95	1.79	0.9830	7.595 p=0.000***
Guilt Feelings (n=88)	2.15	1.40	0.6932	4.669 p=0.000***
Depression (n=88)	2.47	1.69	0.6989	4.632 p=0.000***
Unusual Thought Content (n=88)	2.91	1.78	1.0852	6.755 p=0.000***
Disorientation (n=88)	1.27	1.13	0.4830	4.865 p=0.000***
Poor attention (n=88)	2.44	1.46	0.9148	6.750 p=0.000***
Lack of judgment and insight (n=88)	3.59	2.04	1.4602	7.753 p=0.000***
Disturbance of Volition (n=88)	2.18	1.58	0.4830	4.342 p=0.000***
Active social avoidance (n=88)	2.59	1.43	1.0284	6.178 p=0.000***
Severity of the Illness (n=90)	4.46	2.42	1.8889	10.348 p=0.000***
Global Improvement (n=16)	1.28	1.73	-0.500	-1.232 p=0.237
Depressed Mood (n=84)	0.63	0.32	0.3095	3.732 p=0.000***

Hopelessness (n=84)	0.31	0.11	0.2083	3.253 p=0.02**
Self-Depreciation (n=84)	0.37	0.32	0.0833	1.075 p=0.286
Suicide (n=84)	0.23	0.08	0.1726	2.378 p=0.02**
Apparent Sadness (n=43)	1.41	0.36	0.9070	4.554 p=0.000***
Reduced Sleep (n=43)	1.56	0.35	1.1754	4.538 p=0.000***
Concentration Difficulties (n=43)	2.07	1.03	0.6744	2.691 p=0.010***
Lassitude (n=43)	1.20	0.79	0.2209	1.055 p=0.297
Inability to feel (n=2)	1.28	0.63	1.0000	1.000 p=0.500
Pessimistic Thoughts (n=43)	1.48	0.59	0.8605	3.998 p=0.000***
Suicidal Thoughts (n=43)	0.85	0.25	0.6512	2.770 p=0.008***
Sleep (n=73)	.81	.24	0.6111	6.278 p=0.000***
Irritability (n=73)	1.00	0.50	0.5449	4.667 p=0.000***
Speech (n=73)	0.91	0.29	-0.0548	-0.754 p=0.453
Language (n=73)	0.90	0.25	-0.059	-2.217 p=0.000***
Content (n=73)	1.70	0.48	1.0500	5.278 p=0.000***
Disruptive Behaviour (n=73)	0.67	0.24	0.4278	3.001 p=0.003***
Insight (n=73)	1.35	0.57	0.7667	4.959 p=0.000***
Alcohol Use (n=94)	1.41	1.01	0.3525	3.485 p=0.001***
Cannibinoids Use (n=94)	1.55	0.68	0.7632	5.970 p=0.000***
Cocaine Use (n=94)	0.17	0.04	0.0947	1.630 p=0.106
Hallucinogens Use (n=64)	0.28	0.05	0.2421	3.394 p=0.001***

Social Activity (n=101)	2.95	3.82	0.8416	5.271 p=0.000***
Social Network (n=101)	3.14	3.77	0.5545	3.666 p=0.000***
Social withdrawal (n=101)	3.28	3.97	0.6634	3.842 p=0.000***
Sociosexual relations (n=101)	2.05	2.84	0.6931	3.885 p=0.000***
Extent of QOL (n=101)	2.70	3.49	0.7100	2.994 p=0.003***
Adequacy of QOL (n=101)	2.26	3.40	1.1287	5.824 p=0.000***
Underemployment (n=101)	2.56	3.52	0.9455	4.140 p=0.000***
Sense of purpose (n=101)	3.08	3.76	0.6950	4.570 p=0.000***
Motivation (n=101)	3.24	4.06	0.9257	6.035 p=0.000***
Time Utilization (n=101)	3.27	4.18	0.8663	4.246 p=0.000***
Activities (n=101)	3.83	4.59	0.8267	4.877 p=0.000***
ESRS Restlessness (n=78)	1.32	1.22	0.0705	0.913 p=0.364
BAS objective (n=91)	0.16	0.06	0.0659	1.618 p=0.109
BAS subjective (awareness of restlessness) (n=91)	0.34	0.22	0.1099	1.637 p=0.105
Distress related to restlessness n=91)	0.07	0.04	0.0110	0.332 p=0.741

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

The results for the treatment effects on the variables from first to second year are presented in Table 8. Over the second year in the NL Program, this study found significant improvements ($p \leq 0.01$) on YMRS speech variable. There are significant

results at p≤ 0.05 for patients on PANSS difficulty in abstract thinking variables and BAS objective. The variables that show statistically significant improvements for patients at p≤ 0.10 are PANSS poor attention; and MADRS concentration difficulties and pessimistic thoughts. The rest of the variables are not statistically significant (p≥ 0.10).

Table 8. *Pre-Post treatment results between 12-24 months on several variables within the scales*

VARIABLE	MEAN (INITIAL)	MEAN (12 MONTHS)	MEAN DIFFERENCE	t-value
Delusions (n=62)	2.00	1.99	-0.2339	-1.290 p=0.202
Conceptual Disorganization (n=62)	1.55	1.54	-0.1250	-0.828 p=0.413
Hallucinatory Behaviour (n=54)	1.50	1.61	0.0648	0.548 p=0.586
Suspiciousness (n=62)	1.87	1.86	-0.2016	-1.653 p=0.103
Emotional withdrawal (n=62)	1.94	2.06	-0.1774	-1.591 p=0.117
Passive/Apathetic Social withdrawal (n=62)	1.95	2.06	-0.1048	-0.812 p=0.420
Difficulty in abstract thinking (n=62)	2.56	3.15	-0.6855	-4.754 p=0.000**
Stereotyped Thinking (n=62)	1.66	1.69	-0.1855	-1.588 p=0.118
Anxiety (n=62)	1.79	1.71	0.0242	0.157 p=0.876
Guilt Feelings (n=62)	1.40	1.38	-0.0645	-0.629 p=0.531
Depression (n=62)	1.69	1.50	0.1774	1.281 p=0.205
Unusual Thought Content (n=62)	1.78	1.68	0.0242	0.158 p=0.875
Disorientation (n=62)	1.13	1.10	0.0161	0.306 p=0.760

Poor attention (n=62)	1.46	1.53	-0.1774	-1.943 p=0.057*
Lack of judgment and insight (n=62)	2.04	1.99	-0.1290	-0.662 p=0.510
Disturbance of Volition (n=62)	1.58	1.56	-0.1290	-1.604 p=0.114
Active social avoidance (n=62)	1.43	1.43	-0.0565	-0.399 p=0.691
Severity of the Illness (n=70)	2.42	2.16	0.1571	1.008 p=0.317
Global Improvement (n=70)	1.73	1.45	0.0857	0.602 p=0.542
Depressed Mood (n=62)	0.32	0.29	0.0403	0.546 p=0.587
Hopelessness (n=62)	0.11	0.10	0.0323	0.646 p=0.521
Self-Depreciation (n=70)	0.32	0.27	0.0429	0.725 p=0.471
Suicide (n=62)	0.08	0.06	0.0242	0.554 p=0.582
Apparent Sadness (n=45)	0.36	0.33	0.0556	0.479 p=0.634
Reduced Sleep (n=45)	0.35	0.16	0.0778	0.463 p=0.646
Concentration Difficulties (n=45)	1.03	0.94	-2.111	-1.908 p=0.063*
Lassitude (n=45)	0.79	0.70	-0.0778	-0.627 p=0.534
Inability to feel (n=23)	0.63	0.53	0.1087	0.489 p=0.630
Pessimistic Thoughts (n=45)	0.59	0.69	-0.2222	-1.727 p=0.091*
Suicidal Thoughts (n=45)	0.25	0.21	-0.0667	-0.596 p=0.554
Sleep (n=60)	0.24	0.15	-0.0167	-.219 p=0.827
Irritability (n=60)	0.50	0.49	-.0750	-0.689 p=0.493
Speech (n=91)	0.29	0.13	0.0333	0.389 p=0.698

Language (n=60)	0.25	0.20	0.0333	0.505 p=0.616
Content (n=91)	0.48	0.32	5.0495	9.520 p=0.000***
Disruptive Behaviour (n=60)	0.24	0.20	-0.0250	-0.258 p=0.797
Insight (n=60)	0.57	0.31	0.0500	0.497 p=0.621
Alcohol Use (n=64)	1.01	1.02	0.0391	0.431 p=0.668
Cannibinoids Use (n=64)	0.68	0.67	-0.0703	-0.716 p=0.477
Cocaine Use (n=64)	0.04	0.03	0.0313	1.000 p=0.321
Hallucinogens Use (n=64)	0.05	0.03	0.0469	1.350 p=0.182
Social Activity (n=64)	3.82	3.91	0.1094	0.748 p=0.457
Social Network (n=64)	3.77	3.82	0.1563	1.010 p=0.316
Social withdrawal (n=64)	3.97	4.09	0.1094	0.754 p=0.453
Sociosexual relations (n=64)	2.84	2.79	0.0625	0.429 p=0.670
Extent of QOL (n=64)	3.49	3.79	0.3438	1.322 p=0.191
Adequacy of QOL(n=64)	3.40	3.59	0.1719	0.794 p=0.430
Underemployment (n=64)	3.52	3.83	0.3203	1.477 p=0.145
Sense of purpose (n=64)	3.76	3.95	0.1797	1.215 p=0.229
Motivation (n=64)	4.06	4.12	0.0391	0.250 p=0.803
Time Utilization (n=64)	4.18	4.44	0.2296	1.238 p=0.220
Activities (n=64)	4.59	4.71	0.2266	1.570 p=0.121
ESRS Restlessness (n=58)	1.22	1.20	0.000	0.000 p=1.000

BAS objective (n=60)	0.06	0.11	-0.1000	-2.187 p=0.033**
BAS subjective (awareness of restlessness) (n=60)	0.22	0.16	0.0167	0.299 p=0.766
Distress related to restlessness (n=60)	0.04	0.05	-0.0167	-0.574 p=0.568

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

The results for the treatment effects on the variables from second to third year are presented in Table 9. This study found significant improvements ($p \leq 0.01$) during the third year in the NL Program on PANSS difficulty in abstract thinking and YMRS content.

There are significant patient improvements at $p \leq 0.05$ for The Calgary Depression Scale self-depreciation; MADRS lassitude and inability to feel; and YMRS insight.

Patients also show statistical significance on the following variables at $p \leq 0.10$: PANSS emotional withdrawal, stereotyped thinking and unusual thought content; The Calgary Depression scale depressed mood; MADRS apparent sadness; and Quality of Life Scale social activity.

Patients did not show statistically significant improvements on the remaining variables during this time interval ($p \geq 0.10$).

Table 9. *Pre-Post treatment results between 24-36 months on several variables within the scales*

VARIABLE	MEAN (INITIAL)	MEAN (12 MONTHS)	MEAN DIFFERENCE	t-value
Delusions (n=36)	1.99	2.03	-0.0972	-0.584 p=0.563

Conceptual Disorganization (n=36)	1.54	1.47	0.1389	0.896 p=0.377
Hallucinatory Behaviour (n=36)	1.61	1.60	-0.1250	-0.801 p=0.429
Suspiciousness (n=36)	1.86	1.71	0.0833	0.505 p=0.616
Emotional withdrawal (n=36)	2.06	2.24	-0.2917	-1.950 p=0.059*
Passive/Apathetic Social withdrawal (n=36)	2.06	2.32	-0.3333	-1.560 p=0.128
Difficulty in abstract thinking (n=36)	3.15	3.61	-0.5139	-3.667 p=0.001***
Stereotyped Thinking (n=36)	1.69	1.82	-0.2361	-1.738 p=0.091*
Anxiety (n=36)	1.71	1.84	-0.1667	-1.456 p=0.154
Guilt Feelings (n=36)	1.38	1.42	-0.0833	-0.770 p=0.446
Depression (n=36)	1.50	1.29	0.0417	0.407 p=0.686
Unusual Thought Content (n=36)	1.68	1.87	-0.2778	-1.890 p=0.067*
Disorientation (n=36)	1.10	1.08	0.0139	0.239 p=0.812
Poor attention (n=35)	1.53	1.50	-0.0417	-0.424 p=0.674
Lack of judgment and insight (n-36)	1.99	1.87	-0.0694	-0.492 p=0.626
Disturbance of Volition (n=36)	1.56	1.55	-0.0972	-1.156 p=0.255
Active social avoidance (n=36)	1.43	1.32	0.0833	0.882 p=0.384
Severity of the Illness (n=34)	2.16	2.38	-0.2059	-0.929 p=0.359
Global Improvement (n=34)	1.45	1.61	-0.2206	-1.460 p=0.154
Depressed Mood (n=35)	0.29	0.18	0.1000	1.871 p=0.070*

Hopelessness (n=35)	0.10	0.08	-0.0429	-0.828 p=0.413
Self-Depreciation (n=35)	0.27	0.37	-0.2143	-2.266 p=0.03**
Suicide (n=35)	0.06	0.00	0.0286	1.000 p=0.324
Apparent Sadness (n=35)	0.33	0.42	-0.2286	-1.876 p=0.069*
Reduced Sleep (n=35)	0.16	0.13	-0.0857	-1.358 p=0.183
Concentration Difficulties (n=35)	0.94	0.89	-0.2571	-1.417 p=0.166
Lassitude (n=35)	0.70	0.82	-0.3143	-2.283 p=0.029**
Inability to feel (n=35)	0.53	0.74	-0.3571	-2.152 p=0.039**
Pessimistic Thoughts (n=35)	0.69	0.50	0.0714	0.487 p=0.629
Suicidal Thoughts (n=35)	0.21	0.24	-0.1714	-0.973 p=0.338
Sleep (n=35)	0.15	0.05	0.0286	0.529 p=0.600
Irritability (n=28)	0.49	0.40	-0.1607	-1.000 p=0.326
Speech (n=38)	0.13	0.18	0.000	0.000 p=1.000
Language (n=35)	0.20	0.16	0.0714	0.776 p=0.443
Content (n=62)	0.32	0.79	3.7742	6.018 p=0.000***
Disruptive Behaviour (n=62)	0.20	-6.69	-0.0143	-0.215 p=0.831
Insight (n=35)	0.31	0.68	-0.3857	-2.232 p=0.032**
Alcohol Use (n=37)	1.02	1.13	-0.1351	-1.221 p=0.230
Cannibinoids Use (n=37)	0.67	0.68	-0.1081	-1.000 p=0.324
Cocaine Use (n=37)	0.03	0.00	0.0000	0
Hallucinogens Use (n=37)	0.03	0.00	0.0000	0

Social Activity (n=36)	3.91	4.16	0.3056	1.768 p=0.086*
Social Network (n=36)	3.82	3.97	0.2500	1.505 p=0.141
Social withdrawal (n=36)	4.09	4.19	0.3333	1.394 p=0.172
Sociosexual relations (n=36)	2.79	2.86	0.3333	1.394 p=0.172
Extent of QOL (n=36)	3.79	3.49	-0.0278	-0.122 p=0.903
Adequacy of QOL (n=36)	3.59	3.57	0.1111	0.572 p=0.571
Underemployment (n=36)	3.83	3.84	0.1111	0.520 p=0.606
Sense of purpose(n=36)	3.95	4.53	0.2069	1.063 p=0.297
Motivation (n=36)	4.12	4.35	0.1111	0.681 p=0.500
Time Utilization (n=36)	4.44	4.35	-0.1389	0.695 p=0.492
Activities (n=36)	4.71	4.70	0.2778	1.056 p=0.298
ESRS Restlessness (n=34)	1.20	1.13	-0.0147	-0.215 p=0.831
BAS objective (n=35)	0.11	0.10	0.0000	0.000 p=1.000
BAS subjective (awareness of restlessness) (n=35)	0.16	0.15	0.0000	0.000 p=1.000
Distress related to restlessness (n=35)	0.05	0.10	-0.0571	-0.813 p=0.422

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

The results for the treatment effects on school and employment for the patients from entry to two years are presented in Table 10. This study found significant improvements ($p \leq 0.01$) over two years in the program on employment, but there was no statistically significant improvement ($p \geq 0.10$) in attending school.

Table 10. *Pre-Post treatment results between 0-24months on School, Employment and Hospitalizations for Patients*

VARIABLE	MEAN (INITIAL)	MEAN (24 MONTHS)	MEAN DIFFERENCE	t-value
School (n=88)	1.65	1.67	-0.0341	-0.623 p=0.535
Employment (n=95)	1.76	1.60	0.2000	4.279 p=0.000***

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

4.3 Results from Benchmarking Early Psychosis Patients with CCHS Atlantic Population

During this analysis, the NL early psychosis patients are matched with the CCHS population. From the 120 patients, 97 patients are between the ages of 15-29 and are benchmarked with the 15-29-age population from CCHS Atlantic Canada. They are assessed on several scale variables at entry. The 97 patients are then matched on the various variables at two years into the program, using the 15-34-age range of CCHS Atlantic Canada population. Independent-Sample t-tests are used for the analyses.

The results for the group difference on the variables at entry are presented in Table 11. This study found significant differences ($p \leq 0.01$) between the NL patients and the CCHS population at entry on passive/apathetic withdrawal, mental health status, depression, suicidal thoughts, suicidal attempt, lassitude, reduced sleep, irritability, drinking despite health problem (alcohol), cannibinoids use, friends, activities, interaction, social network, social activity, distress related to restlessness hospitalization.

There are significant differences ($p \leq 0.10$) between the groups on the concentration difficulty variable.

There are no significant differences ($p \geq 0.10$) between the groups on pessimistic thoughts, sleep, alcohol, cocaine and hallucinogen use, restlessness, attending school and employment.

Table 11. *Results from Benchmarking Early Psychosis Patients with CCHS Atlantic Population at entry into the program (15-29 years)*

Variable	EPP initial mean	EPP initial standard deviation	CCHS initial mean	CCHS initial standard deviation	t-value at initiation
Passive/Apathetic social withdrawal	1.35 (n=94)	0.480	1.96 (n=1453)	0.196	-25.617 p=0.000***
Mental health (severity of the illness)	4.16 (n=96)	1.079	2.14 (n=1458)	0.939	20.178 p=0.000***
Depressive Symptoms	1.48 (n=82)	0.502	1.21 (n=200)	0.405	4.741 p=0.000***
Suicidal thoughts	1.79 (n=89)	0.412	1.62 (n=155)	0.487	2.725 p=0.007***
Suicidal attempt	1.79 (n=89)	0.412	1.96 (n=1450)	0.196	-7.411 p=0.000***
Reduced Sleep	1.47 (n=49)	0.504	1.27 (n=155)	0.446	2.629 p=0.009***
Sleep	1.47 (n=49)	0.504	1.46 (n=247)	0.500	0.1000 p=0.920
Concentration difficulties	1.27 (n=93)	0.446	1.17 (n=155)	0.375	1.913 p=0.057*
Pessimistic Thoughts	1.31 (n=48)	0.468	1.34 (n=109)	0.476	-0.329 p=0.743
Lassitude	1.43 (n=49)	0.500	2.08 (n=149)	0.955	-4.571 p=0.000***
Irritability	1.35 (n=95)	0.479	1.57 (n=46)	0.501	-2.495 p=0.014***
Alcohol Use	1.23 (n=96)	0.423	1.19 (n=1452)	0.396	0.835 p=0.404
Drink despite health problem	1.23 (n=96)	0.423	1.94 (n=466)	0.246	-22.228 p=0.000***
Cannibinoids Use	1.31 (n=96)	0.466	1.52 (n=809)	0.500	-3.903 p=0.000***

Cocaine Use	1.86 (n=96)	0.344	1.78 (n=67)	0.420	1.474 p=0.142
Hallucinogen Use	1.81 (n=96)	0.392	1.84 (n=177)	0.366	-0.616 p=0.538
Friends	1.21 (n=96)	0.408	1.98 (n=1452)	0.122	-47.312 p=0.000***
Activities	2.26 (n=97)	0.617	2.69 (n=1452)	0.687	-5.980 p=0.000***
Interaction	1.96 (n=97)	0.776	3.66 (n=1436)	0.662	-24.256 p=0.000***
Social Network	1.42 (n=97)	0.775	3.63 (n=1437)	0.722	-28.960 p=0.000***
Social Activity	1.29 (n=97)	0.763	3.58 (n=1437)	0.714	-30.524 p=0.000***
Restlessness	1.33 (n=86)	0.562	1.46 (n=1453)	0.820	-1.511 p=0.131
Distress related to restlessness	0.08 (n=97)	0.312	0.46 (n=1453)	0.820	-4.523 p=0.000***
School	1.65 (n=96)	0.481	162 (n=1461)	0.592	0.394 p=0.693
Employment	1.76 (n=96)	0.429	1.73 (n=1461)	0.982	0.292 p=0.771
Hospitalization	1.33 (n=97)	0.473	5.93 (n=1461)	0.570	-77.764 p=0.000***

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

The results for the group differences on the variables at two years to see if the NL patient group converges back to the population are presented in Table 12. This study found no significant differences ($p \geq 0.10$) between the NL patients and the CCHS population to suggesting convergence after two years on suicide, pessimistic thoughts, irritability, cannibinoids use; attending school and employment.

There are four variables: mental health, lassitude, alcohol use, and hospitalization that show convergence for the NL group after two years, by looking at the decreasing t-values, although they are statistically significant.

There are statistically significant group differences ($p \leq 0.01$), ($p \leq 0.05$) and

($p \leq 0.10$) on the rest of the variables, suggesting no convergence.

Table 12. *Results from Benchmarking Early Psychosis Patients with CCHS Atlantic Population Two years into the program (15-34 years)*

Variable	EPP 24 month mean	EPP 24 month standard deviation	CCHS 24 month mean	CCHS 24 month standard deviation	t-value at 24 months
Passive/Apathetic social withdrawal	1.03 (n=58)	0.158	1.96 (n=2072)	0.190	-36.760 p=0.000***
Mental health (Severity of the illness)	2.41 (n=64)	1.207	2.12 (n=2072)	0.903	2.509 p=0.012***
Depressive Symptoms	1.68 (n=41)	0.264	1.18 (n=301)	0.384	7.647 p=0.000***
Suicidal thoughts	1.98 (n=41)	0.156	1.25 (n=242)	0.156	10.638 p=0.000***
Suicide	1.98 (n=41)	0.156	1.96 (n=2067)	0.194	0.485 p=0.628
Reduced Sleep	1.93 (n=56)	0.260	1.25 (n=241)	0.433	11.266 p=0.000***
Sleep	1.82 (n=56)	0.260	1.46 (n=318)	0.499	5.167 p=0.000***
Concentration difficulties	1.63 (n=59)	0.488	1.15 (n=243)	0.360	8.433 p=0.000***
Pessimistic Thoughts	1.46 (n=60)	0.539	1.34 (n=166)	0.475	1.632 p=0.104
Lassitude	1.48 (n=56)	0.556	2.05 (n=235)	0.990	-4.144 p=0.000***
Irritability	1.65 (n=56)	0.485	1.51 (n=59)	0.504	1.551 p=0.124
Alcohol Use	1.32 (n=59)	0.471	1.17 (n=2071)	0.380	2.914 p=0.004***
Drink despite health problem	1.32 (n=59)	0.471	1.94 (n=645)	0.236	-17.290 p=0.000***
Cannibinoids Use	1.63 (n=59)	0.488	1.59 (n=1176)	0.492	0.525 p=0.600
Cocaine Use	1.98 (n=59)	0.130	1.83 (n=118)	0.377	3.017 p=0.003***
Hallucinogens Use	1.98 (n=59)	0.130	1.88 (n=262)	0.328	2.418 p=0.016**
Friends	1.06 (n=47)	0.247	1.99 (n=2071)	0.118	-51.317 p=0.000***

Activities	2.41 (n=59)	0.561	2.69 (n=2071)	0.680	-3.148 p=0.002***
Interaction	3.00 (n=47)	1.043	3.64 (n=2053)	0.685	-6.232 p=0.000***
Social Network	2.12 (n=59)	0.646	3.61 (n=2054)	0.736	-15.359 p=0.000***
Social Activity	2.10 (n=59)	0.548	3.55 (n=2054)	0.733	-15.088 p=0.000***
Distress related to restlessness	0.05 (n=56)	0.227	0.96 (n=2072)	0.952	-7.089 p=0.000***
Restlessness	1.22 (n=57)	0.526	1.43 (n=2072)	0.800	-2.016 p=0.044**
School	1.67 (n=88)	0.473	1.72 (n=2073)	0.532	-0.837 p=0.402
Employment	1.60 (n=85)	0.493	1.65 (n=2073)	0.906	-0.528 p=0.598
Hospitalization	1.90 (n=92)	0.299	5.92 (n=2073)	0.595	-64.434 p=0.000***

*$p \leq 0.01$*** $p \leq 0.05$** $p \leq 0.10$**

4.4 Results from matching Early Psychosis Patients with CCHS Population with Psychosis

During this analysis, the NL early psychosis patients are matched with the CCHS population who had psychosis and followed the age-criteria of 15-29 years and 15-34 years. From the 120 NL early psychosis patients, 97 patients are between the ages of 15-29 and are used to match with the 15-29-age CCHS psychotic population. They are assessed on several scale variables at entry. The 97 patients are then matched on the various variables at two years into the program, using the 15-34-age psychotic CCHS population. The differences in the trajectories calculated at this point are then differenced to determine NL Program treatment effects. Difference of differences t-tests

(inference about the difference between two means when there are independent samples) is used for the analyses.

The results are presented in Table 13. This study found significant differences ($t \geq 0.01$) to show a NL Program effect on the following variables: passive/apathetic social withdrawal, mental health status, suicidal thoughts, suicide attempt, concentration difficulties, reduced sleep, sleep, cannibinoids and hallucinogens use, interaction, social network, social activity, restlessness, distress related to restlessness, attending school and hospitalization.

There is statistical significant treatment effects at $t \geq 0.05$ for depressive symptoms; and statistical significant treatment effects at $t \geq 0.10$ for cocaine use, friends and employment.

There are no statistical significant NL Program effects ($t \leq 0.10$) on pessimistic thoughts, lassitude, irritability, alcohol use and drinking despite health problems.

Table 13. *Results from Propensity Matching Early Psychosis Patients with CCHS Population of the Same Age and Who Has Psychosis*

Variable	EPP diff mean	EPP diff s.d	CCHS initial mean	CCHS initial s.d.	CCHS 24month mean	CCHS 24month s.d.	Pooled s.d.	t-value
Passive/ Apathetic Social Withdrawal	-0.2184 (n=87)	0.4492	1.74 (n=84)	0.442	1.68 (n=131)	0.190	0.3133	-5.285***
Mental health	-1.1139 (n=10)	1.7817	3.81 (n=84)	0.963	3.70 (n=132)	0.903	0.9267	-6.503***
Depressive Symptoms	0.1622 (n=37)	0.5535	1.06 (n=66)	0.240	1.06 (n=100)	0.239	0.2394	1.747**
Suicidal thoughts	0.2195 (n=41)	0.4750	1.44 (n=62)	0.500	1.42 (n=93)	0.496	0.4976	2.368***
Suicide	0.1549 (n=71)	0.4358	1.57 (n=84)	0.498	162 (n=131)	0.194	0.3458	3.605***

Reduced Sleep	0.4643 (n=46)	0.5049	1.23 (n=66)	0.422	1.23 (n=93)	0.433	0.4285	5.665***
Sleep	0.4872 (n=39)	0.5064	1.22 (n=46)	0.417	1.20 (n=70)	0.403	0.4086	5.219***
Concentration difficulties	0.3393 (n=56)	0.6113	1.65 (n=17)	0.493	1.60 (n=20)	0.503	0.4985	2.500***
Pessimistic Thoughts	-0.0952 (n=21)	0.6446	1.24 (n=45)	0.435	1.26 (n=72)	0.444	0.4406	-0.499
Lassitude	0.0488 (n=41)	0.7567	1.68 (n=62)	0.919	1.68 (n=93)	0.990	0.9936	0.3422
Irritability	0.2909 (n=55)	0.6360	1.75 (n=4)	0.500	1.75 (n=4)	0.504	1.7500	0.4657
Alcohol Use	0.0674 (n=89)	0.4954	1.24 (n=84)	0.428	1.23 (n=132)	0.380	0.3993	0.9709
Drink despite health problem	0.1311 (n=61)	0.5315	1.70 (n=30)	0.466	1.58 (n=38)	0.236	0.3559	0.1377
Cannibinoids Use	0.2923 (n=65)	0.6306	1.38 (n=64)	0.488	1.48 (n=102)	0.492	0.4905	4.510***
Cocaine Use	0.0678 (n=59)	0.3143	1.67 (n=24)	0.482	1.70 (n=40)	0.377	0.4190	1.471*
Hallucinogens	0.1864 (n=59)	0.4345	1.73 (n=30)	0.450	1.77 (n=44)	0.328	0.3819	3.149***
Friends	-0.1169 (n=77)	0.3965	1.83 (n=84)	0.375	1.79 (n=131)	0.118	0.2516	1.591*
Activities	0.0562 (n=89)	0.8442	1.99 (n=84)	0.885	1.99 (n=131)	0.680	0.7664	0.5425
Interaction	0.4342 (n=76)	1.2570	1.25 (n=81)	0.783	3.06 (n=127)	0.685	0.7246	14.687***
Social Network	0.2386 (n=88)	1.2317	1.38 (n=81)	0.734	3.24 (n=127)	0.736	0.7352	14.905***
Social Activity	0.4205 (n=88)	1.1519	1.26 (n=81)	0.803	2.99 (n=127)	0.733	0.7609	16.091***
Restlessness	0.5543 (n=52)	0.7880	2.86 (n=84)	1.466	2.14 (n=132)	1.106	1.5823	-1.080 *
Distress related to restlessness	0.2209 (n=86)	0.8029	2.57 (n=84)	1.056	1.80 (n=132)	0.952	0.9936	-4.999***
School	0.0341 (n=88)	0.5130	1.64 (n=83)	0.483	1.85 (n=123)	1.025	0.8498	3.029***
Employment	-0.2000 (n=85)	0.4309	1.75 (n=83)	0.437	1.83 (n=120)	1.248	0.9608	-1.463*
Hospitalization	0.5543 (n=92)	0.5419	1.31 (n=84)	0.465	3.03 (n=127)	1.856	1.4706	19.616***

*$t \geq 0.01$*** $t \geq 0.05$* $t \geq 0.10$**

CHAPTER 5

DISCUSSION

5.1 Pre-Post Findings on Patient Assessment Scales

The first objective of this study was to evaluate the impact of the NL Program for patients on a number of clinical and social outcomes. This was done by first performing the pre-post methodology and secondly, by performing the propensity matching methodology, which will be described in section 5.4.

The pre-post analysis was done on the patients over three years by first assessing the eight scales and then assessing the variables within each scale, which will be discussed in section 5.2. Researchers when evaluating early psychosis programs typically use this pre-post methodology (Addington et al., 2004b; & Malla et al., 2001).

The results of the pre-post analysis on patient performances on the multiple clinical scales found significant improvements for patients within the first year of the NL Program on seven scales: PANSS, GAS, The Calgary Depression Scale, MADRS, YMRS, The Case Managers Substance Use Disorder scale, and the Quality of Life scale. In the second year, patients show improvement on only two scales, MADRS and YMRS. There are no significant improvements in the third year. This suggests that the NL Program is having a major treatment effect within the first 12 months. This may be due to the fact that patients are regulated on their medication

during the first year and this is maintained during the rest of their program treatment. As well, patients are receiving psychosocial treatments. A significant improvement on the MADRS and YMRS scales again in the second year, suggests that it may take two years for patients to improve in mood symptom clusters.

5.2 Pre-Post Findings on Variables Within The Scales

The pre-post analysis on patient performances on various scales variables was also done over three years, with assessments made at 12, 24 and 36 months.

On the PANSS, patients show improvement on all scale variables (delusions, hallucinatory behaviour, suspiciousness, emotional withdrawal, passive/apathetic social withdrawal, difficulty in abstract thinking, stereotyped thinking, anxiety, guilt feelings, depression, unusual thought content, disorientation, poor attention, lack of judgment and insight, disturbance of volition and active social avoidance) over the first year. In the second year, patients improve on difficulty in abstract thinking and poor attention variables. In the third year, patients improve on emotional withdrawal, difficulty in abstract thinking, stereotyped thinking and unusual thought content variable. These results suggest that the NL Program has a major treatment effect on reducing psychotic symptoms within the first year of the program. The patients continue to improve on the difficulty in abstract thinking variable during the entire program, suggesting that this variable improvement requires a longer treatment period. The NL Program also seems to improve poor attention, emotional

withdrawal, stereotyped thinking and unusual thought content variables longer than the first year.

On the CGI scale, the patients show improvement during the first year on the severity of the illness variable. In the second year and third year, there were no significant treatment effects on severity of the illness or global improvement variables. These results suggest that the NL Program has an overall effect on the patients during the first year.

On The Calgary Depression Scale, patients significantly improve on all variables (depressed mood, hopelessness, and suicide), except for self-depreciation variable during the first year. In the second year, there are no significant improvements on any of this scale's variables. In the third year, there are significant treatment improvements in depressed mood and self-depreciation variables. These findings suggest that the NL Program continually improves patients on depression throughout the program and has a major effect on self-depreciation by the third year.

On the MADRS, most variables (apparent sadness, reduced sleep, concentration difficulties, pessimistic thoughts and suicidal thoughts) show significant patient improvement during the first year, except for the lassitude and inability to feel variables. In the second year, patients continue to significantly improve on concentration and pessimistic thoughts variables. In the third year, patients improve on apparent sadness, lassitude and inability to feel variables. These findings suggest that it takes at least two years for the NL Program to help patients

with concentration difficulties and pessimistic thoughts, and at least three years for patients to improve on lassitude and inability to feel.

On the YMRS, all variables (sleep, irritability, speech, language, content, disruptive behaviour and insight) analyzed show patient improvement within the first year. During the second year, patients only show significant improvement in the content variable. In the third year, there are also improvements in the content variable as well as the insight variable. Since the NL Program offers psychotherapy and psychoeducation, the program continues to improve patient insight about having an illness.

On The Case Managers Rating Scale for Substance Use Disorder, patients demonstrate significant improvement on all scale variables (alcohol, cannibinoids and hallucinogen use) assessed during the first year. There are no significant improvements on any of these variables during the second and third year of the program. This suggests that the NL Program is successful in addressing substance misuse and its consequences within the first year of the program.

On the Quality of Life scale, patients demonstrate significant improvements on all variables (social activity, social network, social withdrawal, sociosexual relations, extent of quality of life, adequacy of quality of life, underemployment, sense of purpose, motivation, time utilization and activities) during their first year. In the second year, there are no significant improvements on any of the scales. In the third year, there is significant improvement on the social activity variable. These findings suggest that the NL Program significantly helps patients with social

outcomes during their first year of the program, through their therapy support groups and recreational therapy that provides social activities.

On the BAS, patients only show improvement for the objective variable in the second year. There are no patient improvements on the subjective and distress related to restlessness variables.

On the ESRS, only one variable, restlessness is assessed. In all three years, the patients did not improve on this variable. These results coincide with the results found on distress related to restlessness from the BAS. Restlessness is a common side effect from taking psychotic medication. This may explain why patients appear to be restless during the three years in the program.

The pre-post results evaluate school and employment on a two-year assessment because there are no specific scales used by the NL program to request this information on one-year follow-ups. The results found significant improvements in employment after two years, suggesting that many patients have entered or reentered the workforce at the end of two years. Since there were no improvements in schooling at the end of two years, one may speculate that this maybe a result of patients graduating and entering into the workforce.

Therefore, using the traditional pre-post methodology, it can be concluded that the NL program has had a significant impact for patients on a number of clinical and social outcomes.

5.3 Benchmarking Findings

The benchmarking exercise was done to compare the NL early psychosis patients to the Canadian population to see how they perform on clinical and social outcomes at entry into the program and then at two years later. If the patients converge back towards the population at the end of two years, it suggests the NL Program is effective in helping patients to recover and rehabilitate.

The national population was taken from the CCHS that was completed by a random sample of families across Canada. It was decided to benchmark the patients to the CCHS population from the Atlantic region and who are of the same age. Since early psychosis programs are typically designed for 15-29 year olds, this was the age criterion for the patients and the CCHS population at initiation. Since the NL patients will have increased in age by two years, the second CCHS cohort was taken by increasing the age range from 30-34 years, the next interval in the age category of the survey.

To compare the patients to the CCHS population, variables from the various scales were matched as accurately as possible to several questions asked in the survey (See Appendix G for reference). In total, 26 variables from the Early Psychosis scales were matched with 26 questions from CCHS.

The results illustrate a significant difference at entry between the NL patients and the population on the passive/apathetic social withdrawal variable. At the end of the two years, the patients also show a significant difference on the passive/apathetic

social withdrawal variable compared to the population, therefore suggesting no convergence towards the population after 2 years.

At entry and at two years, there is a significant difference between the groups on the mental health variable (severity of the illness) variable. However, the t-value appears to be decreasing, therefore suggesting the patients are showing a trend of convergence towards the population.

The results indicate that at entry, the groups differ on the depressed symptoms, suicidal thoughts and suicidal attempt variables. At two years, there was a significant difference between the groups on depressed mood and suicidal thoughts. However, at two years, there was no difference between the groups on suicidal attempts, suggesting the NL patients are converging towards the population on this variable.

At entry, the groups differ on concentration difficulties, lassitude and reduced sleep, but there is no difference between the groups on pessimistic thoughts and sleep. At the end of two years into the program, the patients differ from the population on reduced sleep, sleep, concentration difficulties and lassitude variables. They did not differ from the group on pessimistic thoughts, suggesting convergence towards the population on this variable. As well, the decreasing t-value for the lassitude variable suggests that the patients are showing a trend of convergence towards the population in lassitude.

The results indicate the patients did differ from the group at entry on irritability, but at the end of the two years they converged towards the population on this variable.

At entry, the patients differ from the population on the drinking despite health problem and the cannibinoids use variables. At the end of the two years, the groups differ on alcohol use, drinking despite health problems, cocaine and hallucinogen use variables. The patients only converge towards the population on using cannibinoids. However, comparing the t-values from entry to two years on the alcohol variable, the results illustrate a decreasing t-value. Thus, patients maybe converging towards the population on alcohol use.

The results indicate that the patients did differ from the population at entry and then again at two years, to suggest the NL patients did not converge towards the population on the social activity, social network, interaction, friends and activities variables.

There is a difference between the groups at entry and then again after two years on the distress related to restlessness variable. Therefore, there was no convergence on this variable.

The patients did not differ from the population at entry, but did differ from the population at two years on the restless variable. Thus, the patients diverge from the population on this variable. This is the only condition where deterioration occurred. This may be a result of patients taking psychotic medication, which may have a side

effect of restlessness. Since the patients on all other variables stayed the same or converge, the restless variable may require further investigation.

At entry, the patients did not differ from the population on school and employment. At the end of the two years, no difference was found between the two groups on these variables, suggesting the patients converge towards the population. The patients, however, did differ from the population at entry and at two years on the hospitalization for mental health variable. However, the t-value appeared to be decreasing, thus suggesting convergence on the hospitalization variable.

Thus, overall, this benchmarking exercise shows that patients are converging towards the population on irritability, pessimistic thoughts and suicidal attempt. It also shows that the NL patients are converging towards the population on cannibinoids use, school and employment issues. Although not statistically significant, there seems to be some evidence of convergence on the mental health, lassitude, alcohol and hospitalization variables. Patient improvement on these four variables may prove to be significant beyond two years of treatment.

5.4 Propensity Matching Findings

One of the main purposes of this thesis is to test a new methodology-propensity matching-on a unique group, in which randomization and comparing to a control group is difficult, and pre-post methodology must be used with limitations since there are no control groups used and maturation maybe the cause of the pre-post changes.

To perform the propensity matching methodology, the NL early psychosis patients were matched to the CCHS population on various characteristics to determine a NL Program treatment effect. The criterion used to match the NL patients with the population was that the population had to have psychosis and was of the same age. Unfortunately, the CCHS population was very limited in the number of people who had psychosis (411 psychotic people). Therefore, propensity matching by matching on demographics as described by Ascher-Svanum et al. (2003) could not be performed in this analysis. However, propensity matching to show a NL Program effect can be performed by first, comparing the patients and the population at entry and then at two years on the various variables to determine the trajectories, and then differencing the trajectories of the patients on these variables to determine the NL Program treatment effects. This meets the study's objectives 2-5.

Therefore, in evaluating the NL Program using propensity matching, there are significant program effects found at the end of the two years on several variables.

There are significant NL Program effects on the passive/apathetic social withdrawal variable.

There are significant improvements in mental health over two years.

The NL Program is having a treatment effect on depressive symptoms, suicidal thoughts and suicidal attempt.

There are significant NL Program treatment effects on reduced sleep, sleep and concentration difficulties variables. However, propensity matching found no program effects on pessimistic thoughts and lassitude variables.

There is no significant program effect for reducing irritability.

There are significant NL Program effects over two years on cannibinoids, cocaine and hallucinogen use variables. However, patients show no significant improvements on alcohol use or drinking despite health problem variables.

There are significant program treatment effects on friends, interaction, social network and social activity. However, there is no program effect at two years on the activities variable.

The NL Program helps patients improve significantly on the distress related to restlessness variable and on the restlessness variable.

Also, there is significant NL Program treatment effects found on the school, employment and hospitalizations variables at the end of the two years.

Therefore, overall, comparing patients to the general population who has psychosis using propensity matching, the results found the NL Program is having a major impact on improving patients on a number of clinical and social outcomes. Thus, this methodology, despite its limitations, can be used to evaluate early psychosis programs.

5.5 Pre-Post versus Propensity Matching Findings

Objective 6 of this thesis is to compare and contrast propensity matching with the traditional pre-post methodology, to determine if propensity matching can be used as an alternative method to show the treatment effect of early psychosis programs.

The variables compared upon in this section are only the variables that could be used in the propensity matching section.

On the PANSS, the pre-post methodology found patients show significant improvement on the social/apathetic social withdrawal variable during the first year. Propensity matching also found the same results for this variable, therefore suggesting that the NL Program reduces symptoms for its patients.

On the CGI scale, pre-post methodology shows patient improvement on the severity of the illness variable during the first year. Similar results were found using propensity matching.

On the Calgary Depression scale, there were significant improvements on the scale and the suicide variable within the first year using the pre-post methodology. These findings were also found using propensity matching.

On the MADRS, using the pre-post, patients show significant improvements on reduced sleep in the first year; significant improvements on the concentration difficulties, pessimistic thoughts and suicidal thoughts variables in the first and second years; and significant improvements in the lassitude variable by the third year. The propensity matching method found significant improvements for patients on reduced sleep and concentration difficulties variables after two years in the program. Since the lassitude variable took three years to show improvement using the pre-post, this may explain why there was no significant improvement on lassitude using propensity matching after 2 years.

On the YMRS, patients show significant improvement on the irritability variable in the first year using the pre-post. However, propensity matching show no significant program effect after two years.

On The Case Manager's Rating Scale for Substance Use Disorder, the pre-post methodology found patients show significant improvement on the scale variables (alcohol, cannibinoids and hallucinogen use) in the first year. There are significant program effects on cannibinoids, cocaine and hallucinogen use after two years in the program using propensity matching.

On the Quality of Life Scale, the pre-post methodology found patients show significant improvements on all the variables (social activity, social network and activities) during the first year and continue significant improvement on the social activity variable by the third year. The propensity matching methodology found there are significant program effects on social network and social activity at the end of the two years. Therefore, the results are similar to the pre-post suggesting the NL Program is helping patients with improving their quality of life.

On the BAS, there are no significant improvements on the distress variable using the pre-post methodology. However, propensity matching did find a significant program effect on this variable.

On the ESRS variable, the pre-post show no significant improvement for patients on the restlessness variable. However, propensity matching methodology did find a significant improvement on this variable over two years. This variable may require further investigation.

The pre-post methodology found significant improvement on employment for patients after two years. Propensity matching also found the same results for employment as well as the school and hospitalization variable.

Overall, both methodologies show NL Program treatment effects on social/apathetic social withdrawal; severity of the illness; depressive symptoms; suicide; reduced sleep; concentration difficulties; cannibinoids, cocaine and hallucinogen use; social activity and social network; employment and hospitalization variables.

There are relative strength and weaknesses of using either the pre-post or propensity matching methodology to evaluate an early psychosis program. See Table 14 for a comparison between the two methodologies.

Table 14. Comparison of Pre-Post versus Propensity Matching Methodology to Evaluate Early Psychosis Programs

	PRE-POST	PROPENSITY MATCHING
STRENGTHS	1. Easy to perform 2. Limited time required to perform 3. No issue of matching questions 4. Evaluator has control over the questions asked 5. Data is reliable	1. Assumes the effects of RCT synthetic control group i.e. Individuals are randomly selected and no baseline differences between groups 2. Confounding effects are taken into account
WEAKNESSES	1. Potentially misleading if confounding effects are taken into account	1. More challenging to perform 2. Time consuming 3. Difficulty in finding a representative

	2. No control group used	population to match the Early Psychosis Program 4. Timing issue of the data used to compare with the program i.e. The date the population data was collected and published 5. Evaluator is unaware of other treatments the population may/may not have received that may alter the results

Therefore, it can be concluded from this research that propensity matching methodology offers a new way to evaluate early psychosis programs to determine social and clinical outcomes.

5.6 Comparison of Study's Findings to Previous Studies

This study's results from the PANSS scale are similar to those found by Addington et al. (2003). The NL patients improve on all positive and negative symptom variables examined over the first year. This suggests that the NL Program helps to reduce symptoms, possibly by getting patients regulated on the appropriate medication within the first year. This is suggested since this study found a decrease in hospitalization rates over two years.

This study's results on the Quality of Life Scale are similar to Malla et al. (2003) and Addington et al. (2003) whose evaluations of their programs found

improvements in quality of life. This study's patients significantly improve in social functioning during the first year on variables such as social activity, social network, social withdrawal, extent of quality of life, adequacy of quality of life, sense of purpose and motivation. After two years into the NL Program, patients also show an improvement in employment outcomes. The propensity matching methodology also show an improvement in schooling after two years. Therefore, the NL Program's occupational therapy appears to be helping patients recover and encouraging them to complete or continue their education and integrate into the workforce, thus providing hope for the future. Newstead & Kelly (2002) state that society may also benefit in time for socially including this group within society since it may provide opportunities to form partnerships with the patients and carers to facilitate a greater understanding of differing value and move towards a common set of principles regarding mental health care.

Sorbara et al. (2003) investigated the impact of substance and alcohol misuse on clinical and social outcomes over two years and found persistent substance misuse had a detrimental impact on clinical outcome. This study found a decrease in alcohol and substance misuse by the patients, suggesting that the NL Program's substance use prevention counseling is effective and may have been a factor in why there was significant clinical outcome improvement. This is important since there has been extensive evidence that suggests substance use, especially cannabis use, is a risk factor for psychotic symptoms (Sorbara et al., 2003).

This study also found the severity of the illness on CGI decreased with treatment. Therefore, confirming previous studies by McGorry (2000a), and McGlashan and Johannessen (1996) that reducing DUP at the earliest possible time and providing early treatment is important.

This study found patients improve on YMRS insight variable and PANSS lack of judgment and insight variable during the first year into the program to suggest that the program's individual and group therapies helped patients realize that they have a mental disorder and that they need treatment. Mintz et al. (2004) also found insight improved for their Calgary patients during the first year of the program.

Program treatment effects are reported on the Calgary Depression Scale for reducing depression. Depression plays a major role in psychotic illness, since patients may feel alienated and lose self-esteem when there is a major change in their life (Jackson & Iqbalt, 2000). Therefore, it is an important for Early Psychosis Programs, such as the NL Program, to be successful in reducing depressive symptoms in patients.

The NL Program also reduces suicidal thoughts within the first year. This finding was found on the MADRS and the Calgary Depression Scale. It has been found that the first year of psychosis is a particular high-risk period for committing suicide (Addington et al., 2004b). Therefore, the NL Program, through its suicide prevention education, has been addressing suicidal issues. This study's results are similar to Addington et al. (2004b) and Verdoux et al. (2001) studies, which found a

reduction in suicidal attempts after patients were treated in Early Psychosis Programs that addressed suicide issues through preventive education.

It can be concluded that the NL early psychosis program has a significant treatment impact for first episode patients. The program reaches its goals of promoting recovery and preventing relapse in this (young) age group. Its case management, low-dose medication regimes, family intervention, psychotherapy, occupational therapy, substance and suicidal counseling has been found to prevent substance misuse and suicide; decrease depression; maintain medication adherence; improve social and vocational functioning and prevent relapse. The NL Program is on par with other early psychosis programs developed in Australia and Canada.

CHAPTER 6

CONCLUSION

6.1 Limitations to this Study

In conducting this study, there are several limitations that may have had an overall effect on the results found.

The first limitation was in the NL early psychosis database. In some cases, the patients were not assessed at all three-month intervals. This maybe due to any number of reasons, such as patients missing appointments. This presented a problem with sample size to assess the patients at 12, 24 and 36 months. Therefore, in order to increase sample size for the analysis, the mean of the assessment months before and after the entry points were used if there were no patient data entered at 12, 24 and 36 months. For example, if there was no entry for the 12-month interval, then the mean of 9 and 15-month entries were used. This may lead to biases of the results since there is no accurate patient measure for that particular point in time to conclude how the patient performed at the time interval.

The second limitation was in using the CCHS, since the survey was cross-sectional and did not provide longitudinal data of the population. Therefore, in order to compare the NL early psychosis patients with the CCHS at two points in time, two cohorts from the CCHS population had to be used. This may have lead to biases of

the results since only the NL Program database provided longitudinal data of its patients.

The third limitation of this study is that the CCHS is self-rated while the early psychosis program scales are professionally rated. Therefore, the responses given in the CCHS are subjectively reported and may not be properly diagnosed. This may lead to questions being interpreted differently by the person taking the survey compared to how the psychiatrist would have interpreted and answered the questions.

The fourth limitation is that while the questions between the survey and the early psychosis scales are matched as closely as possible, the wording and rating scales used are not always identical. This leads to some degree of discrepancy in interpreting the results since the wording for each questions are not written exactly.

The fifth limitation is that in order to perform propensity matching to calculate individual propensity scores and match as closely as possible between the two groups requires a large national population. Two major criteria to propensity match to the NL Program were that the CCHS population also had psychosis and was of the same age. Unfortunately, only 132 people in the CCHS had psychosis. Therefore, propensity matching could not be performed as described by Ascher-Svanum et al. (2003) and Shenyang et al. (2004) described in the literature review.

The sixth limitation is that there may be bias in the results due to multiple comparisons. It is known that the more comparisons made will increase the likelihood that one of the comparisons will come out statistically significant by random chance. However, since two methods were tested, the results did find

consistency of statistical significance on various variables across the methods to suggest that the significant results found were unlikely to occur by random chance.

6.2 Implications For Future Studies

This research tests a novel methodology on a unique population. The results found propensity match to be useful in evaluating early psychosis programs on clinical and social outcomes. Therefore, this method may serve as a model for future program evaluations in mental health research.

It would be interesting in future studies to perform propensity matching by matching early psychosis patients from one program to early psychosis patients from another program. For example, the NL Program could be compared to the NS Program. Propensity matching could be performed as by Ascher et al. (2003) whereby propensity scores could be calculated by matching on age, gender, marital status, living circumstances and area. Then the individuals with the closest propensity scores could be matched on several clinical and social outcomes. This would be a way to evaluate the NL Program to see if the patients do as well as patients in comparable programs elsewhere in the country or the world.

A future study may also look at the NL patients 3 or 4 years later to see if after completing the program, the patients continue to improve and converge towards the population on the same clinical and social outcomes. This would be a true test of the overall impact the NL Program is having on normalizing patient quality of life outcomes.

6.3 Overall Conclusion

This study evaluated the impact of the NL Program by using a traditional methodology and by testing a new methodology, propensity matching. The study found that both methodologies show improvement by patients on social and clinical outcomes within the first and second year, suggesting the NL Program is effectively helping its first episode patients improve and recover through its pharmacological and non-pharmacological interventions.

As well, the study indicates that propensity matching offers a new way to evaluate early psychosis programs whereby randomization into the program is not always ethical, and whereby pre-post methodology has limitations since it does not use a control group, and maturation of the patients maybe the cause of the pre-post changes seen. Propensity matching may be a reliable methodology to use when evaluating programs.

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APPENDICES

APPENDIX A

Early Psychosis Program
Waterford Hospital
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January 5, 2005

Dear Dr. Hogan:

I am doing my Masters in Community Health. My research focus is evaluating clinical and social outcomes of the Early Psychosis Program. I will be comparing the early psychosis patients to the general population using a new methodology called Propensity Matching.

To perform this study, I am requesting your formal consent to use the Early Psychosis administrative data files. The results will become part of my masters thesis. A copy will be provided to the Early Psychosis Program.

If you have any concerns or comments about this study, I can be reached by telephone at (709) 727-2844 or by _____ My supervisor, Dr. Rick Audas, can also be contacted by telephone at (709) 777-7395 or by email at raudas@mun.ca.

I look forward from hearing from you about my request.

Sincerely,

Vanessa Gibbons

HealthCare
Corporation of St. John's

APPENDIX B

Waterford Hospital
Early Psychosis Program

January 11, 2005

Vanessa Gibbons
Division of Community Medicine
MUN Medical School

Dear Ms. Gibbons:

I am writing in reply to your letter dated January 5, 2005 in which you requested access to the anonymous database for the Early Psychosis Program. I understand this will be used for your Masters thesis, which will look at aggregate data only.

I am pleased to grant you permission to use this database for the specified purpose.

The data guardian is Ms. Allison Edwards, Health Research Unit, in the Division of Community Medicine. Ms. Edwards will provide the files to you and will make you aware of all the security measures to ensure they are kept confidential.

Best of luck with your thesis.

Sincerely,

Kevin P. Hogan, MD, FRCPC

/lms
cc: Allison Edwards

APPENDIX C

GENERAL APPLICATION CHECKLIST

Memorial University Human Investigation Committee

One copy of the completed checklist must be attached to each copy of your application.

Please ensure all items are marked either X or NA

Short title of proposal: **Outcome Evaluation of an Early Psychosis Program Using Propensity Matching Scores**

[X] Latest copy of application form has been used. (***October 2003***)

[X] All questions have been answered **in the space provided on the form or in the number of lines allowed**

[X] One copy of the application is signed by applicant

[X] Copies of the budget are attached to ***each*** copy of the application

[X] Questionnaires, chart audit forms, covering letters are attached to each copy of the application. (If standard questionnaires such as the SF36 or EROTC are used, list titles where requested and ensure one copy for the primary reviewer is included in the full protocol.)

[X] One copy of a current curriculum vitae attached (principal investigator if first time applicant to HIC

[NA]One copy of full protocol with signature of local investigator, is attached (*if relevant*)

[X] **Secondary use of data/tissue**: One copy of data/tissue request form and one copy of letter of approval from data/tissue guardian is attached.

[NA]I have read "Guidelines for Preparation of a Standard Consent Form"

[NA] Consent document is attached (written consent using HIC template or script for verbal consent) to each copy of application

[NA]DNA/tissue consent included, if relevant.

[NA]Consent has been assessed at a reading level of _____ (**must be less than grade 9**).

[X] I have verified that the above information is correct.

Printed name of Principal Investigator: Vanessa Marie Elizabeth Gibbons

October 2003

HUMAN INVESTIGATION COMMITTEE
General Application Form

Please complete the application in **bold** or a font which can be easily distinguished from the application form. Applicants are advised to consult Application Guidelines

Forward one copy of the checklist, application, budget, consent form and any other documents (questionnaires, scripts, etc.) for screening to the Human Investigation Committee (HIC) Office, Room 1755/57, Health Sciences Centre, Phone: 777-6974. Twenty-four copies, submitted in sets, will be required by HIC when the application has been screened and allowed to proceed to review.

1. Investigators:

- **Principal Investigator:**

Gibbons	**Vanessa**	**Ms.**
Last Name	First Name	Title (Dr./ Mr./ Ms./ Mrs.)

(a) Faculty [ ]
(b) Employee of HCCSJ, NCTRF [ ]
(c) Undergraduate, graduate, postgraduate student [X]
(c) Other: [*please specify*] [ ]

- Mailing Address:

Internal: **Division of Community Health** _____

Department | Hospital

External: _____ | **P.O. Box 121** | **St. Vincent's**

Street Name & # | P.O. Box | City / Town

A0B 3C0

Postal Code

- Telephone Number: (709) 727-2844 OR (709) 525-2789
- Pager Number: _____
- Email Address

- Co-investigators: **Dr. Kevin Hogan, Dr. Kellie LeDrew**

- Local contact (name and contact information) if principal investigator is external:

- Supervisor: **Dr. Rick Audas**
  Telephone Number: **(709) 777-7395**
  Email: **raudas@mun.ca**

- Research Coordinator (if relevant):
  Telephone Number:
  Email:

2. Title of study

Please include protocol number and date (if relevant):

Outcome Evaluation of an Early Psychosis Program Using Propensity Matching Scores

3. Study timeline:

- Proposed start date *[at least 4 weeks from date of submission]:* **02/20/05**
- Anticipated completion date: **08/31/05**
- Deadline for ethics approval: **01/20/05**
  Indicate below if:
  [ ] course project

4. Setting of study and data sources:

- Setting – **Please specify the institutions and/or communities involved:**
  (i.e. HSC, Janeway, St. John's, etc)

Early Psychosis Program, HCCSJ

- Check relevant data sources:
  (a) Patients [ ]
  (b) Health Providers [ ]
  (c) Clinical Records [ ]
  (d) Pre-existing Dataset [X] *[Please give name of data holder with contact information]:*

Early Psychosis database and the Canadian Community Health Survey database:
Ms. Alison Edwards, Community Health, HSC, (709) 777-6218, aedwards@mun.ca

  (e) Residents in Community [ ]
  (f) Archived Specimens [ ]
  (g) Other [*please specify*]

If using data previously collected for another purpose (secondary use of data) copies of the letter requesting information which describes the information sought and of the letter from the data guardian approving access must be attached. See Application Guidelines.

5. Objectives:

Provide a numbered list of the **main** research objectives of the study in plain language *[no more than 15 lines]*

1. **To evaluate the impact of the NL Early Psychosis Program for patients, their families and the community on a number of clinical and social outcomes.**
2. **To use a new methodology, propensity matching scores, to match psychosis patients with the general population on demographic variables to eliminate baseline differences since randomization into the program is not feasible.**
3. **To use a national database, the Canadian Community Health Survey, as the general population for comparison with the early psychosis program patients.**
4. **To determine how the patients differ from the general population at entry level into the program on variables, such as employment and hospitalizations.**
5. **To determine if the patients at the end of the three year program converge back to the population mean on the same variables.**
6. **To compare and contrast this new methodology with the traditional methodology, which evaluates the patients before and after in a program to determine the treatment effect of early psychosis programs.**

6. Introduction to the study:

- What previous work has been done in this area? Summarize previous human studies *[no more than 20 lines]*

Psychosis is a medical condition that affects the brain. 3% of all Canadians will experience a psychotic episode in their lifetime. It usually occurs in late adolescence – early adulthood. Symptoms of early psychosis include hallucinations, delusions, bizarre behaviours and mood changes. Research has found that psychosis is a treatable medical condition, but recovery varies from person to person.

Several studies have shown that delays in treatment and prolonged duration of psychosis is correlated with poorer clinical outcomes and major health care costs, such as increased hospitializations. Therefore, detecting psychosis at the earliest possible time can reduce symptoms and promote recovery, thereby providing long-term benefits for patients and their families.

Early Psychosis Programs have been developed to reduce delays and improve outcomes. These programs are designed to provide structured treatment up to three years. McGorry et al. (2003) in Australia and Addington et al. (2004) in Canada have evaluated their programs and have found that these programs do reduce delays and hospitalizations, provide patient and family counselling and can help lower medication dosage. Thus, these programs have clinical and economic benefits. Their studies evaluated the programs, by looking at patients before and after in the program to determine the treatment effect. They assumed any differences were a result of the program.

- What is the rationale for this study, i.e., why are you doing this study?
  1. **This is the first time the NL Early Psychosis Program will be evaluated.**
  2. **Early Psychosis Programs are difficult to evaluate since randomization into these programs are not feasible. RCTs are unethical.**
  3. **Trying to compare early psychosis patients to a control group is also difficult since there are baseline differences.**
  4. **Most studies, therefore, that have evaluated these programs use a pre-post methodology, evaluating patients before and after into a program to determine a treatment effect.**
  5. **However this is a methodological flaw. There are no control groups used and they assume any changes from before and after are due to the treatment from the program. However, since this is a young group, treatment effects may be due to natural events (eg. growing older).**
  6. **Therefore, in evaluations whereby randomization and comparing to a control group is difficult, a new methodology, propensity matching, can be used.**
  7. **Propensity Matching allows matching of a unique group to a control group on similar variables to eliminate baseline characteristic differences.**
  8. **Propensity matching is based on a critical assumption that assumes among individuals who are matched on the same characteristics, these individuals can then be sorted into treatments as if randomly assigned.**
  9. **Therefore, with no baseline differences, the groups can then be compared on several clinical and social outcomes, such as employment, substance use and hospitalizations, to evaluate if the program has helped patients improve.**
  10. **This is the first time an Early Psychosis Program will be evaluated using Propensity Matching.**

- Why is this research important? What contributions could it make?
  This research will test a new methodology on a unique population, whereby randomziation and comparing to the general population has been difficult with traditional evaluation methods. The results will then be compared to traditional evaluation results. If this methodology does prove to be more useful in evaluating unique population programs, then this method may serve as a model for future program evaluations in mental health research.

7. **Blood or other tissue sampling which is part of the study:** **Not Applicable [X]**

- List samples to be taken from participants, the frequency of sampling and the amount of sample.

- Will any samples be kept after the completion of this study? Yes [ ] No [ ]

  [If yes, you must include "Storage of Tissue" in the consent form]

- Can participants withdraw their blood, tissue or other sample? Yes [ ] No [ ]
  [If yes, please describe the process of withdrawal]

- Will any samples now archived by a health care institution be used in the study?

Yes [ ] No [ ]

[If yes, attach copies of the letter requesting access and of the letter approving access signed by the data guardian; see Application Guidelines]

8. **Research interventions and/or modes of data collection:**

- List any interventions which would not be part of a participant's daily life.

- List questionnaires, information sheets, covering letters, telephone or face to face interview scripts/outlines or chart audit forms to be used. Include copies of each with each copy of the application; if standard questionnaires are being used – SF36, EROTC, etc. *[see list on HIC website]* include one copy only.

9. **Description of study:**

Give a brief description of the study, including interventions and outcome measures in plain language *[no more than 20 lines]*. Describe briefly what the patient will be asked to do. Attach one copy of the protocol if relevant.

This study will evaluate the impact of the NL Early Psychosis Program. The study will first compare patients with the general population who have psychosis, and then secondly, compare to the entire population at the same age. The Psychosis program has 145 patients. The two sets of controls will be taken from 30,000 people in the Canadian Community Health Survey. Matching will be done by Propensity Matching Scores to remove baseline differences. The variables to use are age, gender, geography and medical history. Matching will be done by matching early psychosis questions on these variables with the most similar questions used in the survey database. Using SPSS on these selected variables, a propensity score will be calculated for each individual. An early psychosis patient is then randomly selected and matched with a control with the closest propensity score. Both individuals are then removed from further matching, and a new patient is selected until they are all matched. Using SPSS, they will then be compared on outcome variables. First, they are compared, to see if the patients differ from the population at entry, and then are compared at the end of the program, to see if the patients converge towards the population. The outcome variables to use are education, employment, substance use, depression, social support, hospitalizations, and suicide. Again, the questions from both databases are matched as closely as possible. Logistic regression and t-tests will be conducted on the data. The results will then be compared to traditional methodological results to see which method shows a greater program treatment effect.

10. Sample size: *[if measuring statistical differences/equivalencies]*

Give the basis – power, alpha, difference to be detected, etc., for the choice of sample size.

There will be no calculation of sample size for the proposed study. The Early Psychosis database has 145 patients. Therefore, 145 people with a potential diagnosis of psychosis out of 30,000 from the Canadian Community Health Survey, will be used as an abnormal

control group to match the 145 early psychosis patients. The early psychosis patients will also be matched by age to a normal control group from the Canadian Community Health Survey. All matching will be done by propensity matching.

11. Participants:

- Describe the participants to be contacted or whose record information will be used.

(a) Adults [**X**] (b) Children under 19 [**X**]
(c) Persons incompetent to give consent [ ] (d) Protected or vulnerable populations [ ]

If including children, incompetent adults or persons in protected or vulnerable populations, please justify their inclusion in the research study.

- Number of participants at this site:

145 patients from Early Psychosis Program.
145 people from the Canadian Community Health Survey out of 30, 000 who have a potential diagnosis of psychosis will be matched to the early psychosis patients.
145 people from the Canadian Community Health Survey out of 30,000 who do not have psychosis, but are of the same age group, will be matched to the early psychosis patients.

- Will pregnant women be excluded? Yes [ ] No [**X**]
- Is this a part of a national/international study? Yes [ ] No [**X**]
  - If yes, what is the total number of participants at all sites.
  - If yes, where is the main study site?

- Will contact be made with potential participants? Yes [ ] No [**X**] records only
[Please specify the means of contact – letter, telephone, advertisement, etc.]

- If yes, who will make the first contact to provide information about the study?

(a) Attending physician [ ] (b) Investigator [ ] *[See guidelines]*
(c) Other: *[Please specify]*

12. Consent process:

- Who will obtain the consent?

Consent for the creation and use of the Early Psychosis database for the purpose of research evaluations has already been approved by HIC. See reference file # 03.218.
For use of the Early Psychosis database for this study, consent has been obtained from Dr. Kevin Hogan, Early Psychosis Program. See attached letter.
The Canadian Community Health Survey database is a freely available public data file for students to use.

- Explain the procedure you will use to obtain consent

[If including children, incompetent adults, or persons in protected or vulnerable populations, describe in detail how parental or proxy consent will be obtained. See Application Guidelines]

13. Risks, discomforts and inconveniences: No.

- What risks, discomforts or inconveniences are involved? [*See guidelines*]

14. Benefits:

- Are there any immediate benefits for participants, including controls?
  No.

15. Privacy and confidentiality:

- What steps will be taken to protect privacy and confidentiality of information?

(a) Oath of confidentiality [**X**]
(b) Locked storage [**X**]
(c) Limited access [**X**] *[Please specify method of limiting access]*
(d) Password-protected computer files [**X**]
(e) Denominalized files provided by data holder to investigator [**X**]
(f) Coded study number [**X**]
(g) Locked room [**X**]
(h) Anonymous responses to investigator [ ]

- **All Early Psychosis Program original data is stored in a locked room at the Waterford Hospital. The original files cannot be accessed without permission given by the Early Psychosis Program Co-ordinators, Dr. Kevin Hogan and Dr. Kellie LeDrew. The Computer files of the patients are password protected and stored in the Health Research Unit. The data guardian is Ms. Alison Edwards. The Principal Investigator will use these computer files throughout the analysis, which will be password protected on a personal computer and accessible only by the principal investigator, Dr. Rick Audas, Dr. Kevin Hogan, Dr. Kellie LeDrew and Ms. Alison Edwards.**
- List below the names of **all** personnel who can access the identities of study participants

1. **Vanessa Gibbons**
2. **Dr. Rick Audas**
3. **Dr. Kevin Hogan**
4. **Dr. Kellie LeDrew**
5. **Ms. Alison Edwards**

16. Debriefing:

Explain the process, if any, for feedback to the research community, participants, agencies, communities. [*See guidelines*]
The results of this analysis will be part of a Masters Thesis in Community Health. The Program Co-ordinators will be sent a summary report of the findings. Publication(s) and presentation(s) of the results are intended.

17. Payments: **Not Applicable [X]**

- Do you intend to reimburse participants for expenses incurred?
  Yes [ ] No [ ] Amount [$]

18. Budget: **Not Applicable [ ]**

Please attach a copy of the budget to each application including the source of funding

- Source of funding: **Principal Investigator is funded jointly by the Early Psychosis Program and Faculty of Medicine**
-
- Will the budget be administered through the University Finance Office? Yes [X] No [ ]
  If no, please specify the person or agency responsible:

19. Potential conflict of interest:

- Is any investigator a shareholder in any company/agency funding this study? Yes [ ] No [X]
- Will any investigator receive direct financial or other benefit? Yes [ ] No [X]
  If yes, please describe:
- Will any investigator receive indirect financial or other benefit? Yes [ ] No [X]
  [share of profits, future royalties, patent rights, et al]
  If yes, please describe:

20. Ownership, storage and destruction of data:

- **The investigator must be free to publish within 6 months after submitting the manuscript to the sponsor for review. Publication of the full study must be assumed no longer than 1 year after the completion of the study. In agreement with the Office of Research, HIC will assume these terms will be negotiated in any research contract.**

- Do you intend to destroy the data collected at the end of the study? Yes [ ] No [**X**]

  If no:

  (a) Please give the anticipated date of destruction: **08/31/12**

  (b) In what form will the data be retained, e.g., frozen samples, computer tapes, paper? **The data from this study will be stored on computer files that will have password protected access.**

  (c) Where will the data be stored? **The data files complied in this study will be stored in the Health Research Unit within the Division of Community Health, Faculty of Medicine.**

  (d) Who will be the data guardian?
  Name: **Ms. Alison Edwards**
  Contact information: **Health Research Unit, HSC, (709) 777-6218**

- Will any form of identifier – name, postal code, **study code**, be retained? Yes [**X**] No [ ]

- If yes, please describe the identifiers to be retained and give the rationale for their retention.
  Numerical identifiers that are associated with individual information will be retained. These identifiers will be used to allow for internal linkages only.

21. Concurrent submissions or approvals:

Has this proposal been submitted to another REB? If already approved, please include one copy of approval.
No.

Reminders:

* *The use of personnel and/or resources of the Health Care Corporation of St. John's requires the approval of the **Research Proposal Approval Committee** (St. John's) subsequent to HIC approval. Such approvals may also be required by institutions outside the HCCSJ and/or by regional health boards.*

* Forward one copy of the checklist, application, budget, consent form and any other documents (questionnaires, scripts, etc.) for screening to the Human Investigation Committee (HIC) Office, Room 1755, Health Sciences Centre, Phone: 777-6974 / 7719
Twenty-four copies, submitted in sets, will be required by HIC when the application has been screened and allowed to proceed to review

Signature of principal investigator

Date January 12th, 2005

Signature of undergraduate/graduate/postgraduate student *(if applicable)*:

Signature of supervisor:

Memorial
University of Newfoundland

APPENDIX D

Human Investigation Committee
Research and Graduate Studies
Faculty of Medicine
The Health Sciences Centre

January 25, 2005

Reference #05.13

Ms. Vanessa Gibbons
Division of Community Health
Health Science Centre

Dear Ms. Gibbons:

Your application entitled "**Outcome Evaluation of an Early Psychosis Program using Propensity Matching Scores**" was reviewed by a Sub-Committee of the Human Investigation Committee and **full approval** was granted.

This will be reported to the full Human Investigation Committee, for their information, at the meeting scheduled for **February 3, 2005**.

Full approval has been granted for one year. You will be contacted for annual update before **January 17, 2006**.

For a hospital-based study, it is **your responsibility to seek the necessary approval from the Health Care Corporation of St. John's and/or other hospital boards as appropriate**.

This Research Ethics Board (the HIC) has reviewed and approved the application for the study which is to be conducted by you as the qualified investigator named above at the specified study site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Human Investigation Committee currently operates according to the Tri-Council Policy Statement and applicable laws and regulations.

Notwithstanding the approval of the HIC, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you success with your study.

Sincerely,

John D. Harnett, MD, FRCPC
Co-Chair
Human Investigation Committee

Richard S. Neuman, PhD
Co-Chair
Human Investigation Committee

JDH;RSN\jd

c Dr. C. Loomis, Vice-President (Research), MUN
Mr. W. Miller, Director of Planning & Research, HCCSJ

APPENDIX E

RESOURCE ALLOCATION REQUEST FOR HUMAN INVESTIGATION PROPOSALS INVOLVING THE HEALTH CARE CORPORATION OF ST. JOHN'S

To complete this application you will need:

1. A copy of your spending budget (if applicable)
2. A copy of any applicable Departmental Agreements

HIC Reference Number: 05.13

Title: "Outcome Evaluation of an Early Psychosis Program using Propensity Matching Scores"

For the information of the members of the Research Proposal Approval Committee please set out in a short paragraph an explanation of the study you intend to perform.

1. To evaluate the impact of the NL Early Psychosis Program for patients, their families and the community on a number of clinical and social outcomes.
2. To use a new methodology, propensity matching scores, to match psychosis patients with the general population on demographic variables to eliminate baseline differences since randomization into the program is not feasible.
3. To use a national database, the Canadian Community Health Survey, as the general population for comparison with the early psychosis program patients.
4. To determine how the patients differ from the general population at entry level into the program on variables, such as employment and hospitalizations.
5. To determine if the patients at the end of the three year program converge back to the population mean on the same variables.
6. To compare and contrast this new methodology with the traditional methodology, which evaluates the patients before and after in a program to determine the treatment effect of early psychosis programs.

1. Does this proposal involve the use of medication (including placebos) other than those normally used for patients? YES ( ) NO (X)

(A) If yes, Please specify

(B) Will medications (Active or Placebo) be dispensed by the Hospital Pharmacy? YES ( ) NO (X)

(C) Who will be responsible for the cost of any medications? N/A

(D) What will be the cost to the Hospital Pharmacy (Total or per subject)? N/A

2. Does the proposal involve laboratory tests, x-rays or other imaging techniques other than required for normal patient care?
YES ( ) NO (X)
(If yes, please attach a copy of your Departmental Agreement)

(A) Please attach a copy of your spending budget. N/A

(B) Estimate cost (Total or per subject) N/A

(C) Who will be responsible for the cost of these tests? N/A

3 Does the proposal require assistance of nurses or other hospital staff?
YES ( ) NO (X)

(A) If yes, please describe

(B) How much time (per subject or total N/A

4. Does the proposal involve admission of subjects to the hospital or the clinical investigation unit?
YES ( ) NO (X)
Please describe I am using participants already admitted to the Early Psychosis Program

5 Is this proposal being formally sponsored by any agency, pharmaceutical company, etc?
YES ( ) NO (X)

Are they responsible for any costs associated with the study? YES ( ) NO (X)

The approval of this proposal is contingent upon the researcher providing regularly or upon request an update/on the progress of the research.

SIGNED: [signature] Principal Investigator

[signature] Date

[signature] Clinical Chief/Director of Program

[signature] Supervisor

All signatures are required prior to review & approval by The Research Proposal Approval Committee (a sub-committee of MAC Health Care Corporation of St. John's).

HealthCare
Corporation of St. John's

APPENDIX F

March 11, 2005

Ms. V. Gibbons
Grad Student, Community Medicine
C/o Dr. R. Audas
Faculty of Medicine
Memorial University of Newfoundland

Dear Ms. Gibbons:

Your research proposal *"HIC # 05.013 Outcome evaluation of an early Psychosis Program using Propensity Matching Scores"* was reviewed by the Research Proposals Approvals Committee (RPAC) of the Health Care Corporation of St. John's at its meeting on March 10, 2005 and we are pleased to inform you that the proposal has been approved.

This approval is based on the understanding that it has the necessary funding and that it is being conducted as outlined in the approved research proposal. Additionally, the Committee requires a progress report to be submitted annually and upon completion of the project, the committee would appreciate receiving copies of any published articles, abstracts or conference presentations. This information would be used to facilitate knowledge dissemination within the Health Care Corporation of St. John's.

If you have any questions or comments, please contact Lynn Purchase, Manager of the Patient Research Centre at 777-7283.

Sincerely,

Mr. Wayne Miller
Director, Planning and Research
Chair, RPAC

cc: Ms. Lynn Purchase, Manager, Patient Research Centre
Dr. R. Audas, Faculty of Medicine, MUN

APPENDIX G

MATCHED QUESTIONS BETWEEN CCHS & EPP

CCHS QUESTION	EPP QUESTION	MATCHED QUESTION
(SCRB_082) In general, would you say your mental health is: (1) Excellent (2) Very Good (3) Good (4) Fair (5) Poor (6) Not stated	CGI Scale: Severity of Illness: (0) Not assessed (1) Normal not ill at all (2) Borderline mentally ill (3) Mildly (4) Moderately Ill (5) Markedly Ill (6) Severely Ill (7) Among the most extremely ill patients	Mental Health Status: 0= Not stated (EPP(0) not assessed) 1= Excellent (EPP(1) normal not ill at all) 2= Very Good (EPP(2) borderline mentally ill) 3= Good (EPP(3) mildly ill) 4=Fair (EPP(4) moderately ill) 5=Poor (EPP markedly ill(5), severely ill (6) and among the most extreme ill patient(7))
(DISB_10e) In the last month, did you feel restless or fidgety? (1) All of the time (2) Most of the time (3) Some of the time (4) Little of the time (5) None of the time	BAS: Distress Related to Restlessness: (0) No distress (1) Mild (2) Moderate (3) Severe	Distress Related to Restlessness: 0= No distress (CCHS (5)none of the time) 1= Mild (CCHS (4)little of the time) 2= Moderate (CCHS (3) some of the time) 3= Severe (CCHS all of the time(1) and most of the time (2))
(DISB_10f)In the last month, you felt so restless you could not sit still? (1) All of the time (2) Most of the time (3) Some of the time (4) Little of the time (5) None of the time	ESRS: Restless, nervous, unable to keep still: (1) Absent (2) Mild (3) Moderate (4) Severe	Restlessness: 1=Absent (CCHS 5) 2=Mild (CCHS 4) 3=Moderate (CCHS 3) 4=Severe (CCHS 1 & 2)
(DEPB_21) People with episodes of being depressed often have other problems at the same time. These include things like feelings of self-worth, and changes in sleep, appetite energy and ability to concentrate	Calgary Depression Scale For Schizophrenia: Total Depression Scale score (0) Absent (1) Mild (2) Moderate (3) Severe	Depressive Symptoms: 1=Yes (EPP 1,2 & 3) 2=No (EPP 0)

and remember. Did you have problems like this during one of your episodes of being depressed? (1) Yes (2) No (6) Not Applicable (9) Not Stated		
(DEPB_26g) During two weeks, did you have a lot more trouble than usual either falling asleep or waking up too early nearly every night? (1) Yes (2) No (6) Not Applicable (9) Not Stated	MADRS: Reduced Sleep (0) Sleep as usual (2) Slight difficulty with sleep (3) Sleep reduced (6) Less than 2 or 3 hours sleep	Reduced Sleep: 1=Yes (EPP 1,2,3,4,5,6) 2=No (EPP 0)
(DEPB_26r) During two weeks, did you have a lot more trouble concentrating than is normal for you? (1) Yes (2) No (6) Not Applicable (9) Not Stated	MADRS: Concentration Difficulties: (0) No difficulty in concentrating (2) Occasional difficulties (4) Difficulties in concentrating which reduces ability to read or hold a conversation (6) Unable to read or converse without difficulty	Concentration difficulties: 1=Yes (EPP 1,2,3,4,5,6) 2=No (EPP 0)
(DEPB_26v) During two weeks, did you feel totally worthless? (1) Yes (2) No (6) Not Applicable (9) Not Stated	MADRS: Pessimistic Thoughts (0) No pessimistic Thoughts (2)Fluctuating ideas of failure, self-reproach or self depreciation (4)Persistent self-accusations (6)Delusions of ruin, remorse or unredeemable sin	Pessimistic Thoughts 1=Yes (EPP 1,2,3,4,5,6) 2=No (EPP 0)
(DEPB_a) Think of the period of two weeks or longer when your feelings	Calgary Depression Scale: Suicidal Thoughts (0) Absent	Suicidal Thoughts: 1=Yes (EPP 1,2,3) 2=No (EPP 0)

of being depressed and other problems were most severe and frequent. During that time, did you seriously thought about committing suicide or taking your own life? (1) Yes (2) No (6) Not Applicable (9) Not Stated	(1) Mild (2) Moderate (3) Severe	
(DEPB_28a) Two weeks or longer, how often were you unable to carry out your daily activities because of your feelings of being depressed? (1) Often (2) Sometimes (3) Rarely (4) Never (9) Not stated	MADRS: Lassitude (0) Hardly any difficulty in starting (2) Difficulty in starting activities (4)Difficulty in starting simple routine tasks (6)Complete lassitude, needs assistance	Lassitude: 1=None (EPP 0) 2= Rarely (EPP 2) 3= Sometimes (EPP 4) 4=Often (EPP 6)
(DEPBFSLA) Did you ever attempt suicide in your lifetime? (1) Yes (2) No (6) Not Applicable (9) Not Stated	Calgary Depression Scale Suicide Attempt: (0) Absent (1) Mild (2) Moderate (3) Severe	Suicide Attempt: 1=Yes (EPP 1,2,3) 2=No (EPP 0)
(MIAB_06) A period of several days when you were very irritable or grouchy? (1) Yes (2) No (6) Not Applicable (9) Not Stated	YMRS: Irritability (0) Absent (1) Subjectively increased (2) Irritable during interview (3) Hostile and uncooperative	Irritability: 1=Yes (EPP 1,2,3,4) 2=No (EPP 0)
(MIAB_07j) During the episode, did you sleep far less than usual and still not get tired or sleepy?	MADRS: Reduced Sleep (0)Sleep as usual (2)Slight difficulty with sleep (4)Sleep reduced (6) Less than 2 or 3 hours sleep	Sleep: 1=Yes (EPP 1,2,3,4,5,6) 2=No (EPP 0)

(ALCB_1) During the last 12 months, did you drink alcohol? (1) Yes (2) No (6) Not Applicable (9) Not Stated	Case Manager Scale for Substance Use Disorder: Alcohol (0) None (1) Mild (2) Moderate (3) Severe (4) Extremely Severe	Alcohol Use: 1=Yes (EPP 1,2,3,4) 2=No (EPP 0)
(ALDB_14) During the past 12 months, did you ever drink alcohol when you knew you had a serious physical or emotional problem that could have been made worse by your alcohol use? (1) Yes (2) No (6) Not Applicable (9) Not Stated	Case Manager Scale for Substance Use Disorder: Alcohol (0) None (1) Mild (2) Moderate (3) Severe (4) Extremely Severe	Continued to drink alcohol despite health problem: 1=Yes (EPP 1,2,3,4) 2=No (EPP 0)
(IDGB_02) Have you used Marijuana, cannabis or hashish in the last 12 months? (1) Yes (2) No (6) Not Applicable (9) Not Stated	Case Manager Scale for Substance Use Disorder: Cannabinoids (0) None (1) Mild (2) Moderate (3) Severe (4) Extremely Severe	Cannabinoids Use 1=Yes (EPP 1,2,3,4) 2=No (EPP 0)
(IDGB_05) Have you used cocaine or crack in the last 12 months? (1) Yes (2) No (6) Not Applicable (9) Not Stated	Case Manager Scale for Substance Use Disorder: Cocaine (0) None (1) Mild (2) Moderate (3) Severe (4) Extremely Severe	Cocaine Use 1=Yes (EPP 1,2,3,4) 2=No (EPP 0)
(IDGB_14) Have you used hallucinogens in the last 12 months? (1) Yes (2) No (6) Not Applicable (9) Not Stated	Case Manager Scale for Substance Use Disorder: Hallucinogens (0) None (1) Mild (2) Moderate (3) Severe (4) Extremely Severe	Hallucinogens Use 1=Yes (EPP 1,2,3,4) 2=No (EPP 0)
(RACB_7a) Because of your mental condition or	Quality of Life Scale: Friends	Friends: 1=Yes (EPP 0,1,2,3,4)

health problem, do you have any difficulty in making friends or maintaining friendships: (1) Yes (2) No (6) Not Applicable (9) Not Stated	Rate 0-6	2=No (EPP 5,6)
(RACBDPAL) Do you have difficulty in participating in activities? (1) Sometimes (2) Often (3) Never (9) Not stated	Quality of Life Scale: Activities Rate 0-6	Activities: 1=Often (EPP 0,1) 2=Sometimes (EPP 2,3,4) 3=Never (EPP 5,6)
(RACBF7) Do you have difficulty in social situations? (1) Yes (2) No (6) Not Applicable (9) Not Stated	PANSS: Passive/Apathetic Social Withdrawal (0) Absent (1) Minimal (2) Mild (3) Moderate (4) Moderately Severe (5) Severe (6) Extreme	Passive/Apathetic Social Withdrawal: 1=Yes (EPP 2,3,4,5,6,7) 2=No (EPP 1)
(SSMB_07) Someone to have a goodtime with? (1) None of the time (2) Little time (3) Some of the time (4) Most of the time (5) All of the time (9) Not stated	Quality of Life Scale: Interaction Rate 0-6	Interaction: 0=None of the time (EPP 0) 1=Little time (EPP1) 2=Some of the time (EPP2,3) 3= Most of the time (EPP4,5) 4=All of the time (EPP 6)
(SSMB_03) Some one to count on to listen to you when you need to talk? (1) None of the time (2) Little time (3) Some of the time (4) Most of the time (5) All of the time (9) Not stated	Quality of Life Scale: Social Network Rate 0-6	Social Network: 0=None of the time (EPP 0) 1=Little time (EPP1) 2=Some of the time (EPP2,3) 3= Most of the time (EPP4,5) 4=All of the time (EPP 6)
(SSMB_18) Someone to do something enjoyable with? (1) None of the time (2) Little time (3) Some of the time	Quality of Life Scale: Social Activity Rate 0-6	Social Activity: 0=None of the time (EPP 0) 1=Little time (EPP1) 2=Some of the time (EPP2,3)

(4) Most of the time (5) All of the time (9) Not stated		3= Most of the time (EPP4,5) 4=All of the time (EPP 6)
(SDCB_8) Are you currently attending school/college/university? (1) Yes (2) No (6) Not Applicable (9) Not stated	Attending School: (1) Yes (2) No	School: 1=Yes (EPP 1) 2=No (EPP 2)
(LBFBJST) Job status over the last 12 months? (1) Job all past year (2) Without a job but looking (3) Without job	Employment: (1) Yes (2) No	Employment: 1=Yes (CCHS 1) 2=No (CCHS 2, 3)
(SERBG_08) Were you ever hospitalized for mental health/alcohol/drugs in the last 12 months? (1) Yes (2) No (6) Not Applicable (9) Not stated	Hospitalization: (1) Yes (2) No	Hospitalization: 1=Yes (EPP 1) 2=No (EPP 2)