A REAL-WORLD IMPLEMENTATION-EFFECTIVENESS STUDY OF COGNITIVE

ENHANCEMENT THERAPY FOR PEOPLE WITH SCHIZOPHRENIA

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A REAL-WORLD IMPLEMENTATION-EFFECTIVENESS STUDY OF COGNITIVE

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ABSTRACT

The purpose of this study was to examine the implementation and effectiveness of Cognitive Enhancement Therapy (CET) within a real-world, community mental health program. Evidence-based programs for people with schizophrenia and other serious mental illnesses are not widely available for eligible clients. Thus, real-world research is essential to address this underutilization of needed programs. This study intended to describe implementation of a 12-month version of CET, including descriptive participant, clinician, and setting information, as well as to test the program effectiveness. Thirty-four individuals who engaged in CET participated in the study. The majority of participants had a schizophrenia or schizoaffective disorder diagnosis. Results indicated that eligible participants attended and engaged with the program, and the majority reported high satisfaction. Implementation of CET was bolstered with funding to support clinician training and utilization of a train-the-trainer model. Using an intent-to-treat model, effectiveness was partially supported; Participants improved in attention, verbal memory, and visual memory, as well as several domains of positive and negative symptoms. This study was the first comprehensive evaluation to demonstrate that CET was successfully and effectively implemented in a real-world program. Research and clinical implications are discussed.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the College of Arts and Sciences have examined a dissertation titled "A Real-World Implementation-Effectiveness Study of Cognitive Enhancement Therapy for People with Schizophrenia," presented by Laura A. Faith, candidate for the Doctor of Philosophy degree, and certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

OVERVIEW

Treatments for people with schizophrenia and other serious mental illnesses (SMI) have improved greatly in the last several decades. Modern evidence-based programs (EBPs) have progressed from ancient treatment models and are now designed to assist individuals to move beyond symptom stabilization. Thus, treatment for people with schizophrenia has changed over the years from a relapse prevention model to a recovery model (Kane, 2003). While a recovery-focused model still includes symptom management, this approach further incorporates living a meaningful life (Lieberman et al., 2008), which often includes achieving personal goals (e.g., employment).

Cognitive Enhancement Therapy (CET) is a recovery-phase psychosocial treatment for people with schizophrenia who have already achieved stabilization of their symptoms (Hogarty et al., 2004). CET integrates neurocognitive and social cognitive training, and is designed to improve real-world functioning in areas such as employment and relationships. Therefore, CET moves beyond symptom management to address functional recovery. Multiple randomized-controlled trials show that CET improves neurocognition and social cognition (Hogarty et al., 2004; Eack, Hogarty, Greenwald, Hogarty, & Keshavan, 2007; Eack et al., 2009) as well as more distal outcomes such as employment (Eack, Hogarty, Greenwald, Hogarty, & Keshavan, 2011). While controlled studies have demonstrated that CET is efficacious, no current studies have examined CET implementation or effectiveness in an uncontrolled, real-world environment.

Purpose

The purpose of this study was to examine the effectiveness and implementation of the 12-month version of Cognitive Enhancement Therapy (CET) in a community mental health program in Kansas City, Missouri. This was the first examination of the entire package of CET in a community program beyond randomized trials. This study utilized the RE-AIM framework (Glasgow, Vogt, & Boles, 1999) to evaluate factors of effectiveness and implementation, thus fitting within a hybrid effectiveness-implementation design (Curran, Bauer, Mittman, Pyne, & Stetler, 2012). While many cognitive rehabilitation programs are efficacious (i.e., significant pre- to post- intervention change in a randomized, controlled trial), few published studies have examined practical factors such as acceptability, the implementation process, and real-world effectiveness of such programs in the community. This is important because practical variables could affect the success of the program, and treatments implemented in community clinics operate differently than in highly controlled research studies (Singal, Higgins, & Waljee, 2014). Examining the effectiveness and implementation of CET in the real world may inform real-world research as well as inform agencies planning to implement similar programs.

CHAPTER 2

REVIEW OF THE LITERATURE

Overview of Schizophrenia and Treatment History

Schizophrenia is a serious mental illness that impairs functioning in daily life such as work, relationships, and/or activities of daily living (ADLs) (American Psychiatric Association, 2013). According to diagnostic criteria, individuals diagnosed with schizophrenia exhibit at least one positive symptom: hallucinations, delusions, or disorganized speech (e.g. derailment or incoherence). Negative symptoms are also common and distinct from other schizophrenia symptoms (Blanchard & Cohen, 2006), and include deficits in typically existing thought processes or behaviors, such as lack of motivation or decreased interest or pleasure. Grossly disorganized or catatonic behavior is also included in the diagnostic criteria as a primary symptom. Although not listed within the formal diagnostic criteria, various other symptoms are considered characteristic features of the diagnosis. For example, cognitive symptoms include problems with functions such as attention, processing speed, and problem solving (i.e., neurocognition; Green et al., 2004). Neurocognitive symptoms affect approximately 65-85% of people with schizophrenia (Reichenberg et al., 2006; Reichenberg et al., 2009). Another common symptom is social cognitive impairment, including difficulties with social perception and knowledge, decreased theory of mind, and reduced emotion processing (Green et al., 2008). Neurocognition and social cognition are thought to interact and affect functioning together (Brenner, Hodel, Roder, & Corrigan, 1992; Fisher et al., 2017; Peer, Rothmann, Penrod, Penn, & Spaulding, 2004; Vauth, Rusch, Wirtz, & Corrigan, 2004). Neurocognitive and social cognitive

symptoms impact employment, social problem solving, social behavior, and community functioning (Rempfer, Hamera, Brown, & Cromwell, 2003; Couture, Penn, & Roberts, 2006; McGurk, Twamley, Sitzer, McHugo, & Mueser, 2007). The above symptoms (i.e. positive, negative, and cognitive) all affect functioning; treatments aim to address these areas to promote recovery.

Schizophrenia was once thought by treatment providers to be a desperate disease; individuals were institutionalized for their entire lives and offered various passive treatment strategies focused on compliance and symptom management (e.g., Faurbye, 1958; Keith, Gunderson, Reifman, Buchsbaum, & Mosher, 1976). When the first antipsychotic, Thorazine, was introduced in the 1950s (Lehmann & Hanrahan, 1954) it replaced treatments such as electroconvulsive therapy and frontal lobotomies (e.g., Lorr, Holsopple, Jenkins, & O'Connor, 1955; Rodnick, 1942), and some would say this shift in treatment paved the way for improved treatment options (e.g., Keith et al., 1976). In later decades, psychosocial treatment research started to grow with emerging promising findings (May, 1976a; May, 1976b Mosher & Keith, 1980). During this time, a greater number of antipsychotic medications were being introduced, including better treatment for poor or inadequate response (e.g. treatment resistance; Kane, 1996), including Clozapine, the first and still only drug approved for treatment resistant schizophrenia (Kane et al., 1989). These refined treatments accelerated treatment response and stabilization, preparing more people to benefit from psychosocial, recovery-oriented treatments.[1]

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[1] While this perspective about improvements in psychiatric treatment was the dominant treatment and research viewpoint at this time, it should be noted that there was a simultaneous movement among dissatisfied mental health consumers (also referred to as psychiatric survivors or ex-patients; C/S/X) that has also influenced modern, recovery-focused mental healthcare. The C/S/X movement was a grassroots political movement aimed to protest against forced psychiatric treatment that was perceived to be inhumane, impersonal, and disempowering (Chamberlin, 1995; Everett, 1994). The C/S/X movement advocated for improvements in

As investigations continued to grow, researchers increasingly recognized the benefit of psychosocial interventions for schizophrenia and other serious mental illnesses (SMI) beyond medication management (Schooler, Keith, Severe, & Matthews, 1995). The federal definition of a SMI is a condition that meets diagnostic criteria for a mental illness which has resulted in significant functional impairment and interferes with one or more major life activities (Substance Abuse and Mental Health Services Administration, 2013). As schizophrenia is classified as a SMI, psychosocial treatments are often designed for schizophrenia and other SMIs inclusively to reach a wider population and treat overlapping functional difficulties. Early psychosocial intervention research for schizophrenia focused on individual psychotherapy, group psychotherapy, and psychosocial skills training, with cognitive rehabilitation as a promising area of interest (Scott & Dixon, 1995). Recovery-oriented treatment models were emerging but not yet established as a best practice (Anthony, 1993), and psychosocial treatments were still new and largely confined to research settings rather than available in the community.

Overview of Current Treatments

Nearing the twenty-first century, additional targeted treatments that went beyond positive symptom management were tested through controlled trials (e.g., Dickerson, 2000; Dixon, Adams, & Lucksted, 2000; Dixon & Lehman, 1995; McFarlane et al., 1995; Mueser, Bond, Drake, & Resnick, 1998; Rector & Beck, 2001; Scott & Dixon, 1995). Some of the earliest evidence-based psychosocial interventions included family interventions, program of assertive community treatment (PACT), cognitive-behavior therapy for psychosis (CBTp),

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mental healthcare, including more holistic treatments, peer support programs, collaborative treatment with an emphasis on choices, more emphasis on hope, and less emphasis on symptom reduction as the primary goal in recovery (Deegan, 1996; Frese & Davis, 1997).

supported employment, and social skills training (Lehman et al., 2003), which were later supported through randomized controlled trials. Mueser, Deavers, Penn, and Cassisi (2013) reviewed these early (and now established) EBPs as well as more contemporary (and now accepted) treatments, such as cognitive rehabilitation and illness self-management (IMR). This review aimed to highlight the most efficacious treatments existing for people with schizophrenia. EBPs were informed by the Schizophrenia Patient Outcomes Research Team (PORT) guidelines for schizophrenia treatment based on scientific evidence (Lehman & Steinwachs, 1998). Although many of these treatments include positive symptom management, the ultimate goal is to increase functioning, achieve personal goals, and work towards recovery.

Efficacious EBPs exist, however prior research recognized that less than 50% of people with schizophrenia were receiving care that met PORT recommendation criteria (Lehman et al., 2003), and recent research continues to find that access to EBPs is lacking (Harvey & Gumport, 2015). Recent efforts focus on implementation of existing programs or treatment packages by using available resources in the community. For example, the RAISE (Recovery After an Initial Schizophrenia Episode) initiative aims to address the complex and heterogeneous needs of individuals through existing EBPs (Insel, 2016; Mueser et al., 2015). The RAISE initiative uses a comprehensive program to refer individuals to the best mental healthcare with a collaborative treatment team. The program focuses on four existing EBPs: medication management, family education, individual resiliency training (IRT), and supported employment and education (SEE). The RAISE program is effective at improving quality of life, symptoms, and involvement in work or school (Kane et al., 2016). Rather than creating a new intervention, this program aims to improve access to care through

incorporating existing resources and maximize participation in treatment. The RAISE study is an example of a real-world study utilizing existing EBPs with a focus on dissemination, a critical need in schizophrenia research.

Cognition and Cognitive Treatments

Some of the most researched and efficacious psychosocial treatments for schizophrenia are cognitive treatments. Among these, treatments differ in terms of the underlying theoretical models and operational definitions of cognition. For example, cognition defined within cognitive behavioral treatments such as CBTp refers to cognitions as patterns of thinking that organize a person's view of themselves, others and the world (Beck, 1976). CBT protocols target automatic thoughts to create more balanced reactions (Barlow, 2014) and CBTp protocols focus on the client's interpretation of their psychosis (Steel, 2012). Alternatively, cognition within cognitive rehabilitation programs (i.e., neurocognition) is defined as thought processes (e.g., attention and memory). A related cognitive process is social cognition. Social cognition includes processes related to social skills, such as social cues and communication. Thus, cognition in cognitive rehabilitation refers to cognitive processes (either neuro- or social cognition) rather than cognitive content, as targeted in CBT programs (Spaulding et al., 1999).

Social cognition and neurocognition continue to grow as important research and treatment focuses for people with schizophrenia and other SMIs. Many available EBPs focus on neurocognition, social cognition, or a combination of both. The remaining sections of this paper will focus on EBPs that target neurocognition and social cognition. As will be discussed later, these treatments have strong efficacy, but real-world studies demonstrating

effectiveness and dissemination lag behind expected progress (Medalia, Erlich, Soumet-Leman, & Saperstein, 2019).

Social Cognition and Social Cognitive Training

In the past two decades, social cognition has been a fundamental psychosocial treatment target for people with schizophrenia (Couture, Penn & Roberts, 2006). In March 2006, an expert panel identified theory of mind, social perception, social knowledge, attributional bias, and emotional processing as the most important domains of social cognition (Green et al., 2006). Theory of mind involves the ability to infer the mental states of others (e.g. intentions or beliefs). Social perception includes the ability to recognize social roles, rules, and context. This may involve the skill of processing nonverbal or verbal cues in ambiguous social situations. Social knowledge is defined by recognizing social roles, norms, and goals in certain social situations. For example, recognizing social expectations in different environments (e.g., formal vs. informal settings). Attribution bias is how a person typically interprets a positive or negative event. People either perceive events as related to external personal (i.e., other people), external situational (i.e., related to the situation), or internal (i.e., oneself) attributes. Emotion processing is defined by perceiving and using emotions, and may include emotional intelligence. Individuals with schizophrenia perform worse in social cognitive domains compared with individuals without a serious mental illness (Savla, Vella, Armstrong, Penn, & Twamley, 2012).

Several social cognition training programs exist that aim to improve social cognitive deficits and social functioning (Brown, Tas, & Brune, 2012). These programs often teach concrete skills and integrate role-plays for practice. Many programs focus on facial and emotion recognition specifically (Ekman, 2003; Wölwer et al., 2005). Other programs are

more integrative, such as Social Cognition and Interaction Training (SCIT), which includes facial and emotion recognition as well as attributional style and theory of mind (Penn et al., 2005). Since these programs tend to teach such specific skills, many are brief, about 12 or fewer sessions (Lecardeur, Stip, & Champagne-Lavau, 2010). These programs promote recovery outcomes because social cognition is linked to social functioning, community functioning, and relationships (Couture, Penn, & Roberts, 2006).

Some researchers have criticized social cognitive programs for a lack of consideration to important barriers to functioning specific to schizophrenia, such as motivation, metacognition, and learning (Brown, Tas, & Brune, 2012). As schizophrenia is a multifaceted and complex illness, programs should also be multifaceted to address the needs of this population. Many programs use proximal measures of social cognition (e.g. facial recognition), but do not demonstrate improved distal outcomes such as overall functional improvement. Some researchers have suggested that neurocognitive deficits directly affect social cognitive functioning. For example, attention problems can interfere with learning, or memory deficits could disrupt applying skills (Spaulding, 1997). Therefore, targeting neurocognition in an adjunctive or combined program may be a fruitful strategy to further improve functional outcomes beyond traditional social cognitive training programs (Dark, Cairns, & Harris, 2013).

Neurocognition and Cognitive Rehabilitation

Neurocognition has historically been recognized as an important area of schizophrenia research (Bellack & Mueser, 1993) and research grew rapidly from its initial development in the 1990s, from about 50 publications per year in 1990 to 300 publications in 2001 (Hyman & Fenton, 2003). Neurocognitive impairment is common in people with schizophrenia

(Reichenberg et al., 2006; Reichenberg et al., 2009) and is linked to employment, social functioning, quality of life (Medalia & Saperstein, 2013), and daily living skills (e.g., Rempfer, et al., 2003). To identify the most important cognitive domains in schizophrenia and to create a 'gold standard' cognitive battery, The Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) initiative was established. As part of this initiative, a panel of schizophrenia experts and other scientists identified a consensus assessment battery targeting the most relevant cognitive domains in schizophrenia: working memory, attention/vigilance, verbal learning and memory, visual learning and memory, reasoning and problem solving, speed of processing, and social cognition (Green et al., 2004). The resulting cognitive battery, called the MATRICS Consensus Cognitive Battery (MCCB) included the most reliable and valid tests that were practical for people with schizophrenia. The development of the MCCB increased standardization of cognitive measurement and are now frequently used in treatment studies as the 'gold standard' neurocognitive assessment for people with schizophrenia.

Neurocognition is one of the strongest contributors to functioning and overall outcome (Kahn & Keefe, 2013), such as everyday functioning (e.g., grocery shopping; Rempfer et al., 2003), real-world problem solving, social interactions (Bromley, Mikesell, Mates, Smith, & Brekke, 2012), social behavior (Fett et al., 2011), and work (McGurk & Meltzer, 2000; Tan, 2009). These aspects of functioning are important for everyday living and contribute to independence, an important recovery goal for many people.

Although research has shown that social and neuro- cognition are distinct factors (Mehta et al., 2013), they are evidently related. A meta-analysis by Fett (2011) showed several relationships between social cognition, social outcomes, and neurocognition, including

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associations between verbal learning & memory and visual learning & memory with social behavior in the milieu as well as an association between social problem solving with reasoning and problem solving. Both social and neuro- cognition are related to community functioning, although social cognition may have a stronger association. For neurocognition, verbal fluency, verbal learning & memory, and processing speed have the strongest relationships. For social cognition, theory of mind is strongest, followed by social perception & knowledge and emotion perception & processing. Neurocognitive functioning also affects social interactions. For example, selective attention is important when conversing with a person in a loud party. Divided attention applies when interacting with a group of people and switching between each person talking. Complex social interactions require judgements, problem solving, recognizing cues, etc.

A myriad of cognitive rehabilitation programs have been developed in recent years. Most researchers use the term 'cognitive' in cognitive rehabilitation referring to neurocognition, not including social cognition. Neurocognitive rehabilitation programs often utilize computerized neurocognitive training that aims to use "drill and practice" techniques to strengthen neurocognitive functioning in a specific domain (e.g., attention) with repeated practice (Paquin, Wilson, Cellard, Lecomte, & Potvin, 2014). The primary difference between programs is their specific curricular content (e.g., interactive problem solving vs. individual computer activities) and their length. Some programs exclusively use computerized neurocognitive training, while others are more integrative (e.g., using social cognitive training). Although there is currently no consensus for essential elements of cognitive rehabilitation, many effective programs use common therapeutic factors of strategy-based learning and combining cognitive rehabilitation with psychosocial

rehabilitation (Dark, Cairns, & Harris, 2013). It was recognized by early researchers that social and neuro- cognition are intertwined and should be incorporated within psychosocial treatments to maximize treatment gains (Spaulding, 1997). For example, one of the first comprehensive cognitive rehabilitation treatments that was created was called Integrated Psychological Therapy (IPT; Brenner, Hodel, & Roder, 1990). IPT addresses several cognitive domains that are taught in a hierarchical manner from least to most difficult. The program integrates neurocognitive and social cognitive domains and relies on the interaction between neurocognitive deficits and social cognitive dysfunction that are referred to as "vicious circles" (Brenner, Hodel, Roder, & Corrigan, 1992). In these "vicious circles", rudimentary neurocognitive processes (e.g., attention and encoding) interfere with more complex cognitive processes involved with integrating incoming information (e.g., forming concepts and retrieving information). These neurocognitive processes affect social perception and responding as well as acquisition of coping skills, which could expose people to more stressors. Conversely, these stressors could interfere with learning and acquisition of new skills and neurocognitive deficits may worsen. See Figure 1 for a depiction of these Vicious Circles.

Although integrated neuro- and social cognitive programs exist, the majority of research examines either targeted neurocognitive training or social cognitive training. Controlled trials have shown efficacy for primary outcomes (e.g. neurocognitive improvement) in multiple review articles (Grynszpan et al., 2011; Kurtz, Moberg, Gur, & Gur, 2001; McGurk et al., 2007; Wykes, Huddy, Cellard, McGurk, & Czobor, 2011) as well as secondary outcomes, such as improving negative symptoms (Cella, Preti, Edwards, Dow, & Wykes, 2017) and increasing successful employment (Chan, Hirai, & Tsoi, 2015). While a great deal of

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research has shown positive results for cognitive rehabilitation, some critics have argued that neuro- and social cognitive rehabilitation is not as powerful as publicized (Pilling et al., 2002). Others argue that cognitive rehabilitation is effective, but practicing skills in real-world settings is necessary to improve functional outcomes (Medalia & Saperstein, 2013).

To clarify factors related to cognitive improvement, research has more recently focused on predictors of improvement after cognitive rehabilitation program participation. Much cognitive rehabilitation research focuses on people in the early phase of schizophrenia, as this phase is thought to be most responsive to improvement, and findings generally show positive outcomes (Barlati, Peri, Deste, & Vita, 2015). Additionally, younger age has been shown as a predictor of cognitive or functional improvement after cognitive rehabilitation (Corbera, Wexler, Poltorak, Thime, & Kurtz, 2017; Lindenmayer et al., 2017; Vita et al., 2013). Also, less severe symptoms (i.e., negative symptoms, disorganization, and delusions) and higher baseline neurocognition is associated with greater improvement (Lindenmayer et al., 2017; Vita et al., 2013). Another study found that worse neurocognitive functioning and poor insight were related to lower rates of treatment utilization, measured with attendance rates, in a cognitive rehabilitation program (Gooding, Saperstein, Mindt, & Medalia, 2012). This information is valuable to clinicians for referral purposes to match the most appropriate clients to interventions, and identify clients needing alternative or adjunctive resources.

Some researchers believe that comprehensive cognitive rehabilitation programs integrating drill and practice training with social cognition or other problem-solving exercises increase the program gains. Research has begun to investigate this comparison, finding that the addition of social cognitive exercises to neurocognitive training can improve social skills, including prosody identification and self-reported experience of pleasure (Fisher

et al., 2017), emotion recognition and discrimination, social functioning (Lindenmayer et al., 2013), and emotion recognition (Fernandez-Gonzalo et al., 2015). Another study found that cognitive rehabilitation combined with functional skills training increased gains in functional competence and real-world behavior compared with either program alone (Bowie, McGurk, Mausbach, Patterson, & Harvey, 2012). Thus, combined approaches could be more powerful than either cognitive rehabilitation or social cognition programs alone (Dark, Cairns, & Harris, 2013).

Cognitive Enhancement Therapy (CET)

Cognitive Enhancement Therapy (CET) is a cognitive rehabilitation program developed for people with schizophrenia that combines neurocognitive and social cognitive training (Hogarty & Flesher, 1999). The program begins with 3 months of weekly 1-hour computerized neurocognitive training. After the first 3 months, participants engage in weekly 1.5-hour interactive social cognition groups in addition to the computer groups. Computer sessions are structured in pairs of participants per computer. Participants take turns engaging in activities, work together to develop strategies, and encourage each other to participate. Social cognition groups include sharing homework, psychoeducation, and problem-solving activities. Each participant has the opportunity to share their own experiences as well as ask questions and provide feedback to other participants. Activities become progressively more difficult throughout the program. The CET package includes 60 hours of computer training and 45 hours of social cognition groups total. CET groups are small, consisting of about 6-12 participants engaging in real-world scenarios to build confidence in social exchanges and social skills.

Computer sessions address neurocognition, one of the components included in the vicious circles described by the developers of the IPT program, which is theoretically similar to CET (Brenner, Hodel, Roder, & Corrigan, 1992). To address these vicious circles, participants are first asked to address basic cognitive processes, such as attention, progressing later to more complex cognitive processes, such as memory and problem-solving. These neurocognitive processes are thought to affect functional outcomes as described in the vicious circles. During CET computer sessions, participants are guided through activities with active coaching and peer support. In the social cognition groups, activities are designed to integrate and support neurocognitive and social cognitive training, further supporting the neuro/social cognitive vicious circles. Specifically, problem-solving activities involve practice of skills that integrate neurocognitive (e.g., problem-solving and attention) with social cognitive skills (e.g., theory of mind, and social perception). Problem-solving activities include feedback from other participants and coaches, supporting both neurocognition (e.g., working memory) and social cognition (e.g., theory of mind and social perception). Psychoeducation provides introduction of topics related to social knowledge with reinforcement through homework assignments. Thus, each CET activity is designed to build neurocognitive skills that are thought to influence development of social cognitive skills and coping.

Research supports the efficacy of CET in multiple randomized, controlled trials that show improvements in neurocognition and social cognition (Hogarty et al., 2004; Eack et al., 2007; Eack et al., 2009). See Table 1 for a summary of CET efficacy research. These studies have recruited, randomized, and enrolled community participants in either CET or an active control condition, Enrichment Supportive Therapy (EST), which is an illness management

and psychoeducation approach to treatment. The majority of these trials include data from 18 months or 2 years of treatment. The existing published studies were conducted at the University of Pittsburgh Western Psychiatric Institute and Clinic, a specialty outpatient research clinic (e.g., Eack et al., 2011). Compared to control participants, cognitive improvements for CET participants were preserved at 1-year follow up (Hogarty, Greenwald, & Eack, 2006). After engaging in CET, participants were more likely to be employed, earn more money, and be more satisfied with their employment (Eack et al., 2011). CET participants also showed improvement in negative symptoms after treatment completion (Eack, Mesholam-Gately et al., 2013). One study compared individuals with schizophrenia and schizoaffective disorder, and found no relationship between diagnosis and treatment effect; this can be interpreted to mean CET is equally as effective for people with either schizophrenia or schizoaffective disorder (Lewandowski, Eack, Hogarty, Greenwald, & Keshavan, 2011). Another study recruited and randomized individuals with schizophrenia spectrum disorders who were currently misusing substances to examine feasibility and efficacy with this population (Eack at al., 2015). In regards to acceptability, the authors found that attrition was greater than previously published CET studies. However, efficacy for treatment completers was comparable to other controlled CET studies. Recent studies have expanded use of CET to include people with autism spectrum diagnoses (Eack, Bahorik et al., 2013); initial findings established feasibility as well as improved neurocognition and social cognition for this population (Eack, Greenwald et al., 2013; Eack et al., 2018).

Researchers have also explored neuropsychological features that could predict CET performance, as well as resulting brain changes after CET. One study found that measurements of cortical surface area and gray matter volume predicted social-cognitive

response to CET (Keshavan et al., 2011). In a study conducted by the same CET research team, emotional intelligence was linked to gray matter density in the parahippocampal gyrus (Wojtalik, Eack, & Keshavan, 2013), suggesting that physical brain areas are related to specific areas of functioning. Thus, information regarding structural brain features may aide clinicians in recruitment and treatment matching. One study found post-CET neuroprotective features, including less gray matter loss and more gray matter increase, which suggests improved long-term cognitive outcomes (Eack et al., 2010). This neurological improvement after CET participation suggests neural plasticity (e.g. measurable changes in the brain) after treatment, further demonstrating the preservation of CET improvements.

In summary, CET has been established as an EBP for people with schizophrenia or schizoaffective disorder, with promise for people with autism spectrum disorders. The majority of published CET research is conducted in highly controlled environments, with structured recruitment, and specific, strict criteria for program administration & delivery. There is limited CET research conducted in uncontrolled, real-world environments to establish effectiveness and guide implementation. Nonetheless, serious mental illness treatment research outside of CET is starting to evaluate programs in less controlled, real-world environments. The development of real-world treatment effectiveness and implementation research for SMI will be outlined further below.

Real-World Research: Feasibility, Effectiveness, and Implementation

As noted previously, although EBPs for people with schizophrenia and serious mental illnesses exist, they are not easily accessible to the majority of individuals needing care (Jolley et al., 2015; Kingdon & Turkington, 2019; Medalia et al., 2019). There are limited studies investigating EBPs for schizophrenia in real-world environments (Dhillon &

Dollieslager, 2000; van der Krieke et al., 2015) and more research is needed in this area (Kauth, Sullivan, Cully, & Blevins, 2011). Given the impact of serious mental illness in terms of functional difficulties for those diagnosed, economic costs, caregiver/family stress (Berry & Haddock, 2008), and disadvantaged healthcare access (e.g., due to socioeconomic status and stigma; Rowlands, 2004) there is an urgent need for improved treatment dissemination and access. Relevant real-world methodologies to address this issue include feasibility, effectiveness, and implementation research. These real-world research approaches to improve program dissemination and access to care will be further detailed below. See Table 2 for a summary of these study methods.

When an EBP is designed, researchers strive to publish a randomized-controlled trial (RCT) to demonstrate efficacy (i.e., efficacy trials). When planning an RCT, researchers often conduct feasibility studies (also referred to as pilot studies). The purpose of feasibility/pilot studies is to determine (1) if the intervention methodology and processes are practical for a larger trial and (2) if there are any preliminary effects (Thabane et al., 2010). These studies are less controlled than RCTs and include descriptive, practical information in preparation for a larger study. For example, researchers can determine timing for study sessions, equipment needs, and data management (i.e., storage of data, data entry, etc.). Researchers may also examine participant-level processes, such as recruitment, retention rates, and adherence. After a feasibility study is conducted, the researchers determine if an RCT to demonstrate efficacy is feasible, if the protocol needs adjustments, or if the study needs close monitoring on any of the variables examined. Because of the inclusion of descriptive, practical information, published feasibility studies may provide useful information within real-world research and for clinicians considering implementation.

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RCTs are considered the gold standard to demonstrate efficacious treatments and are the end-goal for many treatment researchers. However, efficacy trials are systematically different than clinical settings, and implementing programs can be different in real-world environments. Practical information regarding recruitment, the setting, billing, and other real-world information is not typically included in published RCTs, and data are often limited to primary outcomes. Effectiveness and implementation studies that are conducted in real-world environments can address issues that are not addressed in RCTs and thus improve the possibility that the treatment will reach its target population.

Following RCTs to demonstrate efficacy, effectiveness trials may be conducted. The purpose of effectiveness trials is to determine if an intervention provides meaningful change for participants in a real-world setting (e.g., community clinics, mental health programs, etc.). With the differences in efficacy trials versus real-world settings, effectiveness studies are important to determine if an intervention remains effective under naturalistic conditions. Researchers conduct effectiveness trials to demonstrate outcomes in populations and settings that may be more heterogeneous and unpredictable than randomized-controlled trials (Singal, Higgins, & Waljee, 2014). In effectiveness studies, clinicians are more representative of usual providers, whereas RCTs frequently include specialized or more highly trained professionals. The intervention is strictly enforced and standardized (i.e., high fidelity) in RCTs, while effectiveness trials sometimes involve modifications to the intervention. RCT researchers enforce strict inclusion criteria, while participants in effectiveness trials could be more representative of the general population. Effectiveness trials aim to increase external validity, while efficacy trials are focused on maximizing internal validity. Both types of studies are important, but provide different information and have different aims.

Implementation study researchers focus on understanding strategies to bolster

dissemination of a given intervention often to inform clinical programming. The field of

implementation science aims to identify factors involved with treatments utilization, best

practices for facilitating use, and barriers/solutions to treatment use (Douglas, Campbell, &

Hinckley, 2015). Implementation studies tend to be descriptive and focused on the processes

involved in implementing a program, rather than testing treatment outcomes. Increased

interest in implementation research was born from the somewhat disappointing utilization of

EBPs (Fixsen, Blase, Naoom, & Wallace, 2009). According to implementation science

researchers, successful implementation occurs in the following stages: exploration,

installation, initial implementation, and full implementation (The National Implementation

Research Network, 2018). *Exploration* involves the acquisition of information and

exploration of options. The *installation* stage involves the allocation of resources toward the

upcoming task. This includes selecting staff, identifying sources for training and coaching,

providing staff training, selecting fidelity measures, locating office/intervention space,

locating materials/equipment, and other processes involved with planning the intervention.

Initial implementation involves the first attempts to provide the intervention, which includes

adapting to practical realities of providing the intervention (e.g., adjusting to changes in daily

routines). This stage can be very fragile and is bolstered by support from the organization,

co-workers, and mentors. *Full implementation* occurs when more than 50% of the target

clinicians are using the intervention. These implementation stages are not necessarily linear

and consist of several components (Fixsen, et al., 2009). Staff selection involves choosing

clinicians who are most qualified to provide the treatment (e.g., academic qualifications,

knowledge of the field, willingness to learn). Training includes any necessary learning to

facilitate effective treatment, including practice, coaching, advice/encouragement, supervision or formal certification(s). Fidelity measurement includes feedback designed to help clinicians improve their effectiveness with clients. Implementation components should be flexible to allow for the program's specific needs and to maximize successful implementation. Implementation barriers are often structured in terms of organizational/agency, individual, and system-community levels.

RE-AIM Framework

Within these real-world study models, The RE-AIM framework has been proposed. The RE-AIM framework is a model to evaluate the public health impact of interventions and to move beyond the efficacy models (e.g., RCTs) that dominate current scientific literature (Glasgow, Vogt, & Boles, 1999). The framework incorporates program effectiveness with implementation variables to provide five stages of interventions and evaluate how well programs work in the real world. The five stages are reach, effectiveness, adoption, implementation, and maintenance. *Reach* refers to the amount of eligible people in a given population (e.g., a particular clinic, city, etc.) versus the amount who actually participate in treatment. *Effectiveness* measures how well an intervention works in the real world if delivered with high fidelity. This stage should examine both positive and negative outcomes (i.e., benefit vs. cost) and measure secondary outcomes (e.g., functioning, quality of life, etc.). *Adoption* refers to the proportion and representativeness of the settings that utilize the treatment. Adoption has also been interpreted at the individual-level to examine the participants who adopted an intervention (e.g., Patel et al., 2018). *Implementation* refers to the degree to which a program is delivered as intended. When an efficacious program is delivered as intended in a real-world setting, it has potential to demonstrate high

effectiveness. Implementation at the individual level can be measured with adherence (e.g. attendance rates). At the setting level, fidelity to the treatment (e.g. clinician adherence) is an important measure. Implementation research is essential to determine if an intervention is practical to deliver in the real world. Lastly, *maintenance* refers to long-term preservation of behavior change. At the individual level, this can be measured by following participants to evaluate if treatment outcomes are maintained long-term. At the organizational level, this can be evaluated with the extent to which the program becomes routine and part of the everyday culture and norms of an organization (e.g., the *full implementation* stage of implementation; The National Implementation Research Network, 2018). The RE-AIM model provides a framework to guide evaluation of interventions that are worth investment and could work in real-world settings. The RE-AIM framework (Glasgow, Vogt, & Boles, 1999) will be utilized in the current study.

Real-World Schizophrenia Research

Current schizophrenia research aims to improve clinical effectiveness, promote dissemination, and standardize psychosocial interventions to bridge science and practice (or lack thereof; Dhillon & Dollieslager, 2000; van der Krieke et al., 2015). For example, The National Institute of Clinical Effectiveness (NICE) guidelines for schizophrenia were created to ultimately improve access and engagement, clarify roles of each intervention, provide advice, and promote implementation (NICE, 2002; NICE, 2009; NICE, 2014). The report was created by multidisciplinary teams informed by scientific evidence to guide clinicians towards best practices as well as help service users and families to make informed decisions about care. The guidelines include physical health interventions, peer-provided & self-management interventions, psychosocial interventions, pharmacological interventions, team

interventions, and vocational rehabilitation. Following the first published NICE guidelines

for schizophrenia, unmet need was evident, for example, only 46% of individuals received

CBTp and 53% received family interventions (FI; Berry & Haddock, 2008). Researchers

have continued to find unmet need, for example it was estimated that between 4-100% of

eligible clients received CBTp and between 0-53% eligible clients received FI (Ince,

Haddock, & Tai, 2016). Cognitive rehabilitation researchers have postulated that unmet need

is evident for these interventions as well (Medalia et al., 2019). Therefore, unmet need is

likely, although estimates are inexact, so it is unclear how much these interventions are

actually being utilized in clinical settings. Nevertheless, EBPs for SMI and schizophrenia are

not reaching the intended audience, and more research is needed to address this need for

improved treatment dissemination. Common barriers to implementation include

organizational issues, attitudes/beliefs of staff members, and client factors (Ince et al., 2016).

The range in implementation factors and level of success may reflect the complexity of

implementing evidence-based psychosocial interventions for schizophrenia. Overall,

implementation research suggests that dissemination of EBPs for schizophrenia is behind its

target, thus leaving eligible clients untreated.

Schizophrenia and SMI Feasibility Studies

Feasibility studies appear to be the most common real-world study among published

schizophrenia and SMI research. Recent feasibility studies have demonstrated positive results

of a novel computerized cognitive rehabilitation program (Byrne et al., 2013; Cellard et al.,

2016; John, Yeak, Ayres, & Dragovik, 2017) and social skills training modified from

existing EBPs (Taksal, Sudhir, Janakiprasad, Viswanath, & Thirthalli, 2016; Wauchope,

Terlich, & Lee, 2016). These studies measured feasibility with various indices, including

attendance, dropout rates, and program outcomes. Reported attendance rates ranged from 79-80% (Taksal et al., 2016; Wauchope et al., 2016) and drop-out rates ranged from 21-38% (Byrne et al., 2013; Taksal et al., 2016). All studies demonstrated some improvement in neuro- or social cognition, although results varied between participants and were generally less robust than controlled studies. John, Yeak, Ayres, and Dragovik (2017) also measured occupational status and living situation, but did not find any significant improvements after participation in the program.

Schizophrenia and SMI Effectiveness Studies

As mentioned above, published effectiveness studies among people with schizophrenia and other SMIs are rare. However, the developers of one evidence-based, manualized social skills program, Social Cognition and Interaction Training (SCIT), have begun to report effectiveness outcomes in real-world settings. The SCIT researchers label their studies as feasibility studies because they include information typical in these types of studies (i.e., acceptability). However, these studies are conducted after the RCT phase, thus can be interpreted as effectiveness studies that include some implementation information. SCIT researchers have attempted to fill the gap of real-world studies in the literature and have published several effectiveness/implementation studies.

The first SCIT real-world study used 20-24 sessions of Social Cognition and Interaction Training (SCIT) in New York City across 5 months (Roberts, Penn, Labate, Margolis, & Sterne, 2010). This study utilized a "collaborative research approach" to balance the rigor of controlled studies with the challenges of clinical settings. The collaborative research approach involved increasing clinician and administrative incentives for participation, maximizing internal validity within a real-world setting, and incorporating

clinician/administrator input. Primary resource challenges related to implementation included client recruitment and time to administer outcome assessments. Client recruitment was resolved by relaxing inclusion criteria and outcome assessment was resolved by modifying assessments to fit a group format. Telesupervision was utilized to gain clinician feedback to improve practicability and transportability for future SCIT manual revisions. To prepare for treatment delivery, clinicians read the manual, attended a half-day workshop, and consulted with treatment developers prior to implementation. During treatment delivery, clinicians participated in weekly supervision calls. The study did not use a comparison group. Regarding acceptability/adoption, participants attended 69% of sessions and 24% of participants dropped out of the intervention. Participant satisfaction ratings were generally positive, as the majority of participants rated SCIT as "helpful" or "very helpful". Clinicians participated in similar satisfaction surveys, also with positive feedback. Outcome assessments revealed statistically significant improvements in social cognition.

A second study evaluated SCIT effectiveness with twelve people in their first episode of schizophrenia in Australia without a comparison group (Bartholomeusz et al., 2013). There were 75% of participants (*n*=9) who completed the intervention (i.e. attending at least 50% of sessions) and these participants attended an average of 69% of the sessions. Participants' responses on satisfaction surveys including topics such as usefulness of the program, likelihood of recommending the group to others, and the intervention helping with participants' routine were positive for the majority of people (e.g. answering "agree" or "strongly agree"). Further, participants improved in social cognition outcomes.

A third study evaluated SCIT effectiveness with individuals diagnosed with schizophrenia in Finland (Voutilainen, Kouhia, Roberts, & Oksanen, 2016). The treatment

was translated to Finnish prior to the intervention. Psychologists and occupational therapists administered 22-24 sessions of SCIT. This study did not have a comparison group. The average attendance was 94.76% and there were no dropouts (*N*=31). Feedback from participants was generally positive, and participants improved in social cognitive outcomes.

Schizophrenia and SMI Implementation Studies

Implementation science studies in real-world environments including people with serious mental illnesses are also scarce. Many studies are descriptive and highlight barriers and solutions to implementation. Van Erp, Van Vugt, Verhoeven, and Kroon (2009) found that implementation of a training module to improve skills of persons with schizophrenia was not feasible in three Dutch agencies due to lack of reach to clients and staffing issues. Pogoda, Cramer, Rosenheck, and Resnick (2011) described barriers of supported employment implementation in the Veterans Affairs (VA) system. They found patient-level as well as organization-level barriers, many of which were misconceptions. For example, one of the themes from employee interviews was: "people with serious mental illness are fragile and incapable of working". Such misconceptions led to low levels of referrals to the program. Organization-level barriers included misconceptions about the treatment model, lack of resources, and low buy-in. Kemp, Zelle, and Bonnie (2015) described implementation challenges of advance directives for people with SMI in a 3-year span. Advance directives are written legal documents or oral statements that allow individuals to declare treatment preferences or designate a proxy decision-maker to act on their behalf. Some of the challenges included client difficulty understanding and utilizing the document/statement effectively, and difficulty incorporating the document/statement into treatment by the agency. Other studies describe the implementation process. For example, Chinman, Shoai, and Cohen

(2010) described the implementation process of Peer Support Technicians (PSTs) in the Veterans Administration. In this report, they shared their decision-making process from team discussions and focused on reporting possible barriers in hiring and implementing these services to prevent such barriers in the future. The results discussed topics such as goals and responsibilities for PSTs, hiring processes, boundaries, and supervision.

CET Real-World Studies

Only two real-world, uncontrolled CET studies have been published: one in 2013 to evaluate feasibility with people with autism (Eack, Bahorik et al., 2013) and one in 2017 to evaluate delivering CET in a group home setting (Schutt, Seidman, Eack, Deck, & Keshavan, 2017). The purpose of the first study (Eack, Bahorik et al., 2013) was to evaluate acceptability and preliminary outcomes of CET with people with autism to prepare for an upcoming RCT. In this non-randomized study, participants were selected based on the following research criteria: age 18-45 years old, have an $IQ \geq 80$, had not abused substances for the past 3 months, did not exhibit behavior problems that would affect group cohesion, and demonstrated cognitive and social disability on the Cognitive Style and Social Cognition Eligibility Interview (Hogarty et al., 2004). The study procedures were supervised by psychologists, and CET administration was provided by master's or doctoral level clinicians who were experts in CET for schizophrenia, and were further trained in CET for autism. Of 25 participants referred for treatment, 14 met inclusion criteria. The retention rate for 18 months of treatment was 79% (*n*=11). Treatment adherence (e.g. attendance rates) was 89% for neurocognitive training and 85% for social cognitive groups. Satisfaction rates were high, with the average rating for participants between "mostly satisfied" to "very satisfied". The researchers also found statistically significant improvements in both neuro- and social

cognition. In the second study (Schutt et al., 2017), the researchers aimed to describe implementation and effectiveness of an adapted version of CET in a group home, and included data after the first 2 months of CET. In this study, participants were selected based on the following criteria: DSM-IV diagnosis of schizophrenia or schizoaffective disorder, age 18 years or older, can speak English, stability of positive symptoms, maintenance of antipsychotic medications, have an IQ $\geq$ 80, demonstrated cognitive and social disability on the Cognitive Style and Social Cognition Eligibility Interview, and having no medical contraindications. Six of the fifteen group home residents were eligible, and one dropped out. Four group home staff were trained to deliver CET with an all-day training, a 2-hour orientation, and a review of the CET manual. Trained staff supervised sessions and a CET expert supervised staff weekly. Results after the first two months of CET indicated that CET participants had a positive first impression of CET. No significant pre- to post- improvements were found in neurocognition, social cognition, self-confidence, or depression.

Gap in the Literature

As noted above, the majority of EBPs for people with schizophrenia and other SMIs lack real-world studies (Dhillon & Dollieslager, 2000; Shidhaye, 2015; van der Krieke et al., 2015). Most of the available studies evaluate feasibility intended to inform future RCTs (e.g., Byrne et al., 2013; Cellard et al., 2016; John, Yeak, Ayres, & Dragovik, 2017); few studies evaluate effectiveness or implementation of existing EBPs after the RCT phase. Evaluating the implementation of an EBP is important to address common practical issues within clinical settings, such as recruitment, attendance, and engagement (Douglas, Campbell, & Hinckley, 2015), which could inform clinical programming. RCTs serve as an experiment in ideal conditions to evaluate optimal efficacy of the program outcomes. However, real-world

environments are far from ideal, which may impact program effectiveness (Singal, Higgins, & Waljee, 2014).

The only two published studies assessing real-world outcomes of CET lack information to elucidate implementation and confirm effectiveness for people with schizophrenia in a real-world setting (Eack, Bahorik et al., 2013; Schutt et al., 2017). The primary aims of these studies were to evaluate the feasibility of CET for people with autism and to deliver CET in a group home setting. However, both studies were small (N=14 and N=5, respectively), there was limited information about the setting, training provided, clinician characteristics, and other real-world variables related to the intervention. No studies have evaluated the effectiveness of the entire CET package in a real-world setting, or to describe implementation after CET is completed (e.g., the setting, attendance, engagement, satisfaction) to guide clinicians in utilizing the program.

The Current Study

The current study will be the first attempt to evaluate the implementation and effectiveness of the entire CET package in a real-world environment. This study utilizes the RE-AIM framework (Glasgow, Vogt, & Boles, 1999) to evaluate reach, effectiveness, adoption, and implementation. The maintenance phase of implementation according to RE-AIM has not yet occurred and will be addressed in the discussion section of this paper. See Table 3 for an overview of the RE-AIM framework and the current study measures of each element. The study examines a CET program administered from 2016 to 2018 in a community mental health program within an academic medical center in an urban setting. This study fits best into a hybrid Type 1 effectiveness-implementation design (Curran, Bauer, Mittman, Pyne, & Stetler, 2012). The Hybrid Type 1 model tests the clinical effectiveness of

an intervention while collecting implementation data. That is, the effectiveness portion of the study is what is being tested or manipulated. The implementation information will be collected during the natural process of implementation in a real-world environment.

Aims and Hypotheses

Aim #1. Participant-Level Reach & Adoption: To evaluate participant-level factors based on Reach and Adoption elements of RE-AIM.

Aim 1a. CET Participant-Level Reach. To evaluate the participant-level reach of the CET intervention, participants will be described in terms of the following: (1) diagnoses, (2) demographics, and (3) enrollment (i.e. number of participants beginning in one of the CET groups).

Aim 1b. **CET Participant-Level Adoption (Satisfaction)**. To address the participant-level adoption of the CET intervention, participant satisfaction will be described. Satisfaction will be measured with qualitative interviews and quantitative surveys.

Aim 1c. **CET Participant-Level Adoption (Adherence).** To address the participant-level adoption of the CET intervention, adherence will be described in terms of attendance, participation, and retention.

Aim #2. **Clinician- and Setting- Level Implementation:** To evaluate the setting- and clinician- level implementation element of RE-AIM, the process of CET utilization will be described, including information about the treatment delivery, clinician characteristics, agency/site characteristics, and barriers/solutions to implementation. This will be described in terms of implementation stages (i.e., exploration, installation, initial implementation, and full implementation; The National Implementation Research Network, 2018).

Aim 2a. Setting- and Clinician- Level Training. To evaluate the exploration, installation, and initial implementation stages of setting-level implementation, the treatment delivery will be described in terms of trainings and support that clinicians participated in, and how fidelity was maintained.

Aim 2b. **CET Clinician Characteristics.** To evaluate clinician-level implementation in the installation and initial implementation stages of implementation, the clinicians will be described in terms of the following: (1) professional qualifications, and (2) retention.

Aim 2c. Setting-Level Characteristics and Implementation. To evaluate setting-level implementation in the installation and initial implementation stages, the agency of implementation will be described in terms of (1) agency type, (2) agency funding, (3) agency resources, (4) CET site physical space, (5) CET site resources.

Aim #3. Effectiveness: To evaluate the RE-AIM element of effectiveness, pre- to post-intervention improvement of CET will be assessed. Using an intent-to-treat model, we included all participants beginning the CET intervention. The following hypotheses are intended to test the effectiveness of CET in a real-world environment.

Hypothesis 3a. **Effectiveness of changes in neuro and social cognition after CET.** Participants engaging in CET will show improvement from pre- to post-intervention in primary outcomes (i.e., neurocognition and social cognition).

Hypothesis 3b. **Effectiveness of changes in positive and negative symptoms after CET.** Participants engaging in CET will show improvements post-intervention in secondary symptom outcomes (i.e. positive and negative symptoms).

CHAPTER 3

METHODOLOGY

Participants

The current study examined data collected from a CET program at Truman Medical Center (TMC), an academic medical center, from 2016-2018. Data included two cycles of four CET groups (two groups per year). Participants included individuals referred to enroll in CET based on clinician judgment regarding the following inclusion criteria: having a diagnosis of schizophrenia or other SMI, neurocognitive impairment, and interest in the CET program. It should be noted that previous CET research recommends that participants have an IQ of at least 80 to participate, however routine IQ testing was not available at this site. Clinicians used clinical judgment to determine eligibility based on this intellectual functioning cutoff. Participants were compensated for their participation in the study. Participants were paid $25 for study session #1, $15 for study session #2, and $25 for study session #3 for a total possible amount of $65. Procedures for each study session is outlined below. The current study was approved by University of Missouri Institutional Review Board (IRB). *N*=34 participants consented and enrolled in the current study.

Setting

The current study was conducted at TMC, a public, academic-affiliated medical center in Kansas City, Missouri. TMC is an urban agency that consists of several locations within the Kansas City metropolitan area. The current study utilized locations from two Behavioral Health programs operated by TMC. Participants were referred to CET by providers within the agency. Once enrolled in CET, all program participants were invited to the study by the researchers.

CET Intervention

The current study examined a community-based version of CET consisting of 48 sessions administered over the course of approximately 12 months (Center for Cognition and Recovery, LLC, 2018; CET Cleveland, 2015). This version is shortened from the research version of CET, which involved treatment for a 2-year (e.g., Eack et al., 2009) or 18-month period (e.g., Eack et al., 2018). The primary distinction between the two treatment versions relates to the computerized neurocognitive training, which shortens the timeframe in the community-based version and consists of a different software program. The research version of CET administers several months of computerized training alone before social cognitive training is added on, while the community-based version begins with 3 sessions of computerized training alone before social cognition groups begin. The number of social cognitive groups (45 sessions), structure and format of groups (homework review, psychoeducation, problem-solving activities, and homework assignment), and general CET content is comparable between the two versions. During the current study, coaches participated in ongoing training for CET certification. This training will be described in more detail in the results section.

Measures

Measures used in the current study are described below. The primary treatment outcomes, neuro- and social cognition, were measured with instruments used in previous CET published research. For comparison with previous CET research, positive and negative symptoms were also assessed with similar measures. Quantitative and qualitative measures of satisfaction were included to capture participant views of the intervention. Satisfaction measures were researcher-created for use in the current study. Implementation data was

collected observationally by the researchers.

Neuro- and Social Cognition

The MATRICS Consensus Cognitive Battery (MCCB) was utilized to assess neuro- and social-cognitive functioning. The MCCB is a battery of cognitive tests standardized for use with people with schizophrenia and other related disorders (Green et al., 2004) and is the only cognitive performance measure developed under a National Institute of Mental Health (NIMH) contract with participation from the U.S. Food and Drug Administration. It was developed through expert consensus by a team of representatives from academia, pharmaceutical companies, and governmental agencies that determined the most relevant cognitive domains in schizophrenia (Marder, 2006). It measures speed of processing, attention/vigilance, working memory, verbal working memory, verbal learning, visual learning, reasoning/problem solving, and social cognition. *Speed of processing* is measured with the following tests: (1) Trail-Making-Test (TMT) A, a timed task which asks participants to draw a line to connect consecutively numbered circles in an irregular order, and (2) Category Fluency: Animal Naming, which asks participants to orally name as many animals as possible in 60 seconds. *Attention/vigilance* is measured with the Continuous Performance Test (CPT), a computer-administered test which asks participants to press a response button to consecutively matching numbers. *Working memory* is measured with the following tests: (1) Letter Number Span (LNS) which asks participants to orally reorder strings of letters and numbers, and (2) Wechsler Memory Scale: Spatial Span which asks participants to tap irregularly spaced cubes on a board in the same or reverse order as the administrator. *Verbal learning* is measured with the Hopkins Verbal Learning Test (HVLT) which asks participants to immediately recall a list of twelve words from three taxonomic

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categories over three trials. *Visual Learning* is measured with the Brief Visuospatial Memory Test (BVMT), which asks participants to immediately recall six geometric figures over three trials. *Reasoning and problem solving* is measured with the Neuropsychological Assessment Battery (NAB) Mazes test, which asks participants to complete seven timed mazes that increase in difficulty. *Social cognition* is measured with the Mayer-Salovey-Caruso Emotional Intelligence Test (MSCEIT): Managing Emotions subscale, which asks participants to answer questions based on scenarios of how people manage emotions. The MATRICS committee chose measures for inclusion in the battery based on sound psychometric features, particularly test-retest reliability (Nuechterlein et al., 2008). Further, all tests have evidence of only small practice effects and no significant ceiling effects or constrictions of variance. Further, the MATRICS battery is considered to have strong evidence of practicability, tolerability and relationship to functioning. It should be noted that the computer-administered Continuous Performance Test (CPT) was omitted in this study for practical reasons and was replaced with the d2 test of attention, a paper-and-pencil test.

The d2 test of attention is a measure of selective attention and processing speed (Brickenkamp & Zillmer, 1998). This test involves a timed task of letter cancellation. The d2 has acceptable construct validity as it is significantly correlated with several related measures (Bates & Lemay, 2004). In this same study, the d2 also showed excellent internal consistency, with alpha levels ranging from $\alpha=.90$ to $\alpha=.97$, with the exception of commission errors, which was $\alpha=.60$, although the authors noted that participants made few errors of commission. The d2 has been used in a number of studies with individuals with schizophrenia and other serious mental illnesses (Brown, Rempfer, & Hamera, 2008; de Montalembert, Coulon, Cohen, Bonnot, & Tordjman, 2016; Nielsen, Haugaard, Jensen,

Munk-Jorgensen, & Christensen, 2013; Zayat, Rempfer, Gajewski, & Brown, 2011).

Symptomatology

The Scale for Assessment of Negative Symptoms (SANS; Andreasen, 1984a) and the Scale for the Assessment of Positive Symptoms (SAPS; Andreasen, 1984b) are semi-structured interviews that assess the common negative and positive symptoms in schizophrenia and related conditions. The SANS measures affective flattening or blunting (e.g. facial expression, eye contact, etc.), alogia (e.g. content of speech, response latency, etc.), avolition-apathy (e.g. hygiene, physical anergia, etc.), anhedonia-asociality (e.g. recreational interests, relationships, etc.), attentional impairment (e.g. attention during mental status testing or during social interaction). Interrater reliability of the SANS has been established ($r=0.70$ to 0.93; Andreasen, 1982). Internal consistency was measured with Cronbach's Alpha and was $\alpha=.89$ for the total score. For the subscales, internal consistency was $\alpha=.81$ for affective flattening, $\alpha=.83$ for alogia, $\alpha=.84$ for attentional impairment, $\alpha=.80$ for avolition-apathy, and $\alpha=.63$ for anhedonia-asociality. The SAPS measures hallucinations, delusions, bizarre behavior, and positive formal thought disorder. The intraclass correlations ranged from $r=.75$ to $r=.97$ on most subscales (Schuldberg, Quinlan, Morgenstern, & Glazer, 1990). However, bizarre behavior was lower, $r=.40$. Temporal stability was measured by retesting in a 24-month timeframe and ranged from $r=.38$ to $r=.57$ for all but bizarre behavior, which was a $r=.02$. Internal consistency ranged from $\alpha=.72$ to $\alpha=.86$ for the subscales and was $\alpha=.91$ for the composite of items.

CET Satisfaction

The CET Satisfaction Survey is a 13-item questionnaire that aims to assess participants' level of satisfaction with CET. This measure was developed for use in the current project

based on the core components of the CET intervention (i.e., neurocognitive training, social cognitive group, coaching, and homework). The CET Satisfaction Survey can be found in Appendix A.

The Perceptions of CET Interview is a semi-structured interview to examine participant's subjective satisfaction and perceptions of CET. This exploratory interview asks open-ended questions to assess participant's experiences of CET and provide the opportunity to share their perception of the meaning of CET participation for them (Fontanella, Campos, & Turato, 2006). This interview was audio recorded for transcription purposes. This measure was also developed for use in the current project. The Perceptions of CET Interview can be found in Appendix B.

Procedure

For the current study, data collection began in 2016 and ended in late 2018. Study enrollment and all research procedures occurred at Truman Medical Center. After eligibility was determined, interested participants were referred, and, if still interested, completed informed consent.

The study involved three data collection sessions. Study session #1 included symptom, social cognitive, and neurocognitive assessment, which occurred as close to the beginning of CET as possible. Study session #2 occurred mid-treatment and included the satisfaction survey and perceptions of CET interview. Study session #3 occurred after CET participation and involved post-treatment evaluation of symptom, social cognitive, and neurocognitive measures, as well as the satisfaction survey and perceptions of CET interview. For the purpose of the current study, satisfaction is reported at post-testing only (study session #3).

Data Analysis

Sample Size & Power

The sample was a convenience sample dependent on enrollment in the CET program. Using G*Power software, a power analysis was used to determine the minimum number of participants needed to achieve adequate power (e.g. 0.80) to reach a significance level of $p<.05$ to detect pre- to post- differences of the intent-to-treat CET group sample (Cohen, 1988). For a medium effect size of .5, a total sample size of N=34 was determined.

Analytic Plan

Aim #1. Participant-Level Reach & Adoption: To evaluate participant-level factors based on Reach and Adoption elements of RE-AIM.

Aim 1a. CET Participant-Level Reach. To address Reach, CET participants were described using descriptive statistics in terms of the following: (1) diagnoses, (2) demographics, and (3) enrollment (i.e. number of participants beginning in each CET group).

Aim 1b. CET Participant-Level Adoption (Satisfaction). To address the participant-level adoption of the CET intervention, participant satisfaction was described. Satisfaction was measured with post-CET qualitative interviews and quantitative surveys. Quantitative data from the satisfaction survey was described using descriptive statistics. Interviews were first transcribed by a research assistant. Then, semi-structured interviews were analyzed following the six-phase procedures of thematic analysis to describe patterns that emerged related to satisfaction (Braun & Clarke, 2006). In the first phase (*familiarization with the data*), the coder thoroughly read transcribed interviews. In the second phase (*generating initial codes*), the coder coded interviews to summarize information. For phase three (*searching for themes*), the coder recognized potential themes and organized codes into themes. For phase

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four (*reviewing themes*), the coder refined themes by organizing potential subthemes, and reviewed codes within each theme to check accuracy of each theme. In phase five (*defining and naming themes*), the coder identified participant quotes for each theme and tallied all codes within themes. To complete phase six (*producing the report*), content of each theme was reported in the results section.

Aim 1c. **CET Participant-Level Adoption (Adherence).** To address the participant-level adoption of the CET intervention, adherence was described using descriptive statistics in terms of acceptability (i.e., attendance rates, records of participation in computerized training, and retention rates).

Aim #2. *Clinician- and Setting- Level Implementation:* To evaluate the setting- and clinician- level implementation element of RE-AIM, the process of CET utilization was described using descriptive statistics and qualitative information, including information about the treatment delivery, clinician characteristics, agency/site characteristics, and barriers/solutions to implementation. This was described in terms of implementation stages: exploration, installation, initial implementation, and full implementation (The National Implementation Research Network, 2018).

Aim 2a. Setting- and Clinician- Level Training. To evaluate the exploration, installation, and initial implementation stages of setting-level implementation, the treatment delivery was described with descriptive qualitative data in terms of trainings and support that clinicians participated in, and how fidelity was maintained.

Aim 2b. **CET Clinician Characteristics.** To evaluate clinician-level implementation in the installation and initial implementation stages of implementation, the clinicians were

described using descriptive statistics in terms of the following: (1) professional

qualifications, and (2) retention.

Aim 2c. **Setting-Level Characteristics and Implementation.** To evaluate setting-level

implementation in the installation and initial implementation stages, the agency of

implementation was described using descriptive qualitative data in terms of (1) agency type,

(2) agency funding, (3) agency resources, (4) CET site physical space, (5) CET site

resources.

Aim #3. Effectiveness: To evaluate the RE-AIM element of treatment effectiveness, pre- to

post- intervention improvement of CET was assessed. Using an intent-to-treat model (ITT;

Little & Yau, 1996; Mazumdar, Liu, Houck, & Reynolds, 1999), we included all participants

beginning the CET intervention. ITT posits that any participant beginning an intervention

(even those that drop out) should be included in analyses to detect any possible treatment

effects. The following hypotheses were intended to test CET effectiveness in a real-world

environment.

Hypothesis 3a. **Effectiveness of changes in neuro and social cognition after CET.** To

evaluate post-intervention improvements in neurocognition and social cognition, a series of

paired samples t-tests were completed for each MCCB subtest raw score and the d2 test of

attention. This analytic approach was intended to decrease the possibility of Type II Errors

(i.e., not detecting a true effect), given our small sample and uncontrolled study design.

Paired samples t-tests have been utilized in studies that aim to provide preliminary data in

real-world environments, especially those with small samples and within-group designs (e.g.,

Voutilainen et al., 2016). Alpha level for each analysis was set at $p<.05$.

Participants who complete CET were further evaluated using Reliable Change Index (RCI) to detect clinically significant changes (Jacobson & Truax, 1991). The RCI was calculated by dividing the difference between the pre- and post- treatment scores by the standard error of measurement. If the RCI was greater than 1.64 (i.e., 90% confidence interval), then the difference is considered reliable, meaning that the change was not due to measurement error. Although 1.96 is typically used for RCI in clinical measures, 1.64 is conventional for neuropsychological measures (Duff, 2012). Thus, if the RCI was 1.64 or less, the change is not considered reliable (i.e. it could have occurred from measurement error).

The following formula illustrates this calculation:

$$RCI = (posttest - pretest) / SE_{measure}$$

Hypothesis 3b. **Effectiveness of changes in positive and negative symptoms after CET.**

To evaluate improvements from pre- to post-intervention in positive and negative symptoms, a series of paired samples t-tests were completed using the raw score for each subscale of the SANS (negative symptoms) and SAPS (positive symptoms). Alpha level for each analysis was set at $p<.05$.

The RCI was also calculated for SANS and SAPS subscale raw scores (Jacobson & Truax, 1991). If the RCI was greater than 1.96 (i.e., 95% confidence interval), then the difference is considered reliable, meaning that the change was not due to measurement error.

CHAPTER 4

RESULTS

Aim 1. Participant-Level Reach & Adoption.

Aim 1a: CET Participant-Level Reach. *N*=45 individuals initially enrolled in CET.

Participants who engaged in CET with completed pre- to post- intervention data included

N=34 participants (i.e., the intent-to-treat sample). Of these, *n*=27 participants graduated

CET and *n*=7 dropped out. See Figure 2 for descriptive information regarding retention and

participant flow. Participants had a mean age of 39.47 (*SD*=13.14) and were majority male

(*n*=25, 74.5%). Most participants had a schizophrenia (*n*=26, 76.5%) or schizoaffective

disorder (*n*=4; 11.8%) diagnosis. Comorbid diagnoses included depression (*n*=8, 23.5%),

anxiety (*n*=5, 14.7%), PTSD (*n*=3, 8.8%), and ADHD (*n*=1, 2.9%). See Table 4 for full

demographic information of the intent-to-treat CET sample.

Aim 1b: CET Participant-Level Adoption (Satisfaction). Quantitative data from the

satisfaction surveys indicated that participant satisfaction with CET was high and positive for

the majority of participants. The majority of participants indicated that they either *agreed*

somewhat or *completely agreed* to satisfaction questions, ranging from 79.31% to 96.55% for

all 13 satisfaction questions. See Table 5 for descriptive information for each satisfaction

question.

Qualitative satisfaction measured with semi-structured interviews was similarly

positive. *n*=24 participants completed interviews and agreed to have their interview responses

audio recorded. Eight major themes emerged from the thematic analysis: 1) Coaching was

valuable, 2) Criticism of coaching, 3) Satisfaction with a particular CET activity 4) Dislike of

a particular CET activity 5) Functional improvements 6) Improved confidence 7) Peer

support, and 8) Motivated for education or employment. These themes will be described in more detail below. Themes, subthemes, and representative quotes from participants are presented in Table 6.

Theme 1: Coaching was valuable. Participants mentioned their appreciation for CET coaching, including both group and individual coaching. The majority of participants (n=21; 87.50%) discussed the value of coaching. Many participants had not experienced this level of individualized guidance before. Thus, coaching was particularly salient for a number of participants. Participants had positive views of individual and group coaching and generally had a good relationship with their individual coach.

      Subtheme 1. Coaches helped with homework. Coaches provided tangible support with weekly individual coaching meetings to help participants with homework. Some participants noted that they would have had difficulty completing and/or understanding the homework without the coach. A few participants suggested that coaches' guidance was helpful, although coaches did not provide answers for participants. One participant notably stated that they would have stopped attending CET if the coach did not allow the participant to answer on their own. Therefore, participants suggested that coaching was collaborative.

      Subtheme 2. Coaches motivated or supported participant. Coaches provided encouragement by motivating participants or showing their support. Several participants mentioned coaches providing positive reinforcement for attending sessions. Some participants were appreciative of coaches being sensitive to missed sessions, as to avoid discouraging or shaming participants. Other participants noted that the coaches provided support during CET groups, which included positive reinforcement, guidance, and setting high expectations.

Subtheme 3. Coaches were skilled. Many other participants mentioned that they perceived the coaches as being skilled in their work. For example, many participants mentioned that the coaches were good teachers. Each group had three coaches during this CET training period; some participants mentioned that the coaches worked well together and provided different styles of teaching and coaching. Others mentioned that the coaches provided useful feedback, and were enthusiastic or energetic.

Subtheme 4. Participant complimented coach. Some participants showed their appreciation of coaching through complimenting their coaches. For example, participants noted that coaches were nice, reliable, and friendly. Many participants said the coaches were "good" or "great" coaches throughout CET.

Theme 2: Criticism of coaching. A small number of participants provided a criticism of coaching (*n*=4; 16.67%). One participant felt like their coach gave them the answers in homework and felt rushed. Two participants mentioned that they had some difficulty understanding how some coaches explained concepts in CET. Another participant felt pressured to give correct answers.

Theme 3: Satisfaction with a particular CET activity. Participants expressed satisfaction with a range of CET activities, and varied their opinions of favorite activities and why they enjoyed them. The majority of participants discussed activities they enjoyed (*n*=18; 75.00%). Participants mentioned every CET activity (computerized neurocognitive training, homework, problem-solving, and psychoeducation) when discussing positive experiences of CET, indicating that participants were generally satisfied with CET activities.

Subtheme 1. Enjoyed challenging self. Many participants enjoyed challenging themselves during CET groups. For some, the neurocognitive activities (either during

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computer or social cognitive groups) were a rewarding challenge. For example, some participants specifically mentioned enjoying the computer activities, while others enjoyed the partnered problem-solving activities. For others, social aspects of the group were a fulfilling challenge (e.g., public speaking).

Subtheme 2. Enjoyed learning something new. Participants enjoyed learning something new during CET, such as information or skills. Many mentioned the psychoeducation portion as their favorite activity because they enjoyed learning a new topic that was relevant to them. For example, participants mentioned gaining information about their mental illness to understand themselves better and/or improve their coping skills.

Theme 4: Dislike of a particular CET activity. Some participants mentioned that they did not enjoy at least one of the CET activities (*n*=11; 45.83%). Many participants mentioned that they did not care for the computerized neurocognitive training. Some participants mentioned aspects of the social cognitive training that they disliked (e.g., public speaking, problem-solving activities, interacting with other peers).

Subtheme 1. Computer activities were boring or repetitive. Participants mentioned that computer activities were too repetitive and/or boring. Some commented that the computer software was noticeably outdated and that their personal computer and/or phone games were more entertaining. Others mentioned that the computer portion of the groups were too long and should be shortened and/or restructured. Some commented that other participants dropped out of CET because the computer activities were too boring or repetitive.

Subtheme 2. Computer activities were too difficult or confusing. Some participants mentioned that the computer activities were too difficult or confusing. For

example, a few participants mentioned that the computer activities were so difficult that they had trouble passing any levels. Others mentioned being confused by some of the activities, and that made it difficult for them to complete them.

Subtheme 3. Recognized computer activities were helpful, but disliked them.
Others recognized that the computer activities were helpful, but did not enjoy them. These participants understood why computer activities were part of CET, but did not enjoy or look forward them.

Subtheme 4. Disliked one (or more) social cognitive activity. Although less common, some participants did not enjoy one or more social cognitive group activities. Some of these participants did not enjoy personal challenges that went along with the social cognitive group, for example public speaking or sharing personal experiences. Others did not enjoy activities that did not feel like the right level of difficulty, either too difficult or too easy.

Theme 5: Functional improvements. The majority of participants mentioned aspects of their functioning that improved as a result of CET (n=21; 87.50%). Participants gave examples of their functional improvements in daily life, either with their family, activities of daily living (e.g., hygiene), or in other situations.

Subtheme 1. Improved social skills. Participants discussed various social skills that improved. Many mentioned improved communication with others. Some discussed improved social skills as a result of improved thinking. For example, one participant reflected that his mind used to go blank in social situations, but since graduating CET he is better able to make social judgements.

Subtheme 2. Improved thinking. Participants mentioned aspects of their thinking that improved. Some mentioned improvements in their thoughts, for example increased flexibility, clearer thinking, and faster thinking. Others mentioned neurocognitive improvements, such as attention, problem-solving, and memory.

Theme 6: Improved confidence. Participants described increases in confidence during or after the CET group (n=10; 41.66%). Some participants described confidence increasing after a specific CET activity, for example successful completion of problem-solving within the CET group. Others noted that completing the entire CET course improved their confidence.

Theme 7: Peer support. Participants described peer support during CET participation (n=13; 54.17%). This peer support often including help and/or encouragement from other group members, both in the social cognitive group and computer neurocognitive training.

Subtheme 1. Enjoyed learning from other people. Participants mentioned enjoying learning from other people, frequently occurring during homework-sharing of the social cognition group. For example, one person noted that they enjoyed learning from others' experiences and believe this benefitted them. Others noted that they felt humbled by hearing others' experiences.

Subtheme 2. Enjoyed interacting with other people. Participants mentioned their enjoyment of interacting with other people. For example, being part of the group, getting to know people, and engaging in activities together.

Subtheme 3. Noticed improvements or successes of peers. Participants mentioned that they noticed improvements or successes of their peers. For example, other peers opening up to the group or improving their thinking. Some of these participants noted their sense of pride of other peers' improvements.

Theme 8: Motivated for education or employment. Participants expressed feeling

motivated to gain employment or enroll in schooling (*n*=12; 50%). Many participants had

this goal at the start of CET, and realized increased confidence through learning skills

relevant to jobs or educational endeavors. Some participants began schooling previously and

wanted to finish, while others would be starting a program for the first time. Participants had

varied employment goals, but many expressed this as a possibility following CET. Some

participants successfully gained employment during CET.

Aim 1c: CET Participant-Level Adoption (Adherence). *N*=45 participants began CET

and *n*=29 graduated, resulting in a retention rate of 64.44%. Attendance for CET graduates

was measured by percent and number of groups attended. Exact number of days attended was

available for *n*=16 participants, and attendance percent was available for *n*=29 participants.

For participants with exact number of days attended data, attendance percent was calculated

by dividing days attended by the total number of available CET sessions. For participants

without exact number of days data, percent attended was estimated and reported by CET

coaches. Participants attended *M*=39.88 days (*SD*=6.42) and 80.62% of sessions. Regarding

engagement, records of computerized neurocognitive training provided the number of levels

passed for each participant. Engagement data was available for *n*=33 participants in the

intent-to-treat sample. The mean number of levels passed was 17.53 (*SD*=12.92). The range

was 0-52. The majority of participants passed between 11-20 levels (*n*=10) or 10 or fewer

levels (*n*=10). There were *n*=7 participants who passed between 21-30 levels and *n*=5

participants who passed 31 or more levels. Lastly, there was *n*=1 participant who did not pass

any levels. Of the participants with engagement data, *n*=4 were CET dropouts. Of this

subgroup of CET dropouts, *n*=1 participant did not pass any levels, *n*=2 participants passed 3 levels, and *n*=1 participant passed 17 levels.

Aim 2. Clinician- and Setting- Level Implementation.

Aim 2a. Setting- and Clinician- Level Training. The *exploration stage* of implementation occurred prior to the current study when CET was piloted in 2012 by two clinicians. Clinicians independently learned the intervention by purchasing the CET manual created by researchers in Pittsburgh (e.g., Eack et al., 2009). At this time, there was no formal agency-sponsored training. One of the barriers to implementation during this stage was that CET was difficult to organize, prepare, and successfully implement according to the manual, as CET is an intensive and complex program. Additionally, CET did not grow within the agency to provide multiple groups or with a clinical team. To overcome this barrier, more resources were allotted to CET, including funding and training, which is further explained below.

During the *installation stage* of implementation, setting-level implementation was supported with various resources (e.g., training, supervision, and observation). From 2016-2017, *n*=7 clinicians were formally trained by the Center for Cognition and Recovery (CCR) to receive clinical certification (Center for Cognition and Recovery, LLC, 2018). CCR is a non-profit agency that provides treatments and trainings. Their mission is: "…to serve the community through innovative training and education. We change lives and inspire hope through outcome driven and/or evidence-based practices" and their vision is: "[We aspire] to change lives by providing quality, innovative solutions through training, education and services." The first year of training included weekly tele-observation of each CET group and monthly in-person didactic and experiential training. Weekly observation included the trainer participating in each group, monitoring fidelity, and providing feedback to coaches. Monthly

in-person training included instruction of each new social cognition problem-solving exercise, practical tips for delivering the intervention, and supporting practical planning of CET lessons.

In the second year of training, the *initial implementation* stage, two coaches completed training to become CET trainers to have the ability to train future CET coaches within TMC. Coaches becoming trainers prevented the possible barrier of lack of resources to provide CET and maintain the program, namely limited number of staff available to deliver the intervention. During this second year, CCR continued to monitor fidelity with monthly observation. TMC continues to work with CCR to maintain certification and uphold licensing fees.

Aim 2b. CET Clinician Characteristics. During the study period, during both *installation* and *initial implementation* stages, coaches included a total of *N*=11 clinicians who participated in CET certification. These included *n*=4 Bachelor's level clinicians, *n*=2 Master's level clinicians, *n*=2 psychiatrists, *n*=2 nurses, and *n*=1 music therapist.

The first training year began in the *installation* stage with *N*=7 clinicians participating in CET certification. After the training year, *n*=6 coaches became certified, and *n*=1 coach left the agency before completing certification. Retention for CET certification after the first year was 85.7%.

At the beginning of *initial implementation* in the second year, *n*=3 coaches decided not to continue coaching CET due to other professional obligations. Regarding training in the second year, *n*=4 new coaches began training for CET certification, and *n*=3 coaches from the first training year began training to become a CET trainer. After this second training year, *n*=1 coach who was training to be a trainer left the agency. Another coach (*n*=1) left the

agency upon completing coach certification. Retention for new coaches participating in training this second year was 66.67%.

Regarding retention for active CET certified coaches for all coaches beginning training, 4/11 coaches remained, with a retention rate of 36.36%. See Figure 3 depicting coach retention and turnover.

Aim 2c. **Setting-Level Characteristics and Implementation.** The CET program was implemented at Truman Medical Center (TMC), an academic medical center with several locations in the Kansas City metropolitan area (Truman Medical Center, 2018). Their mission statement is: "Truman Medical Centers is an academic health center providing accessible, state-of-the-art quality healthcare to our community regardless of the ability to pay" and their vision is: "Leading the way to a healthy community". It is affiliated with the University of Missouri Kansas City (UMKC) and is the primary teaching hospital for UMKC School of Medicine. TMC is one of the primary resources for people with mental illnesses in metropolitan Kansas City, as it has the "largest, most comprehensive behavioral health program in the area". TMC Behavioral Health includes outpatient and inpatient community mental health services in Eastern Jackson County, MO (e.g., individual therapy, group therapy, and psychiatry services), outpatient mental health services in downtown Kansas City (e.g., individual therapy, group therapy, psychiatry services, and supported employment), and other community programs (e.g., drug and alcohol services, homeless services, and psychiatric rehabilitation).

A barrier to implementation was training, which was overcome through securing funding and identifying resources for training. During the *installation* stage, to support the CET program training, Truman Medical Center was awarded a grant from the Health Care

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Foundation of Greater Kansas City (now known as Health Forward Foundation). This grant provided $100,000, which supported the training provided by Center for Cognition and Recovery to facilitate implementation of the program.

Another barrier was the location and space to provide CET services. In the first cohort (2016-2017) during the *installation* stage, groups were administered at two separate locations. This occurred for convenience for staff, as coaches during this stage worked in each of these different locations. Group 1 was provided in a TMC Behavioral Health community program that serves individuals experiencing homelessness. It began in an unused private room and was moved to a larger room in the milieu area of the program due to more space needed. The second room was closed with a sliding door for privacy. Group 2 was administered within a TMC Behavioral Health psychiatric rehabilitation community program. During this first cohort year, Group 2 was provided in a room previously used for storage and was adapted by the coaches and psychiatric rehabilitation program director to provide more space for the group size. In the second cohort (2017-2018) both groups were provided at the TMC Behavioral Health psychiatric rehabilitation program. During this second cohort year, the psychiatric rehabilitation program relocated .2 miles down the road from its original location to a newer building. The old building was subsequently demolished. The new group room is more spacious and has windows, and is primarily used for CET groups. This current group room allows CET to be provided in a central location convenient to participants nearby to a bus line. This centralized location improved the barrier of transportation that was evident for some participants, especially those traveling to the TMC Behavioral Health community program. See Table 7 for a summary of barriers and overcoming barriers in each stage of implementation.

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<center>**Aim 3. Effectiveness.**</center>

Aim 3a: Effectiveness of changes in neuro and social cognition after CET. A series of paired samples t-tests were completed to analyze pre- to post- changes in neuro- and social cognition using the intent-to-treat sample. Of the 10 neurocognitive domains tested (subtests included from the MCCB and the d2), participants significantly improved in three tests, verbal learning as measured with the HVLT, $t(33)=-2.112$, $p=.042$, , $d=.387$, visual memory as measured with the BVMT, $t(32)=-2.145$, $p=.040$, $d=.302$, and attention as measured with the d2, $t(32)=2.98$, $p=.005$, $d=.356$. See Table 8 for descriptive information of cognitive outcomes.

Clinically meaningful change was calculated using the reliable change index for each MCCB subscale using a 90% confidence interval (RCI of 1.64 or greater; Duff, 2012). Overall, $n=27$ people (79.41%) improved on at least one subtest. Of the participants who improved on more than one subtest, $n=9$ participants improved on 2 subtests (26.47%), $n=3$ participants improved on 3 subtests, and $n=1$ participant improved on 5 subtests. The greatest number of improvements was in the d2 test of attention where $n=19$ people (55.88%) improved. Other improvements included the following MCCB subtests: the BACS (speed of processing; $n=9$, 26.47%), TMT (speed of processing; $n=4$, 11.76%), Fluency: Animal Naming (speed of processing; $n=3$; 8.82%), HVLT-R (verbal memory; $n=3$, 8.82%), LNS (verbal working memory; $n=2$, 5.88%), NAB Mazes (reasoning & problem-solving; $n=2$, 5.88%), BVMT-R (visual learning; $n=2$, 6.06%), and MSCEIT (social cognition; $n=1$, 2.94%). There were not any improvements in the WMS-III: Spatial Span (nonverbal working memory).

Aim 3b: Effectiveness of changes in positive and negative symptoms after CET. A series of paired samples t-tests were completed to analyze pre- to post- changes using the intent-to

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treat sample. Of the 5 negative symptom (SANS) subscales, participants significantly improved in 3 areas, avolition-apathy, $t(33)=2.083$, $p=.045$, $d=.458$, anhedonia-asociality, $t(33)=4.226$, $p=001$, $d=.802$ and attention, $t(33)=-2.98$, $p=.005$, $d=.356$. Of the 4 positive symptoms (SAPS) subscales, participants significantly improved in 3 areas, hallucinations, $t(33)=2.811$, $p=.008$, $d=.364$, bizarre behavior, $t(33)=4.343$, $p=.001$, $d=.779$, and positive formal thought disorder, $t(33)=2.692$, $p=.011$, $d=.517$. See Table 9 for descriptive information of cognitive outcomes.

Clinically meaningful change was calculated using the reliable change index for each SANS and SAPS subscale using a 95% confidence interval (RCI of 1.96 or greater). Overall, $n=33$ people (97.06%) improved on at least one SANS or SAPS subscale. For the SANS, $n=25$ people (73.53%) improved on at least one subtest. The greatest number of improvements was in the attention subscale, where $n=20$ participants (58.82%) improved. Other improvements included alogia, $n=11$ (32.35%), affective flattening, $n=8$ (23.53%), avolition-apathy, $n=7$ (20.59%), and anhedonia-asociality, $n=6$ (17.65%). For the SAPS, $n=28$ people (82.35%) improved on at least one subtest. The greatest number of improvements was in the positive formal thought disorder subscale where $n=20$ participants (58.82%) improved, followed by the bizarre behavior subscale where $n=11$ participants (32.35%) improved. There were $n=7$ people (20.59%) who improved in the hallucinations subscale, and $n=9$ people (26.47%) who improved in the delusions subscale.

CHAPTER 5

DISCUSSION

The current study described the implementation and effectiveness of Cognitive

Enhancement Therapy (CET) in a real-world setting. This was the first study to examine the

entire CET package in a real-world environment, as well as the first published study of the

12-month version of CET. Our results demonstrated successful implementation of CET in a

community mental health program within an academic medical center. Additionally, the

current results provided preliminary support for the real-world effectiveness of CET.

Participants were successfully recruited for CET by clinicians from a community-

based outpatient program. This is important to note, as the researchers did not control

recruitment of the CET program, so these participants may be even more representative of

typical clients who are eligible for CET offered in typical community settings. With regard to

the representativeness of our CET participants, our results indicated that current participants

were somewhat similar to the controlled CET published studies, although there were some

differences. In terms of qualifying diagnostic criteria, the majority of our participants had

diagnoses comparable with previous studies (i.e., schizophrenia, or schizoaffective disorder).

However, some participants who were referred had other primary serious mental illness

diagnoses not included in previous CET studies (i.e., PTSD), or comorbid mental illness

diagnoses. Staff members referred these participants based on clinical judgment regarding

motivation and presence of neuro- and social cognitive deficits. It is unclear if participants

with PTSD are appropriate for CET, as current research only includes participants with

schizophrenia, schizoaffective disorder, or autism (Eack et al., 2009; Hogarty et al., 2004;

Eack et al., 2018). Many participants received their schizophrenia or schizoaffective disorder

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diagnosis more than 5 years ago, thus were not in the early phase of the illness. Some

published CET studies only included early phase patients (Eack et al. 2009), while others

included people with chronic schizophrenia (Hogarty et al., 2004). Additionally, our

participants were older than the majority of previous studies; Studies reported mean ages

including 25.92 (Eack et al., 2009), 22.55 (Eack et al., 2018), and 37.3 (Hogarty et al., 2004),

compared with our study of a mean age of 39.47. The current study demonstrates that CET

can be effective, successfully implemented, and acceptable to participants who are older and

in the chronic phase of their illness (at least for those participants in the majority of our

sample). This is important to note because cognitive rehabilitation researchers are moving

towards early intervention as potentially more effective in treating symptoms and improving

functional outcomes (Barlati et al., 2015; Revell, Neill, Harte, Khan, & Drake, 2015).

Researchers have found that decreasing the amount of time between psychotic symptoms and

treatment (i.e., "duration of untreated psychosis") is an important factor in recovery and

functional outcome (Cheng & Schepp, 2016; Kurachi, Takahashi, Sumiyoshi, Uehara, &

Suzuki, 2018), thus early intervention may help decrease "duration of untreated psychosis".

However, it may not be feasible in real-world settings to exclusively recruit people in the

early phase of their treatment. Our study evaluated participants recruited from a typical

setting with outpatients from a range of age groups, and overall demonstrated that

appropriate participants (based on eligibility and efficacy in previous research) engaged with

the intervention in our real-world setting for the CET intervention.

Further examining participant characteristics, our participants were ethnically diverse,

and the majority of individuals were from an ethnic minority. Satisfaction ratings were high

for the majority of participants, supporting the acceptability of CET in our culturally diverse

sample. Previous CET studies utilized majority White samples (Eack et al., 2009; Eack et al., 2018; Hogarty et al., 2004). This is important to note, although our study did not explicitly evaluate cultural competency of the intervention, the intervention appeared acceptable to participants, including those identifying as an ethnic minority. It is possible that content in social cognitive groups may be sensitive to cultural norm differences for participants to effectively respond to prompts and task assignments. For example, previous research has found that communication between clinicians and clients is extremely important, such as incorporating the client's interpretation of their illness, collaborative care, and clear discussion of confidentiality (Aggarwal et al., 2016). Perhaps CET content along with supportive coaching facilitated culturally appropriate communication to support program effectiveness and client acceptability. Additionally, a major component of CET groups is discussing personal, social experiences with participants, which is an important factor in culturally relevant therapies (Lopez & Guarnaccia, 2000). Although we cannot definitively evaluate how cultural differences affected effectiveness or acceptability, it is important to note that this was the first evaluation of CET with individuals from an ethnic minority.

CET was acceptable to participants, as evidenced by positive satisfaction ratings on quantitative surveys and as reported in qualitative interviews. Participants' responses on quantitative surveys indicated high levels of satisfaction regarding core components of CET. Qualitative interview data mirrored much of the quantitative results. CET coaching appeared to be one of the most valuable aspects of the CET intervention for participants. Individualized CET coaching includes collaborative goal-setting, completion of homework, and positive reinforcement throughout the entire treatment. As coaches met with participants weekly for a full year, it likely was a meaningful relationship, and may have been even more

powerful for people who have not had this type of supportive therapeutic relationship before. Research has shown that the therapeutic relationship has a positive impact on recovery (Moran et al., 2014; Neale & Rosenheck, 1995) and is related to empowerment (Russinova et al., 2013). The collaborative CET relationship may also support aspects of shared decision-making (e.g. Hamann et al., 2016). Thus, the coach-participant relationship in CET was a very important aspect of the intervention that supported recovery-oriented treatment. Participants' satisfaction of specific CET activities varied, although were mostly positive. Qualitative analyses additionally found secondary benefits of CET, for example improved confidence, which is an important factor for recovery (Davis, Kurzban, & Brekke, 2012). Peer support was another theme identified by our CET participants, and is recognized as an important recovery factor (Gidugu et al., 2015; Mancini, Linhorst, Menditto, & Coleman, 2013; Resnick & Rosenheck, 2008; Rogers et al., 2016), and supports treatment outcomes (Aschbrenner, Naslund, & Bartels, 2016). The most salient criticism of CET was negative views of computerized neurocognitive training. Many reported that it was their least favorite part of CET, although many recognized the benefit, regardless of whether or not they enjoyed it. Perhaps future research may investigate differences between various neurocognitive software used in CR programs. Further, these CET experiences align with empowerment literature, namely peer support, power, optimism and control, and self-esteem; these results have been published in detail elsewhere (Faith et al., 2019). Regarding CET satisfaction, these results support the acceptability of CET for participants in a real-world setting.

Additionally supporting acceptability, attendance rates were high for the CET graduates and comparable with previous research. As CET is a lengthy and intensive program, attendance may be challenging for participants. Further, people with serious mental

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illnesses could face additional barriers that interfere with attendance, such as symptom

exacerbations in addition to usual practical challenges (e.g., attendance). Thus, high

attendance for participants with SMI in an intensive, lengthy program is especially striking as

an important indicator of the acceptability of the CET program. Conversely, our retention

rate of 64.44% was lower than one previously published CET study, which were reported as

81% at 1-year of treatment (Eack et al., 2009), but higher than another study that reported a

retention rate of 53% at 12 months (Eack et al., 2015). Both studies were randomized-

controlled trials, however the second study included people who were currently misusing

substances. Although we did not measure substance use, perhaps the sample of participants

in this second study was a closer representation of the participants in our study (e.g.,

including participants who have at least one possible barrier to retention). Engagement with

the intent-to-treat sample, measured with number of levels passed during neurocognitive

training, ranged quite a bit. Engagement continues to be an important emerging area in

cognitive rehabilitation and schizophrenia research (Dixon, Holoshitz, & Nossel, 2016).

Current researchers have identified therapeutic alliance, person-centered care, and peer

support as important for treatment engagement. CET supports all three of these variables

with weekly coaching, individualized treatment plans, and partner and group support.

Perhaps participants with higher engagement had more effective or impactful support in these

areas. Participants may attend groups, but engagement with the intervention is essential for

meaningful change. This could explain why some of our participants did not improve in

neurocognition following the intervention (e.g., when measured with the reliable change

index to detect clinically meaningful change). Understanding adherence and engagement is

an issue of great importance in schizophrenia research, and is being investigated in recent

research. For example, one study found that better neurocognitive functioning is associated with better attendance (Gooding et al., 2012). Perhaps intensive support in the beginning of CET may help attendance before neurocognitive improvements occur. Another study found that motivational interviewing improves engagement in cognitive rehabilitation (Fiszdon, Kurtz, Choi, Bell, & Martino, 2016). Perhaps adjunctive treatments in CR programs may be used to support individuals who have difficulty engaging with the intervention. Future studies should continue to understand predictors of engagement and adherence as well as strategies to improve engagement and adherence.

Coach trainings were provided by Center for Cognition and Recovery (CCR), a clinical agency that provides training and support for CET (Center for Cognition and Recovery, LLC, 2018; CET Cleveland, 2015). This level of structured training was extremely beneficial for the clinicians in the current study and facilitated program implementation. A review by Herschell, Kolko, Baumann, and Davis (2010) indicated that a variety of clinician training methods appear to be effective for learning and implementing psychosocial interventions, including written materials, self-directed training (e.g., training videos), workshops, train-the-trainer, or multicomponent training. However, the authors noted that expert consultation, supervision, and feedback are especially useful for improving clinician skills and increasing adoption; Perhaps these elements of the CCR training contributed to the successful implementation of CET in our study. Published studies outlining the train-the-trainer method (one element of the current study's implementation) was limited at the time of this review, as only three studies were conducted. Since this review, more research has evaluated this method. For example, one study evaluated stakeholders' perceptions of training methods and identified train-the-trainer as an acceptable method to implement

evidence-based practices in the U.S. Department of Veterans Affairs (Smith et al., 2017).

Train-the-trainer methods have been used successfully in real-world settings demonstrating

positive treatment outcomes, including a psychosocial group for women with HIV/AIDS

(Weiss et al., 2015) and CBT for binge eating (Zandberg & Wilson, 2013). Thus, the current

study's training methods appear to be effective and promising for future implementation

efforts, but more research is needed to determine sustainability of interventions using these

methods. In particular, our study reports up to the initial implementation stage of the

intervention, but full implementation has not yet been reached in our agency. As the train-

the-trainer method has worked so far in the current study, it may be important to continue to

have CET trainers within the agency to continuously train new CET coaches to facilitate

CET groups. Having on-site trainers is particularly important for TMC, as staff turnover was

a barrier apparent in the beginning stages of implementation. Other agencies considering

delivering an EBP may benefit from formal training as an option to promote initial program

implementation, and consider on-site trainers to remedy staff turnover. Funding allowed

formal training to occur; this type of training may not be feasible for agencies without

financial support. Although CCR provided general tips to program delivery, they were not

involved in the actual implementation process or program maintenance. Fidelity to the

intervention was monitored by CCR throughout this study. Agencies wishing to deliver an

evidence-based program (especially those using different implementation methods) may

utilize a method to assess fidelity to ensure maximal program effectiveness.

  The current study demonstrated successful implementation of CET with typical

clinicians with various backgrounds and experience. This is important to note, as previous

CET research reported Master's or Ph.D. level clinicians administering treatment and/or

extensive experience working with individuals with schizophrenia from a setting boasting

national recognition for its specialty psychosis clinics (e.g., Eack et al., 2009). These types of

settings or clinicians are not widely available outside of the few large medical centers, thus it

is not feasible to compare published efficacy that has access to such resources with

community settings who likely do not have as many resources. Although clinicians were

selected for their interest and experience with people with schizophrenia, clinicians did not

reside in any specialty clinics. Most EBPs are developed by doctoral-level professionals and

are aimed towards this level of experience, however most agencies employ Master's level

clinicians with eclectic orientations (Herschell et al., 2010), and the current study included

those with Bachelor's level experience. The current study provides evidence that staff with

generalist and/or diverse backgrounds and qualifications can deliver an intensive EBP for

people with schizophrenia. Perhaps agencies with similar clinicians may require more

targeted training (as used in the current study) before CET implementation.

CET is an intensive psychosocial program that consists of 48 sessions, with weekly

2.5-hour groups plus weekly individual coaching. Previous studies investigating other real-

world social cognitive and neurocognitive groups included those with 8 (Wauchope et al.,

2016), 12 (Byrne et al., 2013), 20 (John et al., 2017; Taksal et al., 2016), and 40 sessions

(Cellard et al., 2016). Therefore, the current study reports successful implementation of an

intensive program that required weekly planning and individualized support. Important to

note, this intensive program was implemented in the context of a busy community hospital,

and clinicians had to fit CET into their already full schedules. Current published CET studies

evaluate the efficacy of CET for up to 2 years of treatment (Eack et al., 2009; Hogarty et al.,

2004), and more research is needed to understand implementation and effectiveness of the

even more intensive version of CET. The CET intervention received support from the psychiatric rehabilitation program director as well other TMC staff members, in addition to the structured training mentioned above. It is possible that this level of training and support is necessary for successful implementation of complex programming such as CET. This is an important consideration for clinical agencies wishing to adopt CET or other EBPs, especially with intensive interventions.

The current study reported data from Truman Medical Center, which is a public, academic medical center in an urban setting. TMC is an exemplar setting to implement a program like CET because it has resources other community agencies may not have. For example, case managers were available to transport participants when needed; such collaboration may not be feasible in a smaller or less comprehensive agency. Clinicians from different TMC locations were available to participate in training and delivery of the program; a smaller agency may have more limited options for clinicians interested in program delivery. This United States setting is a particular strength of implementation information reported in the current study, as not all previous studies have been conducted in the United States. Other SMI real-world studies have been conducted in Perth, Western Australia (John, et al., 2017), Shanghai, China (Byrne et al., 2013), Quebec City, Canada (Cellard et al., 2016), and Bengaluru, India (Taksal et al., 2016). The results of the current study may be most generalizable to similar settings in the United States and build upon research relevant for this region. For example, CET training may only be available in the United States, so implementation may differ in other countries. Regulatory differences may be apparent in other organizations, states, or countries (e.g., weekly hourly quotas for direct client contact or billing requirements). More research is needed to evaluate this intervention or other similar

interventions in different settings and countries. During the course of the study, CET was administered in various spaces. CET groups began in two different locations during the first cohort, one group in a psychiatric rehabilitation program and one group in a remote TMC location. Relocating CET to the same psychiatric rehabilitation location in the second year appeared to be favorable for both coaches and participants. The new physical space was larger and the location was more central than one of the previous locations. Future programs may consider having CET in a centralized location with a designated room for CET groups that is near public transportation.

Regarding effectiveness of symptom improvement, our results showed initial support for CET effectiveness in a real-world, community setting. These are encouraging findings, given that CET was delivered by generalist clinicians with participants in the chronic phase of their illness as well as those with comorbid psychiatric diagnoses. We found that participants improved in several areas of negative symptoms. Negative symptom improvements had similarities and differences as compared with previous findings. Prior CET studies found differential improvement of the negative symptom domains social withdrawal, motor retardation, and affective flattening for CET participants compared with an active control condition (Eack, Mesholam-Gately et al., 2013). The current study found significant improvements in avolition-apathy, anhedonia-asociality, and attention in our single intervention group. Therefore, improvements in anhedonia-asociality in our study (social withdrawal on the Wing Negative Symptom Scale in previous research) was replicated, and was the noted as having the strongest effect in previous findings (Eack, Mesholam-Gately et al., 2013). It is difficult to directly compare these studies, as our study used the Scale for Assessment for Negative Symptoms (Andreasen, 1984a), and this previous

CET study used the Wing Negative Symptom Scale (Wing, 1961) and the Brief Psychiatric Rating Scale (BPRS; Overall & Gorham, 1962) emotional withdrawal, motor retardation, and blunted affect subscales.

Our study found that participants showed improvements in several domains of positive symptoms (i.e., hallucinations, bizarre behavior, and positive formal thought disorder). Positive symptoms are not routinely directly targeted in cognitive rehabilitation interventions, although are frequently measured as secondary outcomes (McGurk et al., 2007). Prior CET studies have not found differences in positive symptom improvement between CET and an active control condition (Hogarty et al., 2004). Our finding that several aspects of positive symptomatology improved can be viewed in light of specific components of CET. For instance, we identified improvements in positive formal thought disorder, which is directly targeted with coach follow-up questions during homework discussion, one on one homework coaching, and feedback from participants. Bizarre behavior may have improved as a result of participants learning topics relevant to social norms. However, improvement of hallucinations did not align with previous CET research. It is unclear how to interpret these improvements given our study included a single intervention sample that could not be distinguished from non-specific intervention effects.

In terms of neurocognitive improvements, participants significantly improved in verbal learning, visual learning, and attention. There were also clinically meaningful changes in at least one area of neurocognition for the majority of participants, and participants reported noticing changes in their thinking (including neurocognition) in our semi-structured interviews. These findings, similarly to the symptom improvements, are encouraging, given the context of the current study in a real-world environment with typical, community clients.

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Researchers have found that neurocognition predicts functioning in a number of previous studies (Bromley, Mikesell, Mates, Smith, & Brekke, 2012; Fett et al., 2011; McGurk & Meltzer, 2000; Kahn & Keefe, 2013; Rempfer et al., 2003; Tan, 2009), and it is important to consider how neurocognitive improvements may impact functioning. Interestingly, verbal and visual learning were the only two tests on the MCCB that have three trials. Perhaps improvements in these tests indicates improvement in learning, which could bolster success in future functional goals (e.g., employment or educational endeavors). Previous research has found a relationship between learning potential and skill acquisition (Rempfer, Brown, & Hamera, 2011). Therefore, improvements in learning may be an important predictor of translation of skills in real-world settings, supporting recovery goals. Even so, current measures of functioning do not always align with naturalistic behavior (e.g., Faith & Rempfer, 2018). Participants mentioned feeling more motivated for education and employment in semi-structured interviews, however participants were not followed post-CET to determine these functional outcomes, and the current study did not directly measure functional capacity (i.e., daily functioning in the real world; Green, Llerena, & Kern, 2015). Thus, it is difficult to say how our effectiveness findings may translate to functioning and support recovery goals following CET.

Although neurocognitive improvements were promising, they were less robust when compared with previous findings. Level of engagement (measured with number of levels passed in neurocognitive training) may explain why improvements in other areas of neurocognition were not significantly improved, as engagement was low for a subgroup of participants. Ten participants passed less than ten levels, and twelve participants passed between 11-20 levels. There was one participant who did not pass any levels. Given that

participants attend 48 hours' worth of neurocognitive training, these participants passed less than 1 level per session. It would be expected that these participants show less neurocognitive improvements, as well as less social cognitive improvements, given that these two areas are interrelated (Brenner et al., 1992). These participants may have biased these results towards non-significant improvements. Additional measures of engagement, especially measuring engagement during the social cognitive portion of CET, would have provided additional information regarding the relationship between engagement and effectiveness. Participants who are not engaging with the intervention may need additional coaching to encourage active participation and maximize outcomes.

It is surprising that social cognition did not significantly improve in quantitative measures in our sample, as previous CET research has shown social cognitive improvement (Eack et al., 2009; Hogarty et al., 2004). Social cognition was measured with the MSCEIT managing emotions branch, and this measure may not be the most sensitive or comprehensive measure to capture social skill improvements targeted from CET lessons. The MSCEIT managing emotions branch asks participants to provide judgments related to emotion regulation in social situations. However, social knowledge (e.g., social norms) was one of the more salient social cognitive topics throughout CET, and is not measured in the MSCEIT managing emotions branch. Conversely, some of our participants reported understanding social situations better (i.e., social knowledge) in our qualitative analysis of semi-structured interviews. Previous CET studies use a more comprehensive battery of social cognition that may be more sensitive to changes. Several social cognitive measures are used in schizophrenia research, however there is no 'gold standard' assessment and current measures have issues such as inadequate psychometric properties (Green et al., 2008). Recent

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efforts have begun the process to standardize measurement and treatment and to identify

measures with adequate psychometric properties (Pinkham, Penn, Green, & Harvey, 2016),

which may improve future study measurement. Additionally, more research is needed to

determine the mechanism of improvement, such as learning potential. Regarding reliable

clinical change, response profiles varied between participants. More research is needed to

determine predictors of improvement to individualize treatment and improve treatment

matching. For example, it is possible that severe positive symptoms may have interfered with

learning and neurocognitive improvement. Adjunctive treatments may be used to prepare

participants for intensive treatments such as CET.

<center>**Limitations**</center>

The present study should be interpreted with its potential limitations in mind. The use

of multiple t-tests may have increased the possibility of Type I Errors (i.e., detecting a false

effect). The study was an uncontrolled effectiveness-implementation study designed to

evaluate the utility of CET in the real world. The study was highly externally valid to real-

world settings, and this was at the cost to lower internal validity (i.e., lack of randomization

and strict inclusion criteria). We are unable to conclude that improvements in symptoms or

cognition are nonspecific effects of the intervention beyond treatment-as-usual (e.g.,

improvements due to therapeutic alliance, higher 'dosage' of treatment, etc.). Additionally,

this was not a blinded intervention study and therefore researcher expectancy effects are a

potential source of bias. This study utilized a community-based version of CET (Center for

Cognition and Recovery, LLC, 2018), which is briefer than the CET utilized in published

efficacy trials (Eack et al., 2009; Hogarty & Flesher, 1999). One important difference

between the two versions is that the neurocognitive training in the community version is

shortened from approximately 60 hours to 48 hours. The programs are structurally and theoretically identical. It is possible that differences may contribute to effectiveness and even implementation of this version of CET.

Future Directions

Future studies should continue to investigate both effectiveness and implementation of psychosocial interventions for people with schizophrenia, as this area is extremely important to improve dissemination of evidence-based programs. Each intervention is unique with its own challenges, so it is important to evaluate every efficacious program beyond randomized-controlled trials in a real-world setting. Cognitive rehabilitation has been tested in multiple randomized-controlled trials and several reviews and meta-analyses have been published (Kurtz et al., 2001; Kurtz & Nichols, 2007; McGurk et al., 2007). However, access to cognitive rehabilitation programs is low for people who need services (Medalia et al., 2019). Therefore, studies specifically investigating effectiveness and implementation of cognitive rehabilitation is an important area for development.

Additional measures may have included important information regarding implementation. Interviewing coaches is an important future direction to gain the clinician point of view in the implementation of the program. Future research should include additional measures of engagement to strengthen this area, such as clinician-rated engagement (e.g., Kortte, Falk, Castillo, Johnson-Green, & Wegener, 2007).

Effectiveness studies may include a larger sample to increase the generalizability of the findings and increase power. Additionally, it will be important to include follow-up analyses to differentiate predictors of improvement and contributing factors in outcomes. These types of analyses are especially important when working with a heterogeneous sample of

participants who may have multiple diagnoses, different socioeconomic statuses, varied age groups, and other important variables. An equivalent comparison group is also important to differentiate non-specific effects of the intervention.

CET in the current study was still relatively new within our agency, and the maintenance (or "full implementation") phase of implementation needs further investigation. CET is an intensive program, and the current study only reports two cycles of CET. A longitudinal implementation study is therefore important to include data after initial implementation with several years and cycles of CET. A future study may report on additional barriers and solutions that may uniquely arise in the full implementation phase.

Clinical Implications

As mentioned above, the current study reports on successful implementation of a CET program. These data may be useful for clinics planning to implement similar types of programs for their clients. CET may work best in agencies with resources such as a psychiatric rehabilitation program and clinicians who have experience working with individuals with schizophrenia. One of the most important barriers for the present agency prior to successful implementation was the lack of training and resources. This was remedied by obtaining funding and working with trainers to bolster the program. Therefore, structured training may be a helpful tool for other agencies with similar barriers. For those with limited funding, it may be helpful to identify a team leader interested in learning the intervention independently and training interested clinicians.

Effectiveness of CET in a real-world setting showed initial positive findings. Given that our sample was heterogeneous (in terms of co-morbid diagnoses, age, ethnicity, housing status), may lack resources, and mostly people with chronic schizophrenia (rather than early

schizophrenia), these findings are especially striking. For example, those in our sample may have had more natural barriers to attendance (e.g., transportation, amotivation) or may have more difficulty changing persistent behaviors. Many efficacy studies include homogenous samples with people who only have one diagnosis in the early stage of schizophrenia, and may be highly motivated by external factors (e.g., participant payment, rich resources). Therefore, samples in typical RCTs may not represent typical clients in real-world settings.

CET received high satisfaction ratings from participants, and appeared to be an intervention that participants enjoyed. In future CET groups, clinicians may emphasize the coaching element of CET, as this was a very powerful aspect of CET for participants, and frequently *the most important* aspect. Additionally, peer support was meaningful for participants, and should be highlighted. Overall, participants appeared to enjoy the social cognitive portion of CET the most, however frequently critiqued the computerized portion of CET. Future coaching of the computerized neurocognitive training may further emphasize active coaching, client interaction, and active participation. Although computerized training was most often critiqued, some participants noted that it was their favorite aspect of CET. Perhaps collaboration with these clients to encourage enthusiasm for computer activities would be a helpful component of groups.

Overall, CET appeared to be feasible in the agency of implementation. Initial implementation was bolstered by training, and maintained by on-site trainers. Participants improved in several areas of positive and negative symptoms, and shared positive feedback of CET. Agencies wishing to implement CET may consider barriers reported in this study as well as anticipated barriers unique to their setting.

Conclusion

Psychosocial interventions, including cognitive rehabilitation, for people with schizophrenia have been developed, but are not available for those needing these services (Jolley et al., 2015; Kingdon & Turkington, 2019; Medalia et al., 2019). Implementation and effectiveness of psychosocial interventions for people with schizophrenia is an important area of investigation to remedy this problem. The current study provides useful findings contributing to this area regarding a cognitive rehabilitation program implemented in a community academic medical center. Overall, our results provide preliminary positive findings of implementation and effectiveness of Cognitive Enhancement Therapy in a real-world setting. These findings are especially important considering the lack of information in this area, and the inadequate availability of evidence-based services for people with schizophrenia. Implementation was facilitated with structured training of coaches and trainers along with continuous training of new certified intervention staff to maintain implementation. Coaches included staff with diverse backgrounds from a busy community program. Data supporting effectiveness included improvements in positive and negative symptoms as well as verbal memory, visual memory, and attention with ethnically diverse participants with the majority in the chronic phase of their illness. We hope these findings may inform real-world research as well as encourage implementation in clinics hoping to utilize evidence-based programs.

TABLES

Table 1.

Summary of published CET efficacy and cross-sectional studies.

Reference & Title	Sample	Primary Outcomes	Results
Hogarty et al., (2004): Cognitive Enhancement Therapy for schizophrenia: Effects of a 2-year randomized trial on cognition and behavior	*N*=121 individuals with schizophrenia spectrum diagnoses (i.e., schizophrenia, schizoaffective disorder and other psychotic disorder) randomized to either CET EST.	Neurocognition, cognitive style, social cognition, functional outcome, symptomatology	CET was associated with improvements in neurocognition and social adjustment. After 24 months, CET showed significantly more improvements in neurocognition, cognitive style, social cognition, and social adjustment.
Hogarty, Greenwald, & Eack (2006): Durability and mechanisms of effects of Cognitive Enhancement Therapy	*N*=121 individuals with schizophrenia spectrum diagnoses [i.e., schizophrenia, schizoaffective disorder and other psychotic disorder) randomized to either CET or EST.	Neurocognition, social cognition, dysfunctional cognitive style, functional disability, and symptomatology	Neurocognition, cognitive style, and social adjustment continued to be significantly improved at 36 months for people randomized to CET. The neurocognition composite was non-significant at 2 years but did not deteriorate between years 2-3. More CET participants were engaged in social, recreational or therapeutic activities during year 3.
Eack, Hogarty, Greenwald, Hogarty, & Keshavan (2007): Cognitive enhancement therapy improves emotional intelligence in early course schizophrenia: preliminary effects	*N*=38 individuals with schizophrenia or schizoaffective disorder randomized to either CET or EST.	Emotional intelligence	Emotional intelligence was improved in CET compared to EST.

Reference & Title	Sample	Primary Outcomes	Results
Eack, et al. (2009): Cognitive Enhancement Therapy for Early Course Schizophrenia: Effects of a Two-Year Randomized Controlled Trial	*N*=58 individuals with schizophrenia, schizoaffective disorder, or schizophreniform disorder randomized to either CET or CET.	Neurocognition, Social Cognition, Cognitive Style, Social Adjustment, Symptomatology, Employment	People randomized to CET showed improvements in dysfunctional cognitive style, social cognition, social adjustment, and symptomatology during the first year of treatment. After 2 years, CET showed improvements in social cognition, social adjustment, symptomatology, and neurocognition.
Eack, et al. (2010): Neuroprotective effects of cognitive enhancement therapy against gray matter loss in early schizophrenia	*N*=53 individuals with schizophrenia or schizoaffective disorder randomized to either CET or EST.	Neurocognition, social cognition, and broad areas of frontal and temporal gray matter change	CET participants showed differential effects in the left medial temporal lobe, the bilateral anterior cingulate, and the right insula. CET participants showed less gray matter loss in the medial temporal regions, and greater gray matter increases in the left amygdala. These neuroprotective effects were related to social cognition and neurocognitive function.
Eack, Hogarty, Greenwald, & Keshavan (2011): Effects of cognitive enhancement therapy on employment outcomes in early schizophrenia: results from a 2-year randomized trial	*N*=58 individuals with schizophrenia, schizoaffective disorder, or schizophreniform disorder randomized to either CET or EST.	Employment, neurocognition, and social cognition	A greater number of people in CET were employed, earned significantly more money per week, and were more satisfied with their employment. Social cognition and neurocognition predicted employment outcomes.

Reference & Title	Sample	Primary Outcomes	Results
Keshavan, et al. (2011): A broad cortical reserve accelerates response to cognitive enhancement therapy in early course schizophrenia	*N*=33 individuals with schizophrenia or schizoaffective disorder.	Neurocognition, social cognition, and structural brain imaging.	Pre-treatment cortical surface area and gray matter volume predicted social-cognitive response to CET. Temporal lobe gray matter volume contributed to accelerated CET response on social cognition.
Lewandowski, Eack, Hogarty, Greenwald, & Keshavan, (2011): Is cognitive enhancement therapy equally effective for patients with schizophrenia and schizoaffective disorder?	*N*=58 individuals with schizophrenia or schizoaffective disorder.	Neurocognition, social cognition, symptomatology, and social adjustment.	No significant effect of diagnosis was found between improvement and treatment condition for any of the composites.
Eack et al. (2013): Brief report: Is cognitive rehabilitation needed in verbal adults with autism? Insights from initial enrollment in a trial of cognitive enhancement therapy	*N*=40 individuals with autism.	Neurocognition and social cognition.	Participants IQ scores were within normal ranges, but neurocognition, social cognition, and vocational functioning was substantially impaired.
Eack, et al. (2013): Cognitive enhancement therapy for adults with autism spectrum disorder: results of an 18-month feasibility study.	*N*=14 individuals with autism.	Client satisfaction, neurocognition, mental flexibility, social cognition, and dysfunctional cognitive style	Overall participant CET satisfaction was positive. Significant improvements were found in neurocognition, cognitive style, social cognition, and social adjustment.

Reference & Title	Sample	Primary Outcomes	Results
Eack, Mesholam-Gately, Greenwald, Hogarty, & Keshavan (2013): Negative symptom improvement during cognitive rehabilitation: results from a 2-year trial of cognitive enhancement therapy.	*N*=58 participants with schizophrenia or schizoaffective disorder randomized to either CET or EST.	Negative symptoms, psychopathology, neurocognition, and social cognition.	CET participants improved in negative symptoms. Neurocognitive improvement was associated with reduced negative symptoms.
Eack, et al. (2014): Cognitive enhancement therapy in substance misusing schizophrenia: results of an 18-month feasibility trial	*N*=31 participants with schizophrenia or schizoaffective disorder randomized to either CET or EST.	Neurocognition, social cognition, dysfunctional cognitive style, social adjustment, symptomatology, and Previous 30-day substance use	Neurocognition, social cognition, dysfunctional cognitive style, and social adjustment were significantly more improved for people engaging in CET. CET group had significantly less days using alcohol.
Eack et al. (2018): Cognitive enhancement therapy for adult autism spectrum disorder: results of an 18-month randomized clinical trial	*N=54* participants with autism randomized to either CET or EST.	Neurocognition, social cognition, and employment.	CET participation resulted in significant improvements in neurocognition at 18 months of treatment. CET participants showed greater differential improvements in social cognition at 9 months of treatment, but not 18 months.

Table 2.

Comparison of feasibility studies, randomized-controlled trials, implementation studies, and effectiveness studies.

Type of Study	Purpose	Validity	Strengths	Weaknesses
Feasibility	To determine the practicality of a RCT and demonstrate preliminary effects.	High internal validity, may include some information with high external validity (e.g., participant satisfaction).	Informs future randomized trials.	May not be highly powered to confirm efficacy.
Efficacy (Randomized Controlled Trial)	To determine if a treatment is efficacious under ideal conditions.	High internal validity.	Provides evidence that a treatment is efficacious.	May not be externally valid. Does not include practical information.
Effectiveness	To determine if a treatment is effective under real-world conditions.	High External Validity.	Can demonstrate effectiveness in uncontrolled settings in typical usual care settings.	May have low internal validity.
Implementation	To describe the process of implementation in a real-world setting.	High External Validity.	Can inform processes of implementation to increase utility of interventions.	Often does not include effectiveness data.

Table 3.

Using the RE-AIM Framework to Evaluate CET for Schizophrenia.

Re-AIM Element	Definition	Metric
Reach	Characteristics of eligible participants invited to the intervention versus those that completed the intervention.	Descriptive statistics of participants who enrolled in the intervention and those that completed the intervention.
Effectiveness	The amount of change in outcomes.	MATRICS Consensus Cognitive Battery (MCCB), Scale for Assessment of Negative Symptoms (SANS), Scale for Assessment of Positive Symptoms (SAPS).
Adoption (Individual)	The characteristics of participants that adopted the intervention.	Attendance rates (adherence), number of levels passed in computerized neurocognitive training (engagement), satisfaction interviews and surveys.
Implementation	The extent to which a program is delivered as intended. This is described within each implementation stage: exploration, installation, initial implementation, and full implementation.	Clinician training, descriptive statistics of clinicians, descriptive information regarding the setting. Barriers and solutions to implementation.
Maintenance	The long-term effects on key outcomes and quality-of-life impact.	Not evaluated in the present study. See discussion section for recommended future directions.

Table 4.
Demographic characteristics of participants.

Variable		n(%)
Gender	Male	25 (74.5)
	Female	9 (26.5)
Diagnosis	Schizophrenia	26 (76.5)
	Schizoaffective Disorder	4 (11.8)
	PTSD	3 (8.8)
	Bipolar Disorder	1 (2.9)
Race/ethnicity	African American/Black	18 (52.9)
	Caucasian/White	8 (23.5)
	Asian or Pacific Islander	3 (8.8)
	Multi-Racial	4 (11.8)
	Hispanic	1 (2.9)
Marital Status	Never married	26 (76.5)
	Divorced/Annulled	3 (8.8)
	Married	2 (5.9)
	Separated	1 (2.9)
	Widowed	1 (2.9)
Education Level	Some college	15 (44.1)
	High school graduate or GED	10 (29.4)
	Bachelor's degree	3 (8.8)
Living status	Supervised care housing	17 (50.0)
	Independent living	12 (35.3)
	Lives with relatives	3 (8.8)
	Emergency shelter	1 (2.9)
Employment status	Unemployed	30 (88.2)
	Employed	3 (8.8)

Table 5.
CET Satisfaction Survey Descriptive Information.

	M	SD	1	2	3	4	5
					Frequency and Percentage *n(%)*		
1. I am satisfied with CET computer classes.	4.45	1.09	2 (6.9)	0	1 (3.4)	6 (20.7)	20 (70.0)
2. I am satisfied with CET social skills classes.	4.45	1.02	1 (3.4)	1 (3.4)	2 (6.9)	5 (17.2)	20 (70.0)
3. I feel comfortable talking with my CET coach.	4.62	0.82	1 (3.4)	0	0	7 (24.1)	21 (72.4)
4. My CET coach cares about me.	4.52	0.83	1 (3.4)	0	0	10 (34.5)	18 (62.1)
5. My CET coach cares about my success.	4.66	0.86	1 (3.4)	0	1 (3.4)	4 (13.8)	23 (79.3)
6. The CET homework is helpful.	4.24	1.06	1 (3.4)	1 (3.4)	4 (13.8)	7 (24.1)	16 (55.2)
7. The CET computer classes are enjoyable.	4.14	1.30	2 (6.9)	3 (10.3)	1 (3.4)	6 (20.7)	17 (58.6)
8. The CET social skills classes are enjoyable.	4.45	0.95	1 (3.4)	1 (3.4)	0	9 (31.0)	18 (62.1)
9. I am learning in CET social skills classes.	4.66	0.81	1 (3.4)	0	0	6 (20.7)	22 (75.9)
10. I am learning in CET computer classes.	4.52	0.91	1 (3.4)	0	2 (6.9)	6 (20.7)	20 (70.0)
11. My CET coach explains things well.	4.62	0.82	1 (3.4)	0	0	7 (24.1)	21 (72.4)
12. I look forward to CET classes.	4.24	1.12	2 (6.9)	0	3 (10.3)	8 (27.6)	16 (55.2)
13. I think CET classes are worth my time.	4.55	1.06	2 (6.9)	0	0	5 (17.2)	22 (75.9)

Note. Likert scale labels are as follows: 1. Completely disagree; 2. Disagree somewhat; 3. N/A; 4. Agree somewhat; 5. Completely Agree.

Table 6.
CET satisfaction themes and subthemes with representative quotes from semi-structured interviews.

Theme	Subtheme	Representative Quote from Participants
Coaching was valuable.	Coaches helped with homework.	• "The coach helped me through [homework] but they didn't tell me the answers." • "A lot of times I would need [the coach's] insight to get me on the right path to do the homework." • "I never would have done [homework] on my own so having that coach was super instrumental."
	Coaches motivated or supported participant.	• "I feel like the teachers helped me like trust my opinion more." • "[The coach] put a lot of spunk into me." • "[The coaches were] all on my team." • "[The coaches] were just very delicate about [encouraging attendance], they were very sensitive."
	Coaches were skilled.	• "They didn't make us feel less than, they were honest with us…when they were critiquing us they wouldn't all just give out positive feedback they would give comments that were beneficial to learn from and grow from." • "[Coaches] were thorough and relaxed." • "[My coach] did an excellent job instructing and teaching." • "I loved the coaches' feedback." • "[The coaches] were great leaders."
	Participant complimented coach	• "I felt like [the coaches] complimented each other." • "He's a really good guy, he's a really good coach."
Criticism of coaching		• "It seemed like [my coach] …was deciding what I was gonna say on the homework." • "It felt like [my coach] rushed us through [the homework]." • "Some coaches were better than others…some of them were hard to follow…"

Theme	Subtheme	Representative Quote from Participants
Satisfaction with a particular CET activity.	Enjoyed challenging self.	• "My most favorite part [of CET] was…reviewing the homework [because] we had to cognitively explain exactly how we came up with our answers." • "I thought [problem-solving activities were] helpful for us to interact with one another and get comfortable speaking in front of the group." • "[Discussing homework] was a little stressful but I think it was enriching." • "[Computer games] were just fun to challenge yourself."
	Enjoyed learning something new.	• "[After learning psychoeducation topics] …I was like "Wow", I feel [I'm] more than just a mental illness…I feel like I have a brain!"
Dislike of a particular CET activity	Computer activities were boring or repetitive.	• "The repetition part of [computer games made them less enjoyable]…If they had it presented differently it might be better."
	Computer activities were too difficult or confusing.	• [Computer activities were difficult] because they… made you really really process things and sometimes it was like over-processing that…had me stumped a lot of times so I could never pass it."
	Recognized computer activities were helpful, but disliked them.	• "I think [computer activities] helped but I really didn't like em."
	Disliked one (or more) social cognitive activity.	• "Talking in front of everyone [made problem-solving activities difficult]." • "[I didn't like] sharing my personal feelings."

Theme	Subtheme	Representative Quote from Participants
Functional improvements.	Improved social skills	• "I'm able to…know what's going on [in] social [situations] and I'm making better judgements." • "[Since graduating CET], I am able to articulate and express compassion which I think is like a really important thing to know the difference between having compassion and expressing compassion." • "I said 'man that should have been in front stage back stage' I saw it and then I recognized it and I was like wow. I said, *I learned this in CET*." • "I usually get upset when people stare at me but now…I kinda learned that…people look not…just [at] you [but] because they have eyes that…wander so they may give you a glance but it does not necessary mean towards you." • " I am seeing like through [my husband's] eyes a lot better. It's not always through my own eyes as much as it used to be." • "Perspective taking…is very important because I feel strong about what I feel strong about, so to take somebody else's perspective and keep my own values and beliefs I think, will, I think is a great way to keep peace amongst people…"
	Improved thinking.	• "[My thinking became faster] through participation. You realize it's getting quicker because you getting to communicate more together as a group." • "[CET] got the poison out of my thinking."
Improved confidence		• [After coaches told him he did a good job on the homework]: Well I kinda had a little bit of self-confidence." • "[I] learned to be a self-confident"
Peer support.	Enjoyed learning from other people.	• "[I enjoyed hearing others' ideas during homework] because I could take what they said and compare it to what I've said and gain experience through their words to benefit me."
	Enjoyed interacting with other people	• "We got along well when we did the group projects [and when] you got paired with somebody there was always…laughter…[and] good vibes"

Theme	Subtheme	Representative Quote from Participants
	Noticed improvements or successes of peers	• "I distinctly remember the first time I heard [another peer] speak, the first time he made eye contact with me, and the first time he told a joke." • "I was proud of everybody [and] everybody's proud of each other…" • "[I noticed] that the people's intellect had changed." • "I feel like we grew as individuals."
Motivated for education or employment.		• "So after a better me process took its place it actually did start making a better me and the better me turned me into a more confident person, or a skill-oriented person, and ultimately the confidence for me to go out and get a job and now I'm a person that not only has a job, a person who has coworkers saying you are a great worker." • "I know if I can do something like that for a whole year I should be able to get my GED."

Table 7.

CET program barriers and challenges within each implementation stage.

Implementation Stage	Program Barriers & Challenges	Overcoming Barriers in Our Current Program
Exploration	Educating staff members about CET was challenging because motivation for dissemination did not independently facilitate implementation.	Grant funding allowed the opportunity to work with CETCleveland®. This permitted a more experienced team to add support to the program and increase interest within the agency. This training program was chosen for its accessibility, trainer support, and ease of use.
Installation	CET did not grow within the agency after piloting the intervention.	CET coaches were trained from different teams to improve visibility and program growth. Coaches were chosen based on experience with individuals with schizophrenia, interpersonal skills, and motivation.
	CET can be difficult to organize, prepare, and implement according to the manual, as it is an intensive and lengthy program.	CETCleveland® materials reduced time spent on preparation with tools such as posters, activities, and lectures.
Initial Implementation	Client transportation was limited and location was not convenient for all participants.	Collaboration with professionals such as case managers has supported transportation and CET groups are now held at one central location that is near a bus line.
	Coaches left the agency or discontinued coaching after CET training.	Two CET coaches became trainers to have the ability to continuously train new qualified CET coaches.
	It was difficult to locate a dedicated room with adequate space for CET groups.	CET is now provided within a psychiatric program in one centralized location. CET groups are provided in a dedicated room.
Full Implementation (Future directions)	Not evaluated in the present study. See discussion section for potential future barriers.	Overcoming possible future barriers will be discussed in the discussion section.

Table 8.

Descriptives and results of cognitive domains, including t-tests of the intent-to-treat CET sample.

Domain	Measure	Baseline		Post-CET		t	p	d
		M	*SD*	*M*	*SD*			
Speed of processing	TMT	41.93	14.73	40.47	17.76	.579	.566	.089
	BACS-SC	38.68	9.78	38.85	10.22	-.113	.911	.017
	Fluency (Animal Naming)	17.21	5.29	17.79	5.24	-.766	.449	.011
Attention	d2	286.76	87.14	319.61	97.37	-2.98	.005**	.356
Working Memory	WMS-III: SS	13.03	3.16	13.56	3.05	-1.078	.289	.170
	LNS	10.71	3.96	10.56	7.43	.270	.789	.025
Verbal Learning	HVLT-R	18.24	4.57	19.76	3.16	-2.112	.042*	.387
Visual Learning	BVMT-R	17.33	6.75	19.33	6.51	-2.145	.040*	.302
Reasoning and Problem-Solving	NAB Mazes	13.79	7.43	13.53	7.02	.299	.766	.036
Social Cognition	MSCEIT-ME	82.74	10.30	84.62	9.69	-1.487	.146	.188

Note: Abbreviations are as follows: TMT= Trail-Making Test; BACS-SC=Brief Assessment of Cognition in Schizophrenia – Symbol Coding; WMS-III = Wechsler Memory Scale III, Spatial Span; LNS = Letter-Number Span; HVLT-R = Hopkins Verbal Learning Test – Revised; BVMT-R = Brief Visuospatial Memory Test – Revised; NAB Mazes = Neuropsychological Assessment Battery Mazes; MSCEIT = Mayer-Salovey-Caruso Emotional Intelligence Test – Managing Emotions.
*p is significant at the .05 level.
**p is significant at the .001 level.

Table 9.

Descriptive data and results of positive and negative symptoms, including t-tests of the intent-to-treat CET sample.

Variable		Baseline		Post-CET				
		M1	*SD1*	*M2*	*SD2*	*t*	*p*	*d*
Negative Symptoms	Affective flattening	3.15	1.73	2.71	1.61	1.871	.070	.263
	Alogia	2.50	1.89	1.91	1.76	1.894	.067	.323
	Avolition-apathy	4.26	.93	3.74	1.31	2.083	.045*	.458
	Anhedonia-asociality	3.97	1.17	2.79	1.72	4.226	<.001**	.802
	Attention	2.06	1.54	.85	1.44	4.317	<.001**	.373
Positive Symptoms	Hallucinations	3.06	2.26	2.26	2.14	2.811	.008**	.364
	Delusions	3.74	1.80	3.38	1.78	1.089	.284	.201
	Bizarre behavior	2.79	1.37	1.65	1.55	4.343	<.001**	.779
	Positive formal thought disorder	2.59	1.78	1.68	1.74	2.692	.011*	.517

*p is significant at the .05 level.
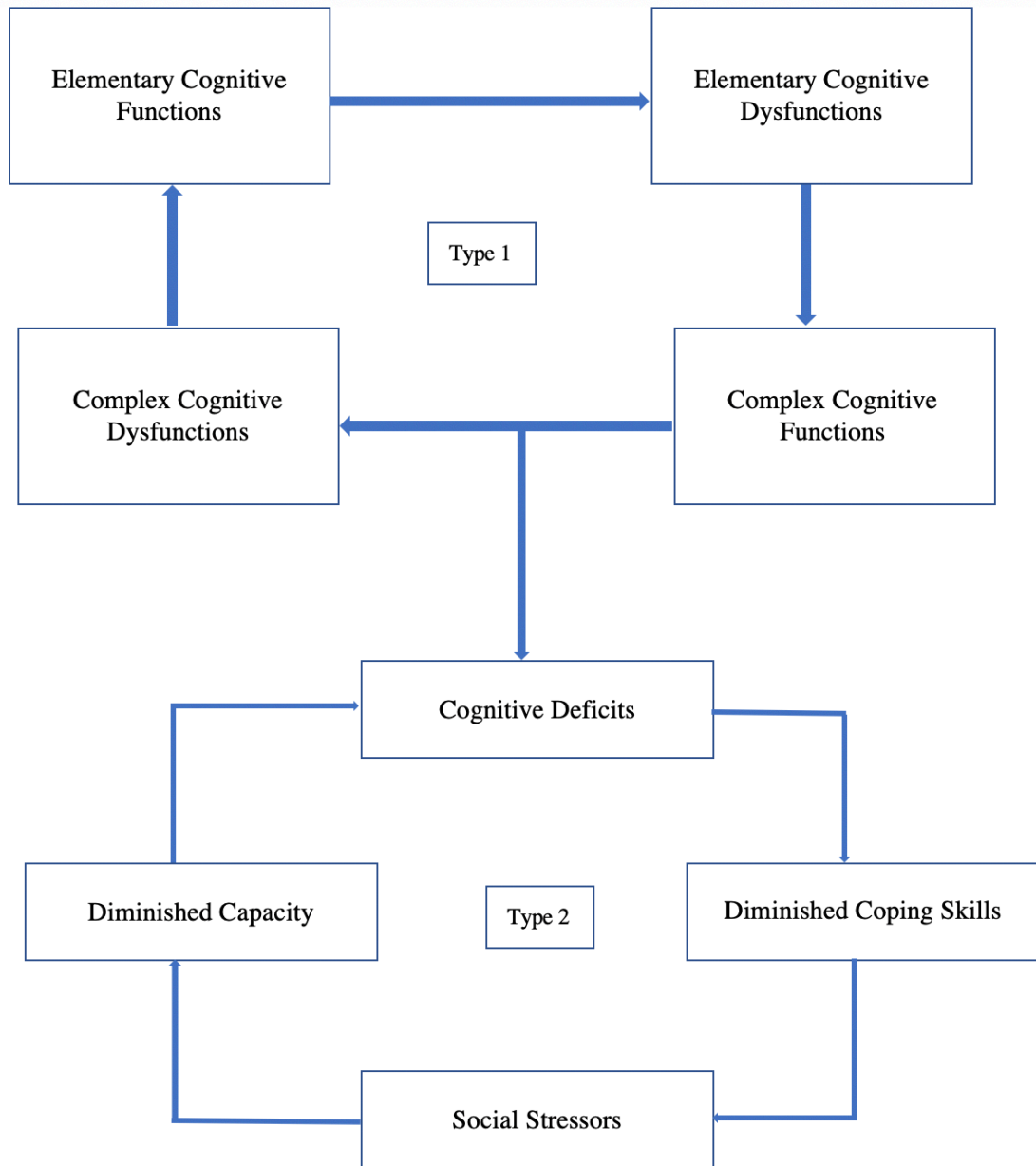**p is significant at the .001 level.

ILLUSTRATIONS

Figure 1.
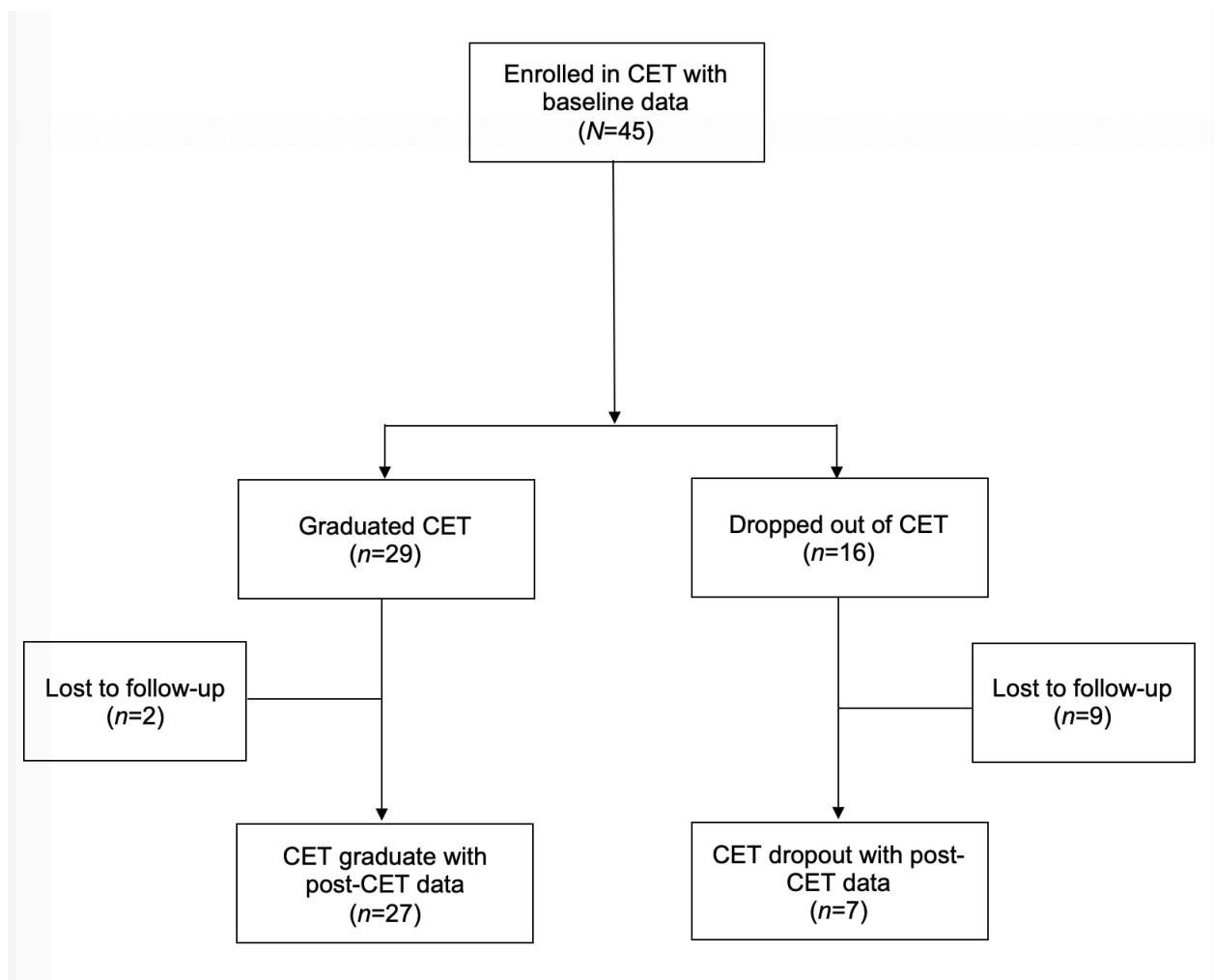*Type 1 and Type 2 vicious circles adapted from Brenner et al., (1992).*

Figure 2.
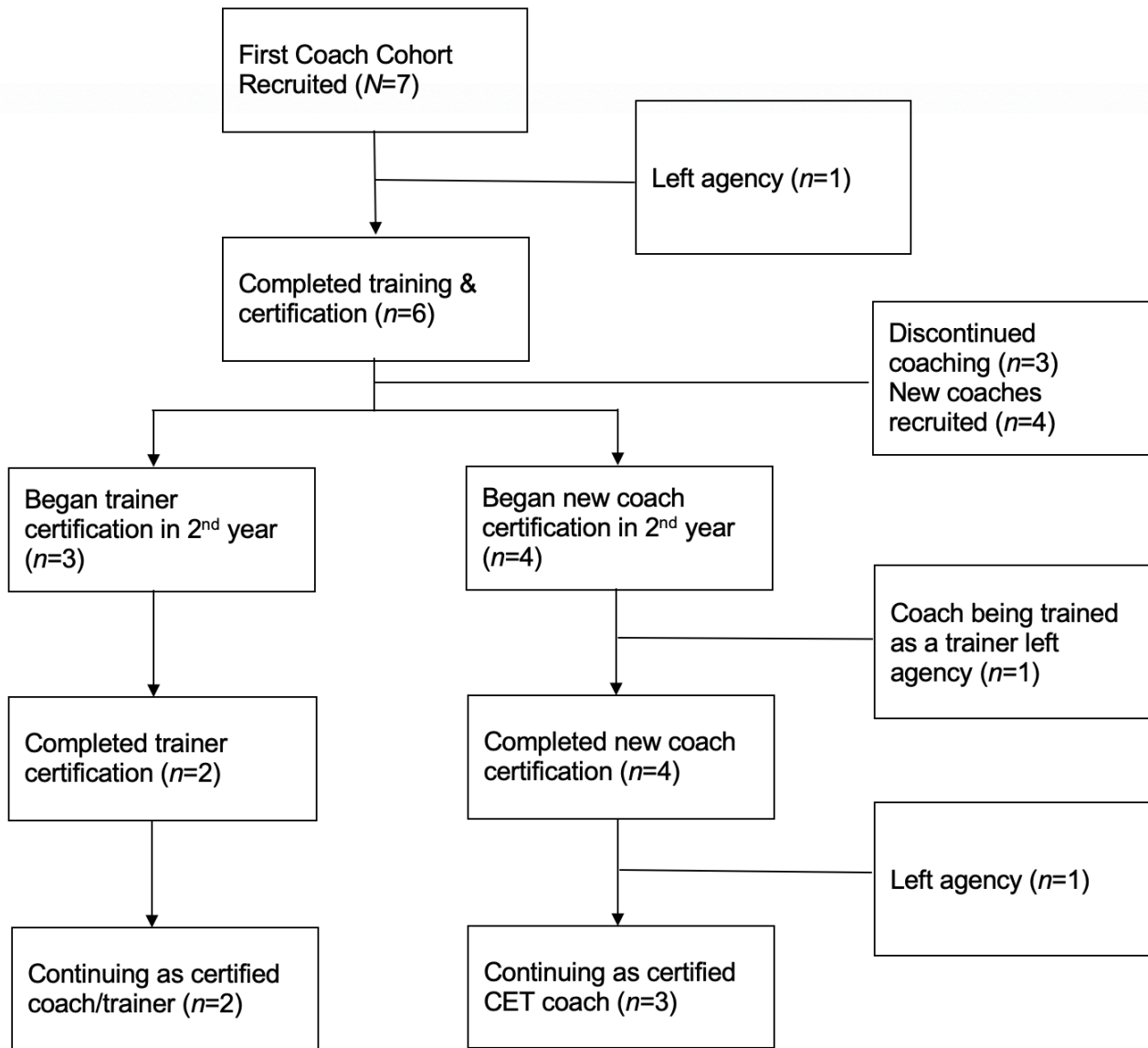*Participant flow of research participation including CET graduates and dropouts.*

Figure 3.
Flow chart illustrating CET coach training and turnover.

Appendix A. CET Satisfaction Survey

	Completely Disagree	Disagree Somewhat	N/A	Agree Somewhat	Completely Agree
1. I am satisfied with CET computer classes	1	2	3	4	5
2. I am satisfied with CET social skills classes	1	2	3	4	5
3. I feel comfortable talking with my CET coach	1	2	3	4	5
4. My CET coach cares about me	1	2	3	4	5
5. My CET coach cares about my success	1	2	3	4	5
6. The CET homework is helpful	1	2	3	4	5
7. The CET computer classes are enjoyable	1	2	3	4	5
8. The CET social skills classes are enjoyable	1	2	3	4	5
9. I am learning in CET social skills classes	1	2	3	4	5
10. I am learning in CET computer classes	1	2	3	4	5
11. My CET coach explains things well	1	2	3	4	5
12. I look forward to CET classes	1	2	3	4	5
13. I think CET classes are worth my time	1	2	3	4	5

Appendix B. Perceptions of CET Interview

1. What do you think of CET so far?

2. Was anything about CET surprising or unexpected?

3. What do you like most about CET?

4. What do you dislike most about CET?

5. What have you done in CET that you are proud of?

6. What is that hardest part about CET?

7. What have you learned in CET?

8. How do you use CET in your everyday life?

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