A Pilot Study Comparing the Effectiveness and Durability of Two Therapeutic Models of Cognitive Remediation in Psychosis-Spectrum Disorders

by

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This thesis is dedicated to all the hard-working participants of this study. Being able to work with many of you has been a truly rewarding and inspiring experience.
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II. Abstract

Schizophrenia is known for its multitude of symptoms that impair every-day functioning, such as interpersonal relationships or vocational life. Symptoms and features include positive (hallucinations, delusions, etc.), negative (anhedonia, alogia, etc.), and cognitive (poor memory/concentration, etc.). Cognitive features manifest independently of the clinical impairments presented by positive and negative symptoms, while also not being well treated by antipsychotic medications. Alternative treatment methods for schizophrenia that specifically target cognitive deficits are needed. Cognitive remediation (CR) is a growing field in schizophrenia. However, the effectiveness and durability of CR still requires further research. Prior research shows the effectiveness of two therapeutic models: a computerized drill-and-practice approach and practice strategy-based compensatory cognitive training group. The present study aims to compare the effectiveness and analyze the durability of these two therapeutic models. It was hypothesized that participants in both conditions will demonstrate improvements in cognitive features in comparison to the control group; however, participants in the CCT condition will show larger improvements in functional outcome compared the PSSCogRehab condition. Furthermore, assessing the durability of CR at RVS will demonstrate significant results for each CR condition compared to control group. Participants were recruited from River Valley Services in Middletown, CT and randomly assigned to either one of two CR groups or treatment as usual (control). Effectiveness of the CR approaches was assessed by multimodal evaluation of symptoms and functioning, collected at baseline, immediately after the intervention, and after 3-months. The results demonstrate
mostly non-significant differences between the treatment and control; however, effect sizes are demonstrating promising improvements amongst the treatment groups compared to the control. Furthermore, the study is currently not indicating strong durable effects.
III. Introduction

Schizophrenia is a chronic psychosis-spectrum disorder that affects the way a person thinks, feels, and behaves. The disorder is characterized by symptoms such as hallucinations, delusions, disorganized thoughts, and cognitive impairments (APA, 2013). Symptoms of schizophrenia are persistent and can cause a great deal of dysfunction. Therefore, living with the disorder can be especially challenging. The disorder effects about 1% of the population (McGrath et al., 2004; Saha, Chant, Welham, & McGrath, 2005) and occurs throughout all cultures and groups of people including, gender, race/ethnicity, socioeconomic status, etc. (Messias, Chen, & Eaton, 2007). However, the incidences rates around the world and within groups vary. The prevalence in men and women is about equal; however, the age of onset differs. Men tend to have a younger age of onset, 15-25, while onset in women is typically around 25-35 (Messias et al., 2007; Patel, Cherian, Gohil, & Atkinson, 2014).

Furthermore, the mortality rates amongst schizophrenia is one of the highest in comparison to other psychiatric illnesses and the general population. People with schizophrenia have a two-threefold increased risk of dying compared to the general population (Gatov, Rosella, Chiu, & Kurdyak, 2017; McGrath et al., 2004). Through the mortality rate, it is clear that the intensity of the disorder can have severe consequences. The large difference in the longevity between people with schizophrenia and the general population suggests that people with schizophrenia have poor access to health care and treatment. Therefore, much of the research investigating this disorder aims to better characterize the disorder in order to develop new and/or existing, treatment methods.
Symptoms

The symptoms of schizophrenia fall into either one of four categories, positive, negative, disorganized, and cognitive (APA, 2013); each of which present a variety of manifestations that impair day-to-day functioning. Symptoms are seen in all four categories, and the severity can vary.

Positive Symptoms

Positive symptoms are the most recognizable because these symptoms refer to abnormal behaviors not usually seen in a healthy individual (APA, 2013; Patel et al., 2014). Common positive symptoms include hallucinations and delusions.

Hallucinations

Hallucinations are seemingly realistic perceptions of auditory, visual, gustatory, or tactile experiences that occur in the absence of an actual stimuli (Brown, 2017; Comer, 2016). The most common in schizophrenia are hearing voices or seeing objects that do not exist.

Delusions

Delusions refer to false beliefs that are continuously held despite contradiction and when proven to be inaccurate (Brown, 2017; Comer, 2016). There are various types of delusions that may surface in schizophrenia. Delusions of persecution are when a person believes they are being plotted or discriminated against. Similarly, delusions of paranoia refer to constant anticipation of catastrophes or thinking others to be sick or dying (Comer, 2016). Delusions of grandeur refer to people believing themselves to be inventors, religious saviors, or empowered in specials ways that others are not, such as being able to read people’s minds. On a similar note, delusions
of control cause people to believe their feeling, thoughts, or actions are being controlled by another (Comer, 2016). In addition, delusions of reference refer to a person attaching special meaning to people or objects in abnormal ways. Lastly, somatic delusions cause someone to have false beliefs about their body, such that they believe they are injured or sick when, in reality, they are not (Comer, 2016).

**Negative Symptoms**

Negative symptoms are characterized by the absence of emotions or behaviors that healthy people possess (APA, 2013; Patel et al., 2014). The most common types are diminished emotional expression (also known as restricted affect) and avolition. Avolition is the inability to pursue routine activities or goal-directed behaviors due to decreased energy or motivation (Brown, 2017; Comer, 2016; Patel et al., 2014). Other negative symptoms include alogia (poverty of speech) and anhedonia (the inability to feel or experience pleasure). Another common negative symptom is asociality or social withdrawal; people who experience this will have difficulty creating and maintaining social relationships (Brown, 2017; Comer, 2016). These symptoms are somewhat harder to diagnose than positive symptoms because they are the absence, rather than presence, of a behavior.

**Disorganized Symptoms**

Formal thought disorder is also common in psychosis-spectrum disorders, including schizophrenia. It is the disturbance or disruption in the production or organization of thoughts and speech (APA, 2013; Brown, 2017; Comer, 2016). Examples of formal thought disorder include, the inability to formulate and conceptualize coherent thoughts or ideas and constantly switching from one idea to
the next when speaking (Comer, 2016). These deficits severely impact a person’s ability to hold conversations and understand certain complexities of language and thought, such as complex syntax or abstract ideas.

**Cognitive Features**

In addition to the clinical symptoms of schizophrenia, about 70% of people diagnosed suffer from cognitive impairments caused by the disorder, which interfere with how the individual thinks and processes information (Walker, Kestler, Bollini, & Hochman, 2004). These types of symptoms are enduring and persistent and can severely impair functioning. The different types of cognitive deficits can be categorized into neurocognitive and social cognitive deficits (Chattopadhyay, 2012) which have their own symptoms and effects.

**Neurocognition**

Neurocognition refers to the process of cognition involving distinct brain areas and particular neural circuits that enable processes such as executive functioning, working memory, attention, and learning and memory (Chattopadhyay, 2012). Schizophrenia can cause significant impairment in an individual’s ability to carry out these neurocognitive processes (Chattopadhyay, 2012; Lepage, Bodnar, & Bowie, 2014) and deficits extend to IQ measures of overall cognitive abilities (Kurtz, 2016).

**Executive Functioning:**

Executive functioning refers to the ability to use complex cognitive processes to achieve a certain goal and have voluntary control over behavioral processes (Kurtz, 2016; Orellana & Slachevsky, 2013). These processes include planning, problem
solving, or modifying behavior. People with schizophrenia have trouble formulating ideas and actions that will help them accomplish goals and control behaviors (Kurtz, 2016). They have difficulty using cognitive processes to carry out goal-directed behaviors (Chattopadhyay, 2012), self-regulatory functioning, and make decisions (Orellana & Slachevsky, 2013).

Working Memory:
Working memory refers to the ability to retain information about recent stimuli and use the information stored to reach a predetermined goal through repeated processing and analyzing of information. This process is important for acquiring and utilizing information; for example, being able to memorize information for a short time in order to carry out another cognitive process, such as reciting a learned phone number. People with schizophrenia show impairments in working memory (Chattopadhyay, 2012; Dickinson, Iannone, Wilk, & Gold, 2004). They tend to have spatial memory deficits that impair their ability to record information about their environment and spatial orientation (Chattopadhyay, 2012).

Attention:
Attention refers to the ability to direct one’s focus onto a particular stimulus while simultaneously omitting other stimuli that is happening concurrently. People with schizophrenia are unable to selectively focus on one stimuli (Kurtz, 2016; Lepage et al., 2014) and can easily be distracted by their surroundings. This makes it difficult for them to use attention processing to rapidly encode information about a single stimulus (Chattopadhyay, 2012).
Learning and Memory:

Learning and memory involves obtaining information from the environment, storing it, and retrieving it for use when needed. People with schizophrenia tend to have trouble quickly encoding new information and take longer to retrieve stored information (Lepage et al., 2014). This also impairs their ability to convert stored information into long-term memory (Chattopadhyay, 2012).

Social Cognition

Social cognition includes the set of cognitive processes involved in interactions with the social world and the ability to perceive, interpret, and process social information. The negative symptoms of schizophrenia can cause social withdrawal, which can directly impact one’s ability to understand the social world and obtain the skills necessary to navigate it (Chattopadhyay, 2012; Penn, Corrigan, Bentall, Racenstein, & Newman, 1997). Common skills of social cognition are theory of mind (ToM), emotion perception (EP), social perception (SP), and attribution style (AS) (Couture, Penn, & Roberts, 2006; Green, Olivier, Crawley, Penn, & Silverstein, 2005). ToM refers to the ability to understand that another’s mental state can be different from one’s own and use this knowledge to make inferences about another’s intent or beliefs. EP is the ability to infer emotional information from facial expressions. SP is the ability to understand social rules and conventions. Attribution styles allows one to explain the cause of an event in their life. People with schizophrenia have difficulties carrying out these various emotional and social processes (Couture et al., 2006).
Diagnostic Criteria

The Diagnostic and Statistical Manual of Mental Disorders, Edition 5 (DSM-5)

A diagnosis of schizophrenia must meet the criteria established in the DSM-5. Criterion A requires that the individual presents at least two or more of the following symptoms: hallucinations, delusions, disorganized speech, grossly disorganized or catatonic behavior, or negative symptoms. The symptoms must be persistent and occur continuously over a one-month period. One of the symptoms must be either hallucination, delusions, or disorganized speech. Criterion B states that the symptoms present must cause decreased functionality in work, interpersonal relationships, or self-care. Criterion C states that dysfunctionality caused by schizophrenia must be persistent over a 6-month period. Criterion D requires that this diagnosis be differentiated from other psychotic disorders, such as schizoaffective disorder, schizophreniform disorder, or bipolar disorder with psychotic features. Criterion E requires that the disturbance is not caused by the effects of a substance or medical condition. Criterion F asserts that if the individual has a history of autism spectrum disorder or other communicational disorders, that the diagnosis of schizophrenia with prominent delusions or hallucinations, or other symptoms, are present for at least one month (APA, 2013).

Etiology

Despite the extensive research on the disorder, the exact causes of schizophrenia continue to remain uncertain. However, many different risk factors have been identified amongst the categories of birth complications, genetics, environmental, and psychological (Messias et al., 2007; Patel et al., 2014).
Risk Factors

Birth Complications

Research has revealed a series of different birth complications that have been linked with the onset of schizophrenia (Messias et al., 2007; Patel et al., 2014; Walker et al., 2004). These complications include complications during pregnancy and delivery, such as bleeding, gestational diabetes, rhesus incompatibility, preeclampsia, emergency cesarean section, and asphyxia. Abnormal fetal growth and development, such as low birthrate, congenital malformations, and reduced head circumference are also researched risk factors (Messias et al., 2007; Walker et al., 2004). Maternal infections, such as the flu, and excess stress during the second trimester have also been linked to doubling the risk of the offspring developing schizophrenia (Walker et al., 2004).

Genetic

Evidence suggests that genetics plays an important role in the causation of schizophrenia (Patel et al., 2014; Walker et al., 2004). Research shows an approximate 10% risk for first-degree relatives (parent, sibling, or child) and 3% for second-degree relatives (cousins, aunts, uncles, grandparents, etc.). In regards to monozygotic twins, if one twin has the disorder, there is a 48% risk that the other twin will have it. Dizygotic twins, however, has a risk of 12% to 14%. Furthermore, if both parents have schizophrenia, the risk of the child having it will be approximately 40% (Patel et al., 2014; Walker et al., 2004). Research with adopted children studies whether the risk comes from biology or the environment the children are raised in (Walker et al., 2004). Studies show that environmental changes do not change the risk
if the biological parents have schizophrenia (Patel et al., 2014; Walker et al., 2004). A genetic basis for the disorder is also supported by findings that show siblings with schizophrenia experience onset at around the same age (Patel et al., 2014).

**Environmental and Psychological**

Environment can also play a role in the development of schizophrenia (Walker et al., 2004). Childhood infections have been shown to play a role in the development of schizophrenia (Marcopulos & Kurtz, 2012). Birth cohort studies have also found increased risk for schizophrenia in relation to urban birthplace. Furthermore, stressful environments can trigger psychological changes that make an individual vulnerable to the disorder (Marcopulos & Kurtz, 2012). These stressors can include childhood trauma or abuse, minority and ethnicity struggles, discrimination, residence in an urban area, social isolation or neglect, or economic adversity (Patel et al., 2014). The development of other psychiatric illness can also cause vulnerability to other disorders.

**Neuropathology**

**Dorsolateral Prefrontal Cortex**

Research has indicated the DLPFC, located on the lateral part of the frontal lobe (Figure 1), as a major site for pathology in schizophrenia (Potkin et al., 2009; Selemon, 2001). Schizophrenia is associated with deficits in prefrontal mediated functions (working memory,
attention, set-shifting, etc.) and the role of the DLPFC is suspected to be involved due to decreased neurotransmitter activity (Huang et al., 2017). Magnetic resonance imaging (MRI) has shown decreased gray matter volume in the DLPFC in the brains of people with schizophrenia, as well as reduced size (Marcopulos & Kurtz, 2012). Studies have also shown neurons are more compact in their arraignment in the DLPFC due to a reduction of neuropil (Selemon, 2001).

**Anterior Cingulate Cortex**

Findings have shown variations of dysfunctionality of the ACC in people with schizophrenia (Selemon, 2001). The ACC is located in the medial frontal lobe (Figure 2) and has been linked to functions such as impulse control, decision-making, and emotion. Dysfunction of the ACC has been associated with negative symptoms in schizophrenia (Nelson, Bjorkquist, Olsen, & Herbener, 2015). Some studies have found decreased activation and lower cerebral metabolic rates, while others have seen increased cerebral blood flow in the right ACC (Selemon, 2001). Nevertheless, the results suggest that the ACC plays a role in the pathology of the disorder.

![Figure 2. Anterior cingulate cortex location in brain.](https://www.hindawi.com/journals/ecam/2011/543648/fig1/)
Temporal Cortex

Studies have shown reduction of a variety of areas in the temporal cortex (Marcopulos & Kurtz, 2012). These areas include gray matter reduction in the left planum temporale (Figure 3) and superior temporal gyrus (Figure 4). In addition, injury to the temporal lobe, specifically in the left hemisphere medial temporal structures, has been associated with psychotic symptoms in schizophrenia (Selemon, 2001).

Ventricles

Another prominent indicator of schizophrenia is the enlargement of the ventricles, fluid-filled cavities in the brain (Figure 5) that produce cerebrospinal fluid (Gaser, Figure 5. Ventricular system in the brain. (https://www.thoughtco.com/ventricular-system-of-the-brain-3901496)
Nenadic, Buchsbaum, Hazlett, & Buchsbaum, 2004; Marcopulos & Kurtz, 2012). An enlarged ventricular system has been associated with poorer outcomes in patients with schizophrenia compared to those without.

**Biochemistry**

*Dopamine Hypothesis*

The Dopamine Hypothesis was first proposed as a possible explanation for the neuropathology of schizophrenia. The hypothesis states that schizophrenia results from excess of dopaminergic activity due to deficits in the mesocortical dopamine (DA) system (Marcopulos & Kurtz, 2012). Various evidence suggested a link between dopaminergic dysfunction and schizophrenia; however, the precise role of DA is still unknown (Thompson, Pogue-Geile, & Grace, 2004). Findings such as drugs that increase DA activity can potentially induce psychotic symptoms in people without schizophrenia and drugs that are DA receptor antagonists are shown to reduce positive symptoms in schizophrenia contributed to the formation of this hypothesis. However, despite extensive research, proving this hypothesis has been met with methodological difficulties.

*Glutamate Hypothesis*

Similar to the Dopamine Hypothesis, the Glutamate Hypothesis was developed due to the observation of biological evidence that supported the role of glutamate in the etiology and pathology of schizophrenia (Marek et al., 2010; Moghaddam & Javitt, 2012). Reductions of cerebrospinal fluid and glutamate levels observed and similarities between symptoms of psychosis caused by phencyclidine (PCP; a NMDA antagonist) and schizophrenia contributed to evidence for the
The hypothesis also suggests that the behavioral effects of NMDAR antagonists associated with schizophrenic symptoms persists in the absences of dopamine activity or dopamine antagonists (Moghaddam & Javitt, 2012). Furthermore, the theory is supported by altered glutamate metabolism in postmortem brains of schizophrenia patients and altered gene expression for NMDA receptor subunits (Marcopulos & Kurtz, 2012). However, similar to the Dopamine Hypothesis, replication of the evidence for the Glutamate Hypothesis are inconsistent.

**Treatment**

Treatment for schizophrenia aims to target the symptoms, prevent relapse, and improve overall functionality to ensure integration into the community (Dipiro et al., 2014). This typically consists of a combination of pharmacological and psychotherapeutic methods in order to increase the effectiveness of treatment.

**Pharmacological Treatments**

Drug treatment is vital when treating schizophrenic symptoms as most illness-related changes in the brain occur within the first five years of the first acute episode (Patel et al., 2014; Walker et al., 2004). Antipsychotic drugs have been the most common and effective type of drug as they target the severity of symptoms, decrease frequency, and improve functionality (Haller, Padmanabhan, Lizano, Torous, & Keshavan, 2014). The first-generation of antipsychotics (FGA), also known as typical antipsychotics, proved effective in treating positive symptoms. FGAs (such as haloperidol, chlorpromazine, fluphenazine) primarily targeted dopamine D-2 antagonist receptors (Haller et al., 2014; Kapur & Remington, 2001). However, FGAs
had adverse side-effects causing extrapyramidal symptoms (EPS) and suboptimal outcomes. This led to the development of second-generation antipsychotics (SGA, also known as atypical antipsychotics), such as olanzapine, clozapine, lurasidone (Walker et al., 2004). Many of the SGAs developed performed better at reducing EPSs compared to FGAs.

**Psychotherapy**

Psychotherapeutic options were developed in order to target other core manifestations of the disorder (Haller et al., 2014) and can be divided into three categories: individual, group, and cognitive behavioral (Dipiro et al., 2014). Recent therapies also include meta-cognitive, mindfulness, and narrative therapies (Dickerson & Lehman, 2011). These types of therapies aim to inform the patient about their illness and discuss various coping strategies designed to reduce symptoms. Cognitive behavioral therapy (CBT), an individual type of psychotherapy, is a common option when treating schizophrenia; consistent evidence of its effectiveness has created a surge of interest in researching the strategy to improve implementation (Cather et al., 2005). CBT is an intervention that aids the patient in understanding their condition and work on ways to change their behavior. It has proved effective in improving the functional outcome of schizophrenia by reducing positive symptoms (Cather et al., 2005; Tarrier et al., 2004). However, similar to antipsychotic drugs for schizophrenia, many of the psychotherapies established for schizophrenia do not target the cognitive features of the disorder.
Cognitive Remediation

Cognitive features manifest independently of the clinical impairments presented by positive and negative symptoms, while also not being well treated by antipsychotic medications. Given the severe cognitive deficits that schizophrenia causes, developing a treatment that specifically targets cognitive features proved to be necessary (John, Yeak, Ayres, & Dragovic, 2017). Cognitive remediation (CR) specifically targets the cognitive features present in schizophrenia through models focusing on learning, retraining information, neurodevelopmental, and executive functioning (Wykes & van der Gaag, 2001). The aim of CR is to improve cognition which will, in turn, improve every-day functioning in the community. Various studies and meta-analyses demonstrate that CR programs are beneficial and effective for people with schizophrenia for treating cognitive, functional, and psychosocial features (John et al., 2017; Lindenmayer et al., 2017; Tarrier & Wykes, 2004; Wykes, Huddy, Cellard, McGurk, & Czobor, 2011). Results across the multiple studies yielded significant results addressing improvements in cognition and functioning. Furthermore, meta-analyses demonstrated that CR was most effective when patients were clinically stable (Wykes et al., 2011). Similar to other treatment methods, CR produces stronger effects when given adjunct to pharmacological and psychotherapeutic treatment. It can be administered in a variety of methods including individual, group, non-computerized, and computerized (Barlati, Deste, De Peri, Ariu, & Vita, 2013; Vita, Barlati, Bellani, & Brambilla, 2014). These different methods proved to be effective in multimodal treatment approaches to schizophrenia. Computer-assisted CR enables a more selective approach to targeting specifics
cognitive domains and demonstrates a wide range of improvements in cognition and social functioning, such as facial affect recognition (Barlati et al., 2013; Kurtz & Richardson, 2012).

**Durability of Cognitive Remediation**

Implementation of CR for schizophrenia has also demonstrated statistical significance in its long-term effects. Commonly, the durability of CR is measured by conducting follow-up testing months after treatment is completed. Wykes et al. (2003) conducted an exploratory study to test the durability of CR. The study found that the effects of CR were measurable even after 6 months following the completion of treatment. Various studies reported in meta-analyses using this method also demonstrated the durability of CR (Wykes et al., 2011). In a study by Fiszdon et al. (2004), participants in the computerized CR therapy showed significantly greater improvements in memory tasks compared to the control and these results were maintained after 6 and 12 months (Fiszdon, Bryson, Wexler, & Bell, 2004). In addition, a study by Penadés et al. (2006) found that significant improvements in neurocognition and social cognition were sustained over a 6-month follow-up (Penades et al., 2006). A study by Eack et al. (2010) demonstrated one-year durability effects using CR as improvements in functional outcome maintained significance compared to the control group (Eack, Greenwald, Hogarty, & Keshavan, 2010).

Ensuring the durability of CR is vital given that the aim is to produce long-term effects that improve overall functioning in every-day life.
IV. Present Study

The present study builds on the previous literature and findings to further assess the efficaciousness of CR for schizophrenia. More specifically, two therapeutic models of cognitive remediation: a computerized drill-and-practice (PSSCogRehab) and manualized practice strategy-based compensatory cognitive training group (CCT), were implemented at River Valley Services (RVS), an outpatient mental health center, in Middletown, CT. The first aim was to directly compare the effectiveness of the two CR models in treating and improving cognitive features and functional outcome. The second aim was to assess the durability of the CR intervention implemented at RVS over a 3-month follow-up.

V. Hypothesis

Hypothesis 1

We hypothesized that participants in both conditions would demonstrate improvements in cognitive features in comparison to the control group; however, participants in the CCT condition would show larger improvements in functional outcome compared the PSSCogRehab condition, as the targeted strategies of CCT better emulate the everyday tasks participants will encounter in their daily-lives and community.

Hypothesis 2

Assessing the durability of CR at RVS would demonstrate significant results for each CR condition compared to control group.
VI. Methods

Participants

Participants were clinically-stable adults recruited from RVS and informed of the program by clinical staff. All participants received a DMS-5 diagnosis of either schizophrenia, schizoaffective, or a mood disorder with psychotic features. Exclusion criteria included current use of illicit substances, a history of intellectual disabilities as evidenced by a history of services, lack of fluency in English, a neurological disorder, or prior enrollment in other CR programs. Participants were admitted to the program after filling out a written consent form and Release of Health information form.

Procedure

The study and all associated personnel (RVS staff and research assistants) were approved by Wesleyan University and the Connecticut Department of Mental Health & Addiction Services (DMHAS) Institutional Review Board (IRB). The experimental design was a single-blind randomized control trial. Participants were randomly assigned to one of three conditions: PSSCogRehab, CCT, or the control: treatment as usual (TAU) using an online random number generator (random.org). During the intervention, participants were treated with their standard doses of antipsychotic medications by their treating psychiatrist. In order to evaluate the progress and effectiveness, participants were assessed by multimodal evaluation of symptoms and functioning, collected at baseline, immediately after the intervention, and after 3-months. Assessments were administered by trained research assistants. To maintain blindness, participants were given subject identification numbers and
examiners were not informed of which condition the participant had been assigned to. Compensation for participation in each experimental condition was given in the form of $30 gift cards after each evaluation.

**Experimental Conditions**

**PSSCogRehab**

Psychological Software Services Cognitive Rehabilitation Therapy System (PSSCogRehab), developed by Dr. Odie Bracy III, consisted of a 12-week long computerized cognitive training program. The program utilized a drill-and-practice method to train cognitive skills. Eighty-four different exercises were designed to target and improve attention, verbal and non-verbal memory, and language processing. Participants attended three sessions per week (45-60 minutes per session) supervised by a trained clinician. The intervention was divided into three, 4-week periods that targeted different cognitive skills, attention, memory, and executing functioning. During each period, participants would start at an elementary level and proceed to higher levels, once gaining 90% accuracy.

**CCT**

Compensatory Cognitive Training (CCT), developed by Dr. Elizabeth Twamley and colleagues, consisted of a 12-week long manualized, group-based program. The program taught compensatory strategies designed to cope with and overcome cognitive deficits. These strategies aimed to establish various life skills in the participants that would improve their ability to complete daily tasks independently. Participants attended weekly two-hour sessions lead by a trained clinician. Similar to PSSCogRehab, the program taught skills that targeted attention,
memory, executive functioning, and prospective memory. These skills were taught using activities that utilized a pencil-and-paper approach. For each targeted skill, leaders introduced the topic and corresponding compensatory strategies designed to cope with the deficit. Participants would practice the strategies using the pencil-and-paper strategy and additional exercises were given to the participants to practice incorporating newly learned skills at home and in their every-day lives.

Control Condition (TAU)

Participants assigned to TAU did not attend either CR intervention, receiving no treatment. These participants, however, were given the opportunity to participate in either of the CR interventions after completing the study. Participants in this condition were only tested at baseline and after the intervention finished.

Assessments and Measures

Demographics

Cover Sheet

The cover sheet for each participant collected various demographics including: date of birth, sex, ethnicity, age, years of education of the participant and parents, employment status, duration of time at current job, maximum years employed, year of first treatment for schizophrenia, number of hospitalizations, duration of illness (years), current support services, last medication appointment, living status (group home, family, own), medical illnesses, history of loss consciousness, and a list of current medications and daily dosage.
Clinical Assessments

Positive and Negative Syndrome Scale (PANSS)

The PANSS is a 30-item psychiatric rating system designed to measure the severity of positive, negative, and general symptoms of a disorder (Kay, Fiszbein, & Opler, 1987). A structured interview is used to gather information on the patient’s current condition. The interview is divided into 10 sections that target specific symptoms such as anxiety, depression, delusions, or conceptual disorganization. The patient is asked to answer each question considering the events of the past week. Using the completed interview, a trained research assistant uses the PANSS rating scale to rate the severity of symptoms. The rating system uses a 7-point scale with 1 being absence of symptom and 7 as extreme severity. Symptoms are divided into three categories: positive, negative, and general. Overall score on the PANSS is determined by summing the total of scores for each category.

Wechsler Test of Adult Reading (WTAR)

The WTAR is an assessment used to measure premorbid intelligence (Wechsler, 2001). The assessment consists of 50 vocabulary words. Participants were required to read aloud each word on the list. Trained research assistants scored one point for every word pronounced correctly. The raw and standard score for the assessment was recorded.

Self-Efficacy Measures

Self-Efficacy Scale (SES)

The SES measures the participant’s confidence in their ability to complete a variety of tasks and measures their control over positive symptoms (McDermott,
The tasks are divided into three categories: positive (e.g. “stop thoughts that others are controlling what you think”), negative (e.g. “use you free time for activities other than watching TV”), and social (e.g. “go out on a date”). Participants rate their confidence level on a scale of 0-100: 0 being least confident and 100 as most confident. If a task did not apply to the participant, they were asked to imagine themselves in the scenario and speculate their confidence level. If answers were unclear or absent, a score of -9 is given. The assessment is scored by summing the score of each item and dividing by the number of items in each category.

Social Cognitive Measures

The Awareness of Social Inference Test (TASIT)

The TASIT measures the participant’s awareness of social inference (McDonald, Flanagan, Rollins, & Kinch, 2003). A series of video clips depicting different types of emotions and social interactions are shown to the participant to assess how well they can understand the emotional or social behavior being portrayed. The TASIT is divided into three parts: Part 1: Emotional Evaluation, Part 2: Social Inference, and Part 3: Social Inference (Enriched). Part 1 assess how well the participant can identify what emotion (happy, sad, surprised, angry, anxious, revolted, and neutral) is being demonstrated by the actor. Part 2 and Part 3 have the participant answer four questions based on the events and conversations in the video. The four questions target (1) what the person in the video trying to make the other person do, think or feel, (2) what is the message a person is trying to get across, (3) what is someone’s underlying belief that may be different from what they are saying,
and (4) what someone is feeling. The participants can use clues such as voice or facial expression to answer the questions.

**Functional Outcome Measures**

**Social Functioning Scale (SFS)**

The SFS is an outcome measure designed to gauge the participant’s ability to engage in prosocial interactions, degree of social engagement/withdrawal, interpersonal behavior, recreational engagement, competence and performance of independent skills, and employment capabilities (Birchwood, Smith, Cochrane, Wetton, & Copestake, 1990). The measure uses a self-report method and a rating system. The participant is given options for answering the questions that they feel best represent their experience (e.g. “How often are you able to carry out a sensible or rational conversation: almost never, rarely, sometimes, or often?). The options correspond to a numerical value: almost never: 0, rarely: 1, sometimes: 2, or often: 3. The measure is scored by summing the numerical value for each question.

**UCSD Performance-Based Skills Assessment (UPSA)**

The UPSA is an assessment of everyday functioning (Mausbach, Harvey, Goldman, Jeste, & Patterson, 2007). The participant is required to role-play different scenarios to measure their ability to understand and complete daily tasks. The UPSA has 7 sections, however, the study utilizes three: Counting Change, Writing Check, and Telephone. Counting Change has the participant use prop money to demonstrate to the examiner their knowledge of currency (e.g. “Using the prop money, show me $1.02 but all in coins.”). Writing Check has the participant fill out a check according to a prop billing statement. The Telephone section has the participant demonstrate
their knowledge of using a telephone to dial emergency numbers (911) or how to use 411 to call for information. In this section, the participant must also use the telephone to call and reschedule an appointment according to a prop letter and subsequently recall details of the letter. The UPSA is scored by recording the percentage of correct answers.

The Specific Level of Functioning Scale (SLOF)

The SLOF is an assessment of observable behaviors completed by clinicians who have a relationship with the given participant (Schneider & Struening, 1983). There are 43 items rated on a 5-point scale. The items are divided into 6 categories: physical functioning, personal care skills, interpersonal relationships, social acceptability, activities community living, and work skills. An additional section, “Other Information”, has the rater comment on any additional information they deemed necessary to comment on that is not included in the previous sections.

Neurocognitive Measures

Wisconsin Card Sorting Test (WCST)

The WCST was used to measure set-shifting (flexibility in thinking) in the participants (Berg, 1948). The participants are asked to sort 64 cards using a set of four cards as guides. The four set cards display different shapes (triangle, circle, star, and cross) that vary in color and number. Participants are given no instructions on how to sort or match the cards. This requires them to make decisions on how to sort the deck of cards by observing similar features such as color, form, or number. The present study used a computerized version of the WCST which informed the participant when their match was either “right” or “wrong”. After the first ten cards
are correctly sorted, the matching rule changes. This change is meant to prompt the participant to figure out the new matching rule through trial and error. The assessment is scored using the overall percentage correctly sorted.

Hopkins Verbal Learning Test Revised (HVLT-R)

The HVLT-R measures verbal learning and memory (Shapiro, Benedict, Schretlen, & Brandt, 1999). There are three trials in which 12 words are read aloud by the examiner and the participants is asked to recall as many words as they can. Each trial ends once the participant states they can no longer recall any words. There are six versions of the assessment, which were rotated throughout the three evaluation periods. The measure is scored by summing the total amount of words recalled to determine the raw score and standard score.

Controlled Oral Word Association Test (COWAT)

The COWAT measures verbal fluency (Lezak, 1995). There are four trials divided into two categories: letter fluency and category fluency. Letter fluency has the participant list as many words as they can in 60 seconds that start with the target letter: “F”, “A”, and “S”. All words are applicable with the exception of proper nouns and the same word with different endings (e.g. sit, sitting, etc.). Category fluency follows the same procedure; however, the participant is asked to list as many different animals as they can 60 seconds.

Memory for Intentions Screening Test (MIST)

The MIST measures prospective memory; the act of remembering to perform a predetermined action or recall intentions or information at a future time (Raskin, 2009). The assessment is completed in a 30-minute period in which the participant is
required to complete tasks using prospective memory. The tasks are given to the participant at specific time intervals by the examiner. While waiting to complete each task, the participant is given a word search to complete as a distraction. The 8 tasks are categorized by either (1) delay period, (2) cue, or (3) type of response. Participants are awarded one point for remembering to perform the task and another point for performing it at the correct time, for a total of two points. The assessment also includes a “Retrospective Recognition” section in which they are asked 8 questions reviewing what they were required to do for each task, for a potential total of 8 points. To score the MIST, the total points from each task are multiplied by 2 and the sum is used to obtain the standard score. For the Retrospective Recognition section, the sum is used to obtain the standard score.

Wechsler Adult Intelligence Scale (WAIS-IV)

The WAIS-IV is a collection of tests designed to measure aspects of intelligence and cognitive ability such as processing speed, perceptual organization, verbal comprehension, and working memory (Wechsler, 2008). Three subtests were used in the present study: Digit Span (DS), Letter-Number Sequencing (LN), and Symbol Coding (CD). The DS and LN measures working memory and attention. The DS required participants to repeat a string of numbers in three different trials: forwards, backwards, and sequencing. LN required participants to alphabetize and sequence a string of numbers and letters. CD required participants to fill in a grid of numbers by matching the number with its corresponding symbol using the key provided in 2 minutes. For each measure of the WAIS-IV the sum of raw score is used to obtain the standard score.
Statistical Procedure

All statistical analysis was done using the IBM Statistical Package for the Social Sciences 23.0 (SPSS). Statistical significance was indicated using an alpha 0.05 ($p \leq 0.05$). A series of one-way analysis of variance (ANOVA) and chi-square tests were used to analyze between-group demographic, symptom, and functional differences before treatment. Chi-square tests were used to analyze between-group differences for categorical demographic variables, including sex, ethnicity, living status, and diagnosis. A series of one-way ANOVA tests were used to test for statistically significant differences between the conditions using the change score (baseline score subtracted from post-training). Effect size was also calculated using Cohen’s $d$ to measure the magnitude of the effect between the treatment and control group, in which $d=0.2$ indicates a small effect size, $d=0.5$ indicates a medium effect size, and $d=0.8$ indicates a large effect size. For analyzing the overall durability of the randomized control trial, paired sample t-tests were used to compare pre-training and post-training performance and post-training and follow-up performance.
VII. Results

Participants Progression through Randomized Control Trial

**Figure 6.** Flow diagram of participant progression through the stages of the randomized control trial.

Baseline Participant Demographics

A series of one-way ANOVA and chi square tests were used to find the percentage, mean, and standard deviation for demographics for each condition (see
Table 1. Chi-square tests were used specifically for categorical demographic variables, including sex, ethnicity, living status and diagnosis. Post-hoc analyses of the demographics revealed no statistically significant differences between the conditions for any variable.

<table>
<thead>
<tr>
<th>Variable</th>
<th>PSSCogRehab</th>
<th>CCT</th>
<th>TAU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>49.0(±11.35)</td>
<td>55.22(±13.09)</td>
<td>54.60(±11.41)</td>
</tr>
<tr>
<td>Gender, % Male</td>
<td>55.6%</td>
<td>66.7%</td>
<td>60%</td>
</tr>
<tr>
<td>Race/Ethnicity, % Caucasian</td>
<td>77.8%</td>
<td>55.6%</td>
<td>100%</td>
</tr>
<tr>
<td>Housing, % Living Independently</td>
<td>33.3%</td>
<td>77.8%</td>
<td>80%</td>
</tr>
<tr>
<td>Education (years)</td>
<td>12.4(±2.00)</td>
<td>13.67(±1.80)</td>
<td>14.00(±2.00)</td>
</tr>
<tr>
<td>Father’s Education</td>
<td>12.33(±5.57)</td>
<td>12.43(±5.16)</td>
<td>16.26(±5.01)</td>
</tr>
<tr>
<td>Mother’s Education</td>
<td>12.5(±2.95)</td>
<td>12.88(±3.44)</td>
<td>14.00(±2.16)</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>57.1%</td>
<td>33.3%</td>
<td>25%</td>
</tr>
<tr>
<td>Schizoaffective</td>
<td>42.9%</td>
<td>44.4%</td>
<td>50%</td>
</tr>
<tr>
<td>MDD with psychotic features</td>
<td>0%</td>
<td>22.2%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Illness Burden</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Hospitalizations</td>
<td>13.0(±15.24)</td>
<td>5.44(±4.61)</td>
<td>8.00(±3.65)</td>
</tr>
<tr>
<td>Duration of Illness (years)</td>
<td>25.89(±13.80)</td>
<td>29.11(±16.52)</td>
<td>26.20(±7.73)</td>
</tr>
<tr>
<td>Positive Symptoms</td>
<td>16.78(±6.32)</td>
<td>13.11(±4.76)</td>
<td>13.4(±3.65)</td>
</tr>
<tr>
<td>Negative Symptoms</td>
<td>16.11(±5.90)</td>
<td>17.89(±4.81)</td>
<td>17.2(±3.90)</td>
</tr>
</tbody>
</table>
Baseline Performance

For all 20 variables, there was no statically significance difference in performance between the groups, with the exception of the Social Efficacy Scale.

Participants scored higher in the TAU condition compared to PSSCogRehab and CCT for both negative (SES_Neg) and social (SES_Social) symptoms, p=0.06 and p=0.05 respectively. Therefore, with this exception, performance during baseline did not vary amongst the three conditions.

Hypothesis 1

PSSCogRehab vs. TAU

Neurocognitive Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>PSSCogRehab Change Score Mean±SD</th>
<th>TAU Change Score Mean±SD</th>
<th>Effect Size (Cohen’s d)</th>
<th>F Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WCST</td>
<td>N=6</td>
<td>N=3</td>
<td>0.69**</td>
<td>0.95</td>
<td>0.36</td>
</tr>
<tr>
<td>HVLT-R</td>
<td>N=7</td>
<td>N=5</td>
<td>0.31*</td>
<td>0.27</td>
<td>0.61</td>
</tr>
<tr>
<td>COWAT_Letter</td>
<td>N=8</td>
<td>N=5</td>
<td>-0.56**</td>
<td>0.99</td>
<td>0.34</td>
</tr>
<tr>
<td>COWAT_Category</td>
<td>1.88(±18.83)</td>
<td>-4.6(±11.37)</td>
<td>-0.39*</td>
<td>0.77</td>
<td>0.40</td>
</tr>
<tr>
<td>Digit Span</td>
<td>N=7</td>
<td>N=5</td>
<td>0.06</td>
<td>0.01</td>
<td>0.92</td>
</tr>
<tr>
<td>Letter_Number</td>
<td>0.14(±1.67)</td>
<td>2.00(4.74)</td>
<td>0.57**</td>
<td>0.94</td>
<td>0.36</td>
</tr>
<tr>
<td>Symbol Coding</td>
<td>N=8</td>
<td>N=5</td>
<td>-0.23*</td>
<td>0.16</td>
<td>0.70</td>
</tr>
</tbody>
</table>

Table 3. Effect Size and Group Differences in Change Score between PSSCogRehab and TAU for Neurocognitive Measures. *small effect size **medium effect size ***large effect size

We predicted improvement in the PSSCogRehab relative to the TAU control on cognitive measures. A one-way ANOVA showed no significant differences between PSSCogRehab and TAU for neurocognitive measures. A small-to-medium
A medium effect size for TAU compared to PSSCogRehab ($d=-0.56$) and category fluency (COWAT_Category) observed a small-to-medium effect size for TAU compared to PSSCogRehab ($d=-0.39$). Lastly, a small effect size is seen in Symbol Coding for TAU compared to PSSCogRehab.

### Social and Functioning Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>PSSCogRehab Change Score Mean(±SD)</th>
<th>TAU Change Score Mean(±SD)</th>
<th>Effect Size (Cohen’s $d$)</th>
<th>F Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASIT</td>
<td>N=6 -5.83(±16.29)</td>
<td>N=5 0.25(±4.19)</td>
<td>0.49**</td>
<td>0.51</td>
<td>0.49</td>
</tr>
<tr>
<td>SLOF</td>
<td>N=6 -0.67(±11.43)</td>
<td>N=2 4.5(±17.68)</td>
<td>0.41*</td>
<td>0.25</td>
<td>0.64</td>
</tr>
<tr>
<td>SES_Pos</td>
<td>N=8 11.25(±22.71)</td>
<td>N=5 2.48(±8.33)</td>
<td>-0.47**</td>
<td>0.70</td>
<td>0.42</td>
</tr>
<tr>
<td>SES_Neg</td>
<td>8.32(±12.87)</td>
<td>-4.22(±14.52)</td>
<td>-0.93***</td>
<td>2.66</td>
<td>0.13</td>
</tr>
<tr>
<td>SES_Social</td>
<td>14.21(±17.02)</td>
<td>-12.93(±20.46)</td>
<td>-1.48***</td>
<td>6.73</td>
<td>0.03</td>
</tr>
<tr>
<td>SFS</td>
<td>-2.12(±26.60)</td>
<td>2.00(±2.55)</td>
<td>0.20*</td>
<td>0.12</td>
<td>0.74</td>
</tr>
<tr>
<td>UPSA</td>
<td>0.63(±8.21)</td>
<td>1.00(±10.25)</td>
<td>0.04</td>
<td>0.005</td>
<td>0.94</td>
</tr>
</tbody>
</table>

Table 4. Effect Size and Group Differences in Change Score between PSSCogRehab and TAU for Social and Functioning Measures. *small effect size **medium effect size ***large effect size

We predicted improvement in the PSSCogRehab relative to the TAU control on social and functioning measures. A one-way ANOVA showed no significant differences between PSSCogRehab and TAU for social and functioning measures, except for social features on the Social Efficacy Scale (SES_Social; $F(1, 11) = 6.73$, $p = .03$). PSSCogRehab showed greater improvements on the social features of the SES compared to TAU. A small effect size is seen with the social features of the
Social Functioning Scale (SFS) for PSSCogRehab compared to TAU ($d=0.20$). A small-to-medium effect size is seen in The Specific Level of Functioning Scale (SFS) for PSSCogRehab compared to TAU. A medium effect size is seen in the TASIT for PSSCogRehab compared to TAU. In addition, large effect sizes are seen for TAU compared to PSSCogRehab in the negative symptoms ($d=-0.93$) and social features ($d=-1.84$) for the SES. A medium effect size is seen for positive symptoms on the SES for TAU compared to PSSCogRehab.

**Clinical Assessments**

<table>
<thead>
<tr>
<th>Measure</th>
<th>PSSCogRehab Change Score Mean(±SD)</th>
<th>TAU Change Score Mean(±SD)</th>
<th>Effect Size (Cohen’s $d$)</th>
<th>F Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PANSS_Pos</td>
<td>0.71(±3.40) N=7</td>
<td>1.25(±5.12) N=4</td>
<td>0.13</td>
<td>0.04</td>
<td>0.84</td>
</tr>
<tr>
<td>PANSS_Neg</td>
<td>-6.14(±3.89)</td>
<td>-1.00(±10.23)</td>
<td>0.77***</td>
<td>1.50</td>
<td>0.25</td>
</tr>
<tr>
<td>PANSS_Gen</td>
<td>-4.00(±4.16)</td>
<td>-2.5(±10.66)</td>
<td>0.21*</td>
<td>0.12</td>
<td>0.74</td>
</tr>
</tbody>
</table>

Table 2. Effect Size and Group Differences in Change Score between PSSCogRehab and TAU for Clinical Assessments. *small effect size **medium effect size ***large effect size

We predicted improvement in the PSSCogRehab relative to the TAU control on clinical assessments. A one-way ANOVA showed no significant differences between PSSCogRehab and TAU for clinical assessments. Small effect sizes for change score of PSSCogRehab compared to TAU are seen in both positive (PANSS_Pos; $d=0.13$) and general symptoms (PANSS_Gen; $d=0.21$) for the PANSS. However, negative symptoms showed a large effect size for PSSCogRehab compared to TAU ($d=0.77$). Overall, greater improvements are seen in PSSCogRehab compared to TAU.
CCT vs. TAU

**Neurocognitive Measures**

<table>
<thead>
<tr>
<th>Measure</th>
<th>CCT Change Score Mean(±SD)</th>
<th>TAU Change Score Mean(±SD)</th>
<th>Effect Size (Cohen’s d)</th>
<th>F Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WCST</td>
<td>N=6 0.83(±23.23)</td>
<td>N=3 11.00(±9.17)</td>
<td>0.5**</td>
<td>0.51</td>
<td>0.50</td>
</tr>
<tr>
<td>HVL-T-R</td>
<td>N=8 -1.13(±5.69)</td>
<td>N=5 5.60(±18.82)</td>
<td>0.55**</td>
<td>0.93</td>
<td>0.36</td>
</tr>
<tr>
<td>COWAT_Letter</td>
<td>1.63(±6.02)</td>
<td>0.4(±7.09)</td>
<td>-0.19*</td>
<td>0.11</td>
<td>0.74</td>
</tr>
<tr>
<td>COWAT_Category</td>
<td>0.5(±8.38)</td>
<td>-4.6(±11.37)</td>
<td>-0.53**</td>
<td>0.87</td>
<td>0.37</td>
</tr>
<tr>
<td>Digit Span</td>
<td>0.38(±2.13)</td>
<td>.6(±0.55)</td>
<td>0.13</td>
<td>0.05</td>
<td>0.82</td>
</tr>
<tr>
<td>Letter-Number</td>
<td>0.26(±2.49)</td>
<td>2.00(4.74)</td>
<td>0.5**</td>
<td>0.78</td>
<td>0.40</td>
</tr>
<tr>
<td>Symbol Coding</td>
<td>N=7 0.00(±1.63)</td>
<td>N=5 0.2(±1.64)</td>
<td>0.12</td>
<td>0.04</td>
<td>0.84</td>
</tr>
</tbody>
</table>

*Table 6. Effect Size and Group Differences in Change Score between CCT and TAU for Neurocognitive Measures. *small effect size **medium effect size ***large effect size*

We predicted improvement in the CCT relative to the TAU control on cognitive measures. A one-way ANOVA showed no significant differences between CCT and TAU for neurocognitive measures. Medium effect sizes are seen for the WCST ($d=0.55$), HVL-T-R ($d=0.5$), and Letter-Number Sequencing ($d=0.5$) for CCT compared to TAU. For TAU compared to CCT, a small effect size is observed for letter fluency (COWAT_Letter) in Verbal Fluency ($d=-0.19$) and a medium effect size is observed for category fluency (COWAT_Category; $d=-0.53$).
### Social and Functioning Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>CCT Change Score Mean(±SD)</th>
<th>TAU Change Score Mean(±SD)</th>
<th>Effect Size (Cohen’s d)</th>
<th>F Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASIT</td>
<td>N=8</td>
<td>N=4</td>
<td>0.54**</td>
<td>0.78</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>-4.13(±9.3)</td>
<td>0.25(±4.19)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLOF</td>
<td>N=5</td>
<td>N=2</td>
<td>0.05</td>
<td>0.004</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>4.00(±6.78)</td>
<td>4.5(±17.68)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SES_Pos</td>
<td>N=8</td>
<td>N=5</td>
<td>0.26*</td>
<td>0.21</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td>-1.62(±18.6)</td>
<td>2.48(±8.33)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SES_Neg</td>
<td>8.51(±6.54)</td>
<td>-4.22(±14.52)</td>
<td>-1.25***</td>
<td>4.81</td>
<td>0.05</td>
</tr>
<tr>
<td>SES_Social</td>
<td>3.49(±7.06)</td>
<td>-12.93(±20.46)</td>
<td>-1.21***</td>
<td>4.51</td>
<td>0.06</td>
</tr>
<tr>
<td>SFS</td>
<td>17.86(±20.00)</td>
<td>2.00(±2.55)</td>
<td>-1.00***</td>
<td>3.02</td>
<td>0.11</td>
</tr>
<tr>
<td>UPSA</td>
<td>2.86(±7.68)</td>
<td>1.00(±10.25)</td>
<td>-0.21*</td>
<td>0.14</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Table 7. Effect Size and Group Differences in Change Score between CCT and TAU for Social and Functioning Measures. *small effect size **medium effect size ***large effect size

We predicted improvement in the CCT relative to the TAU control on social and functioning measures. A one-way ANOVA showed no significant differences between PSSCogRehab and TAU for social and functioning measures, except for negative symptoms on the Social Efficacy Scale (SES_Neg; F(1, 11) = 4.81, p = .05).

For CCT compared to TAU, a small effect size is seen for positive symptoms (SES_Pos) on the SES (d=0.26) and a medium effect size is seen for the TASIT (d=0.54). Large effect sizes are observed for negative symptoms (SES_Neg) on the SES (d=-1.25), social features (SES_Social) on the SES (d=-1.21), and the SFS (d=-1.00) for TAU compared to CCT.
### Clinical Assessments

<table>
<thead>
<tr>
<th>Measure</th>
<th>CCT Change Score Mean±SD</th>
<th>TAU Change Score Mean±SD</th>
<th>Effect Size (Cohen’s $d$)</th>
<th>F Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=7</td>
<td>N=4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS_Pos</td>
<td>-1.86(±3.34)</td>
<td>1.25(±5.12)</td>
<td>0.77***</td>
<td>1.52</td>
<td>0.25</td>
</tr>
<tr>
<td>PANSS_Neg</td>
<td>-5.29(±4.15)</td>
<td>-1.00(±10.23)</td>
<td>0.63**</td>
<td>1.01</td>
<td>0.34</td>
</tr>
<tr>
<td>PANSS_Gen</td>
<td>-5.86(±4.3)</td>
<td>-2.5(±10.66)</td>
<td>0.48**</td>
<td>0.57</td>
<td>0.47</td>
</tr>
</tbody>
</table>

*Table 5. Effect Size and Group Differences in Change Score between CCT and TAU for Clinical Assessments. *small effect size **medium effect size ***large effect size

We predicted improvement in the CCT relative to the TAU control on clinical assessments. A one-way ANOVA showed no significant differences between CCT and TAU for clinical assessments. There is a small-to-medium effect size for general symptoms on the PANSS (PANSS_Gen) for CCT compared to TAU ($d=0.48$). A medium-to-large effect size is seen for negative symptoms (PANSS_Neg) for CCT compared to TAU ($d=0.63$). Lastly, there is a large effect size for positive symptoms (PANSS_Pos) for CCT compared to TAU. Overall, the mean change scores demonstrate that CCT shows greater improvements on the PANSS compared to TAU.

**Hypothesis 2**

**Durability Across Treatment Groups**

Paired sample t-tests revealed no significant differences for all measures, except for general symptoms on the PANSS comparing baseline to post-training performance ($t=3.17$, df=17, p=0.006), negative symptoms on the PANSS comparing baseline to post-training performance ($t=3.39$, df=17, p=0.003), positive symptoms on the SES comparing post-training to follow-up performance ($t=2.54$, df=11, p=0.028), and negative symptoms on the SES comparing baseline to follow-up performance ($t=2.06$, df=20, p=0.05) and post-training to follow-up performance ($t=2.81$, df=11,
p=0.017). Performance improved for both general and negative symptoms on the PANSS. Negative symptoms on the SES demonstrated significant differences across each stage of the randomizes control trial. However, performance improved from baseline to post-training performance but worsened from post-training to follow-up performance (see Figure 6). Performance also worsened for positive symptoms on the SES comparing post-training to follow-up performance. Overall, despite significance, the decline in performance is not alluding to the study having durable effects as of now.

**Figure 6.** Change in SES Negative Symptoms Scores Across Testing Stages. 1: Baseline, 2: Post-Training, 3: Follow-up
VIII. Discussion

Hypothesis 1

Statistical analysis revealed no effect of drill-and-practice CR performance compared to TAU on cognitive measures, symptoms measures, and functional measures. Despite the lack of statistical significance, effect sizes are indicating improvements in areas of symptoms, cognition, and social functioning for PSSCogRehab. Promising improvements from PSSCogRehab were seen in performance on the PANSS, WCST, Letter Number Sequencing, and the TASIT. Similarly, statistical analysis revealed no significant differences between CCT performance compared to TAU, with the exception of negative symptoms on the SES. CCT also showed promising improvements in symptoms, cognition, and social functioning. Effect sizes showed differences in favor of CCT for the PANSS, WCST, HVLT-R, Letter Number Sequencing, and the TASIT. In addition, it was hypothesized that the CCT would be more effective at improving functioning. However, statistical analysis and effect sizes did not reveal any significant differences in favor of CCT for functioning measures such as, the SLOF, SFS, and the UPSA. However, the change score for the SFS for CCT does indicate that significant change is possible if the data continues to follow the trend.

Hypothesis 2

Although statistical analysis demonstrated significant differences and mean scores showed improvement on the PANSS and SES from baseline to post-training performance, statistically significant results on the SES from post-training to follow-up showed a decrease in performance. Therefore, durable effects of the study are not
observed in the results. Due to dropouts, there is less data for follow-up, which could contribute to the lack of durability.

**Strengths**

A notable strength of the study is the involvement and leadership of professionally trained clinical staff. RVS staff created a supportive and encouraging environment for the participants which promoted participant morale and continued involvement in the study. In addition, multiple assessment measures for targeted psychological features, such as cognitive and functioning, increases reliability of the study. In regards to demographics, each treatment group is close to being gendered balanced and CCT is close to being balanced between race.

**Limitations**

The small sample size of the study gives low statistical power of the study and increases the chances of Type II error. A small sample size hinders the study’s ability to produce conclusive results. A factor that consistently contributed to the small sample size is the dropout rate of participants. Nine participants have dropped out over the course the study. In addition, the study is limited by inconsistent attendance throughout treatment due to factors such as participants limited access to transportation. Staff at RVS is also limited. In regards to demographics, overall, the study is not racially balanced and participants are generally older. Cognitive remediation is generally most effective in younger participants (Kontis, Huddy, Reeder, Landau, & Wykes, 2013; Wykes et al., 2009); therefore, the relatively high age-span of the participants is not consistent with previous research findings on the effectiveness of cognitive remediation.
Future Directions

The 4th cohort at RVS is entering our study. Future directions of the study aim to expand the study to other locations, such as the Institute of Living in Hartford, CT. By expanding the study, the sample size is expected to increase. Expanding the study will also require recruiting more research assistants. In addition, conducting the study at other locations will result in modifications to the testing battery.

Conclusions

The randomized control trial has successfully been completed with three cohorts. Once acknowledging the exploratory nature of the study, it can be inferred from the data that the results of the randomized control trial are promising. Both treatment methods are having an effect on cognition and functioning and durability analysis is alluding to possible effects. With a larger sample size, it is expected that the effects will gain statistical power and analysis will produce more significant results.
VII. References

APA. (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5 ed.). United States.


IX. Appendix

Informed Consent Form

Submitted: 12/23/16

RIVER VALLEY SERVICES
DEPARTMENT OF MENTAL HEALTH AND ADDICTION SERVICES
(DMHAS)
INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

PRINCIPAL INVESTIGATOR: Matthew M. Kurtz
DEPARTMENT: Psychology
PHONE: 860-685-2072
EXPECTED DURATION: Five years
SPONSOR: Wesleyan University

Key Information

- You are being asked to consent to participate in a research study.
- The purpose of the research is to compare two different forms of cognitive remediation for people with schizophrenia. You will be in the study for three months and will practice one of the interventions several hours each week.
- The only reasonably foreseeable risk to you is mild fatigue, anxiety or discomfort from some of the study procedures.
- Although there may be no direct benefit to you from the research, your participation may benefit future patients like you.

I. You are being asked to participate in the research study, “Comparing the Efficacy of Two Forms of Cognitive Remediation: Strategy-Based vs. Drill-and-Practice Restoration Training for Cognitive Deficits in People with Psychosis,” because you have been diagnosed with schizophrenia, schizoaffective disorder, or some other mental health disorder involving psychosis. Drill-and-practice restoration cognitive remediation training is an intervention consisting of a series of computerized attention, memory and problem-solving exercises that you practice on and that are designed to improve your concentration skills. Strategy-based cognitive remediation training consists of a series of weekly meetings in which you are coached to develop skills in using calendars, notebooks, and other memory support tools to help you work around any difficulties you may have in your attention and memory.
In order to decide whether or not you wish to be part of this research study you should know enough about its procedures, risks, and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion will go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

The purpose, procedures, and length of your involvement are stated below:

A. **Purpose of research:** To compare the efficacy of two different forms of cognitive remediation for people with schizophrenia.

B. **Procedures:** Your participation in this study will involve the following procedures:

i. You will be asked to answer questions about your education, illness, medications, functioning, and complete a series of neuropsychological assessments before and after your treatment and 3-months after the cessation of cognitive remediation groups. These tests will take a couple of hours and are in addition to your standard clinical care. These tests will help tell us determine whether your treatment has worked and which form of cognitive skills training is more effective at improving your cognition.

ii. You will be assigned, by chance, to one of three groups: a strategy-based training group, a drill-and-practice training group or a wait-list control group.

- For the wait-list control group, you will be assigned to either the strategy-based training group or the drill-and-practice training group following a period of three months.

- If assigned to the strategy-based training group, you will practice cognitive (thinking) exercises one to two hours a day, once a week. This training will occur over a 3-month period.

- If assigned to the drill-and-practice training group, you will practice cognitive exercises one to two hours a day, three to four times per week. This training will also occur over a 3-month period.
You should also know that you will be requested to sign a separate release-of-information form. If you sign this form you will give the researchers conducting this study access to review your hospital records. Information regarding your past and present medical history will be gathered from these files.

You may be asked to be video or audiotaped while completing some of the neuropsychological assessments or clinical treatment groups such as strategy-based training or drill-and-practice training. Confidentiality regarding video or audiotapes will be protected by the researchers running this study. More specifically, media will not be labeled with your name, will be kept in a locked file in the Principal Investigator’s lab suite at Wesleyan University and will be viewed only by staff directly involved in the research study. Recordings will be kept for a maximum of five years after collection.

We will ask whether you want to release information collected as part of this research study to your treatment team at River Valley Services. If so, we will ask you to sign a release-of-information form.

You may decide that you do not want to complete some portion of the cognitive testing and illness assessment that occurs before and after your computer training and still participate in the study.

C. Duration of Participation: This study will take place at River Valley Services Connecticut Valley Hospital, Middletown and your participation in the cognitive remediation training will last for approximately 3 months.

II. The possible risks, discomforts and side effects of the procedures are described below, including what we will do to minimize risk:

1. You may become fatigued or mildly anxious during the interviews and testing. You are free to take breaks at any time. Some of the interview questions may touch on sensitive topics. You are free to skip a question if you feel uncomfortable answering it.

   - You may experience mild anxiety using a personal computer.
- You may become mildly tired from the cognitive exercises and skills training.

- You may experience a feeling of mild discomfort while being video or audiotaped.

- A breach of confidentiality could occur. Nonetheless, your confidentiality will be protected to the greatest extent possible. Your records will be maintained in accordance with applicable state and federal laws.

**III.** There are **possible benefits** to you or others to be expected from your participation in this research as described below:

1. By your participation, you may provide information that will benefit future patients with the same difficulties that you experience.

2. Individual benefits, however, cannot be guaranteed.

**IV.** There may be **other treatments** for your condition. You should consider these as well as the treatments in the study just described. Whether you choose to participate or not you will receive your usual care at River Valley Services.

**V.** The investigator is willing to answer any **questions** you may have concerning the procedures herein described. You do not have to sign this consent until all the questions you have at this time have been answered. Future questions about this study may be directed to Dr. Matthew Kurtz at (860) 685-2072.

If you have any problems or complaints as a participant in this research, you may call Janet Storey, DMHAS IRB Chair, (860) 418-6823, who is not part of the research team.

**VI.** Your participation is voluntary and you may refuse to participate and/or withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your future medical care at River Valley Services.

You will receive financial compensation as discussed below. If you receive compensation, it will be reported as income to the Internal Revenue Service (IRS) if
you receive $600 or more in a year for research studies completed through River Valley Services.

You will be paid $30 for completion of the questions about your medical history and baseline neuropsychological assessments at entry to the study, another $30 for completion of these same questions and tests at the end of your cognitive remediation training, approximately 3 months after entry to the study and then a third time three months after the cessation of your cognitive remediation training. These payments may be reported to the federal government for tax purposes. The payments will be issued via gift cards and will be given to you directly upon completion of each portion of the study.

There is no financial cost to you for participating in the study.

VII. Your confidentiality will be protected to the greatest extent possible. River Valley Services will protect all the information about you and your part in this study just as is done for all patients at River Valley Services. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project. You may request that your records be released to your personal physician.

The information that may be used or disclosed includes the following:

1. Results of tests of attention, memory and problem-solving.
2. Results of tests of your functioning in the community, e.g., ability to plan trips, plan a meal, socialize, etc.
3. The interview we conduct to for measurement of your specific symptoms related to having schizophrenia or schizoaffective disorder or another psychiatric disorder.
4. Age, race and gender.
5. Medical and psychiatric history.
6. Records of your progress in cognitive remediation.

This information may be used or disclosed by:

1. Dr. Matthew M. Kurtz and clinical research staff working under his direct supervision.
2. My treatment team at River Valley Services.
The information may be disclosed to:

1. DMHAS and/or Wesleyan University Institutional Review Board.

The purpose(s) of the use or disclosure of this information is (are):

1. To answer the research question.
2. To ensure the study is being conducted properly and that your rights as a participant are protected.

The use or disclosure of the information is permitted until:

1. Completion of the research study.

Future Research: You should know that data we collect in this project will likely be used for comparison to data from other studies in our center or in cooperation with other researchers. Any data used in this manner will be stripped of information that would identify whom it came from.

By signing this consent, you are also agreeing to the use or disclosure of your protected health information as described above. If you do not agree to the use or disclosure of the information as described and therefore do not sign this consent, you will not be in the study.

If, after signing the consent, you change your mind, you have the right to revoke your consent, in writing. However, you will be withdrawn from the study. If you withdraw your consent you will not be able to continue cognitive training. Regardless of your participation or lack of participation, the rest of your treatment at River Valley Services will not be affected in any way.

VIII. In case of any injuries as a direct result of taking part in this research project, you will receive help in the following way:

If you have medical insurance, River Valley Services will collect fees for medical treatment from your insurance company. RVS will not pay medical expenses at other hospitals or pay for pain and suffering, travel, lost wages, or other indirect costs of taking part in this project.
IX. Signatures

I hereby voluntarily agree to participate in the research study entitled, “Comparing the Efficacy of Two Forms of Cognitive Remediation: Strategy-Based vs. Drill-and-Practice Restoration Training for Cognitive Deficits in People with Psychosis” described in this consent form.

You will be given a signed copy of this informed consent form to keep.

Participant's Signature
Date

Conservator Signature and Relationship to Participant
Date

Investigator’s Signature or Person Obtaining Consent
Date

Witness (person observing the explanation of the above information to the participant) - optional unless consent is presented orally.

I voluntarily agree to have my answers to questions about my illness video and/or audiotaped.

Participant's Signature
Date

Conservator Signature and Relationship to Participant
Date

Investigator’s Signature or Person Obtaining Consent
Date

Witness (person observing the explanation of the above information to the participant) - optional unless consent is presented orally.
HIPAA Authorization Form

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The federal privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects your individually identifiable health information from being shared without your permission. The privacy law requires that you sign an authorization (or agreement) in order for researchers to be able to use and disclose your protected health information and that you receive a copy of the Institution’s privacy practices.

Your signature on this authorization is voluntary. Whether you choose to sign or not to sign has no impact on your treatment, payment, or enrollment in any health plans, or affect on your eligibility for benefits. The only consequence of not signing this form is that you may not be allowed to participate in this research project.

By signing this form you authorize Dr. Matthew Kurtz and his staff to use and disclose your protected health information for the research project titled “Cognitive Remediation for Schizophrenia: Effects on Distal Outcome Measures and Relationship to Social-Skills Training”. You also permit your doctors and other health care providers to disclose your protected health information for this research project.

In addition, State of Connecticut statutes require that any release of information pertaining to AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse be specifically authorized. If this information pertains to you, you should know that the researcher(s) and staff associated with this project might become aware of it. By signing this dual-purpose authorization you acknowledge that you understand there is a chance this information may be subject to use and disclosure as it relates to this project.

This Authorization does not have an expiration date. However, if you sign this authorization you can still change your mind at a later date. You can revoke this authorization by sending a written notice to Dr. Matthew Kurtz, Department of Psychology, Wesleyan University, Middletown, CT. 06459, to inform him of your decision. Once you revoke this authorization the researchers will no longer be able to
use and disclose your protected health information. There are exceptions to this. For example, one exception under which the researchers may continue to use and or disclose your protected health information after receiving your request to revoke the authorization is if you experience(d) an adverse event (bad effect). Another example is that researchers may continue to use and/or disclose only the protected health information collected for the research study prior to receiving the request to revoke this authorization. If you revoke this authorization you may no longer be allowed to participate in this study.

If you have any questions, concerns or complaints about your privacy rights, you may write to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, U.S. Dept. of Health and Human Services Government Center, J.F. Kennedy Federal Building, Room 1875, Boston MA 02203. Complaints should be sent within 180 days of when you knew, or should have known, of the problem.

You may not be allowed to review the information collected for this research project until the study is complete. However, you have the right to request that your medical record be released to your personal physician. When the collection of information is complete, you may have the right to access all of your information.

Your protected health information that may be used and disclosed includes:

- Race, gender, age
- Neuropsychological test data, functional and social skill measurements, and symptom rating data
- Medical and psychiatric history
- The interview we conduct to confirm your psychiatric diagnosis and measurement of your specific symptoms related to having schizophrenia or schizoaffective disorder.
- Records of your progress in cognitive remediation and social skills training.

Your Health Information will be used to:

- To answer the research question.
- To ensure the study is being conducted properly and that your rights as a participant are protected.
Your Protected Health Information may be used by and shared with:

- The Hartford Hospital and/or DMHAS Institutional Review Board.
- The National Alliance for Research in Schizophrenia and Depression (NARSAD).
- The Department of Psychiatry at Dartmouth Medical School.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization, as directed by state and federal law. However, once your health information has been disclosed to anyone outside of this institution, the information may no longer be protected under this authorization.
There may be studies conducted in the future for which you may be an eligible participant. Please initial your preference.

_____ You **give** permission to Dr. Matthew Kurtz or his designated administrator to contact you with information about future studies for which you may be an eligible participant.

_____ You **do not give** permission to be contacted about future studies for which you may be an eligible participant.

You are a voluntary participant in this research study, or you are authorized to act on behalf of the participant. By signing you acknowledge that you have read and understand this form and that you authorize the use and disclosure of protected health information. You will receive a copy of this form after it is signed.

_________________________ __________________________
Signature of the research participant or the research participant’s legal representative* Date

_________________________ __________________________
Printed name of the research participant and if applicable the participant’s legal representative* Date

_________________________
Representative’s relationship to the research subject

*Please provide documentation of your status as an authorized representative
Continued IRB Approval

STATE OF CONNECTICUT
DEPARTMENT OF MENTAL HEALTH AND ADDICTION SERVICES
A Healthcare Service Agency

NED LAMONT
GOVERNOR

MIRIAM E. DELPHIN-RITTMAN, Ph.D.
COMMISSIONER

NOTICE OF CONTINUING OOC IRB APPROVAL

March 15, 2019

Title of Study: Comparing the Efficacy of Two Forms of Cognitive Remediation: Strategy-Based vs. Drill-and-Practice Restorative Training for Cognitive Deficits in People with Psychosis

Principal Investigator: Matthew M. Kurtz, PhD, Professor of Psychology

Reference Number: 16-13

Type of Review: Expedited

Approval Date: 03-15-19

Dear Dr. Kurtz:

An annual review of your study, referenced above, has been conducted and continuation of the study has been approved by the OOC Institutional Review Board. With this review, the IRB is transitioning this research to comply with the requirements of the revised Common Rule. As a result, annual IRB review is no longer required.

In line with this notification the IRB has also approved the following revisions:

- Revision of the consent form to comply with the requirements of the revised Common Rule;
- Addition of Melissa Olgun as key personnel.

Your study was eligible for an expedited review under Category 7.

The IRB must be informed of any adverse events, protocol deviations, complaints or other unanticipated problem involving risks to research participants related to your study. If any changes are contemplated, an Application for Approval of Study Revision must be submitted to the IRB for approval before implementation.

If you have any questions, please feel free to contact me at 860-418-6823.

Sincerely,

Janet Storey, MSW
Chair, DMHAS Institutional Review Board

cc: Celeste Cremin-Endes, CEO, River Valley Services

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