

“Cognitive behavior therapy for work success in veterans with mental illness: A pre-post efficacy study”

Study Protocol and Statistical Analysis Plan

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Overview of the Problem

In 2010, 11.5% of all Gulf War-II veterans were unemployed; that figure rose to 15.2% in January 2011 and continues to grow as the number of veterans from recent wars increases (United States Department of Labor, 2011; Seal et al., 2009). The prevalence of mental illness among veterans is also notable; estimates range from 31% (Seal et al., 2007) to nearly 37% (Seal et al., 2009) for any psychiatric disorder, and over half of these veterans are diagnosed with more than one psychiatric condition (Seal et al., 2007). In addition, empirical evidence suggests that some mental disorders are more prevalent in veterans than in the general population (Kessler et al., 2005). Linking unemployment and mental illness, a recent study found that 65% of veterans using VA healthcare were unemployed, and compared to employed veterans, the unemployed were more likely to have depression, bipolar disorder, post-traumatic stress disorder (PTSD), schizophrenia, or substance use disorders. Vocational dysfunction was reported most often in disabled veterans with schizophrenia, PTSD, and substance use disorders (Zivin et al., 2011). Not surprisingly, this study also found that unemployed veterans had significantly lower income than employed persons. Similarly, a large study focusing specifically on veterans with PTSD concluded that vocational dysfunction is a notable problem among this group, as they were significantly less likely to be employed after participating in VA work programs compared with participants without the disorder (Resnick & Rosenheck, 2008). Because most individuals with mental illness desire to work in regular competitive employment (McQuilken et al., 2003), the nationwide problem of unemployment among veterans with mental illness is particularly troubling.

The VA is addressing this need by implementing supported employment (SE), a psychiatric rehabilitation approach that provides individual vocational assistance to veterans with mental illness. While the SE model is empirically validated and SE programs have been shown to achieve partial success in improving employment outcomes, a sizable proportion of individuals, 40% or more, remain unemployed (Bond et al., 2008). A further challenge is job retention; veterans with mental illness who obtain jobs frequently struggle to maintain them long-term. Even in the context of high quality, evidence-based vocational services, most studies show only modest job retention of a few months (Bond et al., 2008), and consequently, frequent job losses and inconsistent vocational functioning remain a substantial and unsolved problem.

Background

Cognitive behavior therapy (CBT) is an empirically validated, recovery based intervention that has been recommended as a best practice in the treatment of mental illness (Michon, van Weeghel, Kroon, & Schene, 2005). CBT is a standard component of veteran healthcare in the VA—as an integral part of routine outpatient multidisciplinary mental health care effectively treating conditions such as anxiety, depression, and PTSD. CBT is also a central part of Psychosocial Rehabilitation and Recovery Center (PRRC) programming and a core therapeutic technique used in Illness Management and Recovery (Gingerich & Mueser, 2005), an effective and widely implemented severe mental illness self-management program. Furthermore, research indicates that CBT is well accepted by people with mental illness (e.g., Kingdon & Turkington, 1991) and is well suited to meet the treatment needs of diverse patients, including various ethnic groups (Horell & Voss, 2008), a range of diagnostic groups (Butler et al., 2006), inpatients and outpatients (e.g., Drury et al., 1996), and varying illness phases (e.g., acute versus stable; Tarrier et al., 2004).

The majority of psychiatric treatments available to veterans—both

psychotherapeutic (including CBT) and pharmacologic— target symptom reduction. Interventions to improve everyday functioning are lacking, and important veteran outcomes such as subjective quality of life are more strongly related to functional deficits than symptom severity in itself (e.g., Norman et al., 1999). While some psychiatric symptoms in severe mental illness are related to functioning, symptom improvements often do not directly translate to substantial functional improvement; these outcomes are only modestly correlated (e.g., Wykes et al., 2008). In veterans with PTSD, research has demonstrated a stronger relationship between symptom improvement and functional benefits, although functional outcomes in these published studies have most often measured in terms of physical health and social functioning (e.g., Shea et al., 2010), largely ignoring the important area of vocational functioning. Overall, the propensity of research suggests that the utility of therapeutic approaches that solely target symptoms is limited. Furthermore, utilizing a combined approach that focuses on functional improvements (including vocational functioning) in addition to symptomatic relief is consistent with the recovery movement, centered on the notion that people with mental illness can lead meaningful and productive lives despite the challenges imposed by illness (Anthony, 1993). Lastly, as discussed in a later section, the development of interventions to aid functioning in mental illness is critical, given the substantial personal and societal consequences of such deficits.

Previous interventions that have combined CBT with rehabilitation practices targeting instrumental role functioning have had positive results. One that has been studied—CBT combined with social skills training, has shown incremental benefit above and beyond the effects of CBT or social skills training alone. In response to this program, veterans with severe mental illness have shown improvements in long-term social functioning, greater skills mastery, and improved cognitive insight (e.g., Granholm et al., 2005).

Competitive work functioning is a promising next application of CBT intervention. Empirical findings suggest that dysfunctional beliefs about one's ability to excel vocationally seriously damage work outcomes (Gallo, 1994). Specifically, people with severe mental illness endorse the belief of low likelihood of success at work, even with assistance (e.g., Roe, 2001). Influencing these beliefs are other beliefs related to low self worth, low levels of perceived competence, and poor general self-efficacy (e.g., Davis et al., 2004). Studies have also linked negative self beliefs that may impact work ability with illness-related factors such as poor participation in treatment (e.g., Brekke & Long, 2000), ineffective coping styles (e.g., Kleim et al., 2008), poor social functioning (e.g., Lysaker et al., 2007; Roe, 2003), and barren personal narratives characterized by beliefs that one is not an active agent in his or her own life (Lysaker, Buck, Taylor & Roe, 2008). In addition, prior research has demonstrated that such negative expectations are associated with higher levels of alienation, a greater tendency to ignore stressors, and more severe symptoms of emotional discomfort (Lysaker et al., 2008).

Prospective quantitative studies have shown a moderately strong relationship between maladaptive vocational beliefs and employment outcomes. For instance, Regenold and colleagues (1999) found that work-related self-efficacy significantly predicted success in obtaining a job over a 13 month follow-up period in a sample of people with mental illness (i.e., mood disorders, anxiety disorder, schizophrenia, and personality disorders) receiving supported employment services. Similarly, an earlier study (Arns & Linney, 1993) found a moderate association between negative beliefs about work ability and employment outcomes (change from unemployed to employed) over six months in a community mental health sample. Moreover, prior theory-based

research has attempted to explain these findings, highlighting the importance of self-efficacy and perceptions of employment barriers in determining motivation, decisions to seek out work in the community, and purposive action towards career goals (Albert & Luzzo, 1999).

Stigma is another key factor linking negative self beliefs with poor work outcomes. Society often views people with mental illness as being unable to work; accordingly, persons with mental illness are frequently advised to lower their career expectations much below that of their educational background, expertise, and previous work experience (Link et al., 1999). Self stigma, or internalization of this belief, often leads to poor self esteem and expectations of work failure that may take the form of a self-fulfilling prophecy, such as: "I'll never be able to do this job." Consequently, persons with mental illness are often less likely to seek out employment opportunities, tend not to persevere when faced with complex challenges on the job, and engage in less active problem solving (Lysaker et al., 2009). Consistent with these notions, extant studies have found a relationship between endorsement of self stigma, poor self esteem, and lower participation in community activities, including work. In general, stigma is accepted as a barrier to mental health care and personal recovery across psychiatric conditions, including mood disorders, schizophrenia and PTSD (e.g., Corrigan, 2004).

In addition to maladaptive thoughts about work ability, the challenges and deficits imposed by mental illness often substantially decrease the likelihood of gainful employment. In the past 10 years, studies have linked neurocognitive deficits (Green, Kern, & Heaton, 2004), poor intrapsychic functioning (e.g., Rosenheck et al., 2006), deficits in social functioning (Banks et al., 2001), and severe psychiatric symptoms (e.g., Milev et al., 2005) with lower vocational attainment. Recently, studies have also begun to examine the role of metacognition, defined as the ability to think about one's own mental activity and that of others, thinking about oneself and others in a larger social context, and integrating that knowledge to face life's problems and challenges (Semerari et al., 2003). Metacognition has been found to be independently related to work performance (Lysaker et al., 2010) and has been identified as a mediating variable involved in the complex relationship between neurocognition, social discomfort, and vocational functioning (Bell et al., 2009). Metacognition is also inextricably linked with the tenets of CBT, and similarly, several of the other aforementioned challenges and deficits are effectively treated with CBT based approaches.

Despite this solid evidence base and the serious problem of vocational dysfunction among veterans with mental illness, no CBT interventions have been developed specifically to improve competitive employment outcomes. The sole existing CBT program addressing work-related themes is the Indianapolis Vocational Intervention Program (IVIP). The IVIP was designed and tested at the Roudebush VAMC in protected work programs that placed veterans with schizophrenia into temporary sheltered (noncompetitive) work positions within the VA and in businesses contracted by the VA (Davis et al., 2005). However, competitive employment differs in several notable ways from noncompetitive employment: 1) noncompetitive work settings are not integrated (i.e., they are reserved only for those with mental illness); these "protected" work environments are not consistent with the goals of community inclusion and independence (Wehman, Revell, & Brooke, 2003); 2) noncompetitive jobs are most often "low level" jobs and feature less rigorous and complex job demands and responsibilities than competitive jobs; 3) competitive jobs often offer unique and interpersonally complex work environments (Loveland, Driscoll, & Boyle, 2007); 4) noncompetitive jobs typically pay less than minimum wage; 5) noncompetitive jobs are time limited, i.e., temporary; 6)

noncompetitive positions offer little opportunity for career advancement; 7) Lastly and perhaps most importantly, veterans with mental illness overwhelmingly desire competitive jobs in the community in which they can reach their vocational and career aspirations (e.g., Wehman et al., 2003). As a result, an intervention specifically tailored to achieve this goal is essential.

This project is critical for veterans with mental illness and is consistent with national priorities. Recently, federal lawmakers have heavily emphasized the vital need to help veterans succeed vocationally. Accordingly, in November 2011, President Obama signed into law the “VOW to Hire Heroes Act” (P.L. 112-56), which includes measures to target the growing problem of unemployment among veterans with service-connected disabilities. The goals of my proposal are also consistent with the “Americans with Disabilities Act,” which spearheaded the movement to equalize vocational opportunities for all, despite physical or mental challenges (Americans with Disabilities Act, 1990).

This CBT intervention has the potential to complement existing supported employment services within the VA. CBT addresses psychosocial barriers to vocational functioning, whereas supported employment addresses the long-term logistical aspects of finding and keeping a job. Together, these empirically validated approaches will fulfill the mission of improving veteran outcomes by addressing the whole person; this notion is also consistent with the VA goal of providing patient-centered care (Seal et al., 2007). Both CBT and SE further promote patient centered care by focusing on individual preferences, goals, and adopt an educational and collaborative style that is well-accepted by consumers (e.g., Beck et al., 2009; Drake & Bond, 2011; Kingdon & Turkington, 1991).

Significance to Veterans’ Health

Employment is not only a means of economic independence, but it is crucial to maintaining psychological health (see Blustein, 2008). The link between work and mental health benefits has been repeatedly demonstrated in general population studies (e.g., Murphy & Athanasou, 1999). In line with these findings, in psychiatric populations, work is related to better overall functioning (Mueser et al., 1997; Burns et al., 2009) and a host of clinical, social, and quality of life benefits (Bond et al., 2001; Burns et al., 2009; Twamley et al., 2008). Studies of veterans actively employed in VA work programs are consistent with these findings, demonstrating clear benefits of work activity on overall veteran well-being (e.g., Bryson et al., 2002). In contrast, mere participation in supported employment has largely not been shown to improve nonvocational outcomes, including clinical outcomes, quality of life, socialization, and beliefs about the self (Burns et al., 2009; Gold et al., 2006; Mueser et al., 2004; Twamley et al., 2008). For instance, Mueser and colleagues (2004) found that participation in supported employment did not impact self-esteem in persons with mental illness over two years. Work itself, rather than supported employment services, seems to be the critical ingredient positively impacting nonvocational outcomes. That is, persons with mental illness who participate in supported employment services and successfully find and keep work in the community for long stretches have the most favorable outcomes. Conversely, persons with mental illness who engage in SE services, but still cannot find and keep jobs (i.e., the “nonresponders”), have poorer personal outcomes.

In contrast to employment, unemployment in people with mental illness is associated with a higher risk of poverty and a greater reliance on government entitlements and the service system. Psychiatric disabilities represent the largest and

most rapidly growing sub-group of social security beneficiaries (Goodman & Stapleton, 2005). Lower vocational attainment in psychiatric populations is also linked with a range of poor recovery outcomes (e.g., Kukla, Bond, & Xie, 2012). Qualitative research has further highlighted the association between the lack of employment and devastating personal consequences, such as depression, self pity, self absorption, higher risk of substance abuse, and feelings of worthlessness (Marrone & Golowka, 1999).

The mental health and quality of life benefits of work have been demonstrated most strongly for long term employment, as opposed to a working only a short period of time. Steady competitive work (i.e., working 50% or more of the follow-up period) is associated with fewer days of psychiatric hospitalization and improving negative symptoms over time in persons with severe mental illness (Kukla et al., 2012). Other prospective studies have supported a link between steady periods of competitive work and greater rates of symptom improvement, better quality of life, and higher self esteem compared to persons who are unemployed or employed only a short period of time (e.g., Bond et al., 2001). A recent study by Bush et al. (2009) found that people with mental illness who worked in consistent competitive employment over ten years had a significantly more rapid decline across time in service utilization and outpatient mental health costs compared with persons who had an unstable employment course and worked little over time. This is a notable point because veterans with mental illness often have problems with job retention—studies have found that the majority of persons with mental illness experience a job loss within the first four to eight months, even with the assistance of evidence-based supported employment services (Bond et al., 2008; Bond & Kukla, 2011). Short periods of job retention are further harmful because they hinder career advancement and vocational growth that typically evolve over time (Gioia, 2005).

Furthermore, difficulties with job retention in mental illness stem from a variety of causes, such as interpersonal problems in the workplace (e.g., Becker et al., 1998), psychiatric symptom exacerbations (e.g., Biegel et al., 2010), and active substance use. Considering this last point, Zivin et al. (2011) found that unemployment in veterans using VA healthcare was associated with a greater likelihood of having a substance use disorder. Currently, VA vocational services are not designed to directly address these complex causes; cognitive behavioral approaches have been suggested as useful interventions to complement supported employment and overcome individual-level and disease-related barriers to employment (e.g., Loveland et al., 2007).

Preliminary Studies

This current project follows four preliminary studies. In the first preliminary study, veterans with a range of mental illnesses provided their perspectives on factors impacting work success in the community. Findings illustrate a complex set of contributors, including personal motivation, self efficacy, sense of self, interpersonal issues, and an array of other health related factors (Kukla, Bonfils, & Salyers, 2015). This study also demonstrated that veteran-specific facets, such as combat history, notably interplay with factors related to work outcomes (Kukla, Rattray, & Salyers, 2015).

In the second preliminary study, a nationwide sample of 114 VA SE staff, supervisors, and managers rated important factors related to veteran work outcomes and answered qualitative questions regarding additional important factors; they also provided their views on the usefulness of a CBT intervention as an adjunct to existing vocational services. Results emphasize the importance of veteran motivation, psychological stress, and self confidence in work ability (Kukla, McGuire, & Salyers, 2015). Further, SE personnel perceived CBT to be a potentially key intervention to

address these barriers in veterans with mental illness.

Third, a recent study involving a secondary analysis of data examined two important research questions pertaining to CBT outcomes in working veterans with mental illness: (1) What are the predictors of CBT treatment engagement? (2) What are the predictors of CBT treatment success and failure? Findings indicate a nuanced, differential profile of key predictors where neurocognitive factors (i.e., poor attention) played a key role in treatment engagement while psychological factors, such as self esteem played a greater role in successful vocational outcomes (Kukla, Davis, & Lysaker, 2014).

In the fourth preliminary study, the Indianapolis Vocational Intervention program, a CBT program for persons with severe mental illness seeking noncompetitive, time-limited work placements (Davis et al., 2005), was adapted for veterans with a range of mental illnesses who are pursuing/engaged in competitive work in the community. Using an empirically grounded, iterative approach, the revisions and adaptations were guided by existing literature, the findings from the aforementioned preliminary studies, and formative data collected from veteran participants during the study. The resultant new intervention that is the focus of this current study, termed the CBT for work success (CBT_w) program, demonstrated promising preliminary benefits; in a small group of veterans with mental illness, CBT_w was associated improved employment outcomes and was highly acceptable to participants and vocational staff. CBT_w was also feasible to implement (Kukla, Strasburger, & Lysaker, 2016; Kukla, Strasburger, Salyers, Rattray, & Lysaker, 2017).

Rationale

Rationale: Cognitive behavioral therapy (CBT) effectively reduces symptoms across a range of psychiatric conditions (Butler et al., 2006; Wykes et al., 2008); however, its benefit to functioning remains less well understood. Some studies have evidenced a positive influence of CBT on functional outcomes, whereas others have not. One possible explanation for these inconsistencies across studies is that CBT interventions are most often focused on symptoms rather than community functioning. The few CBT interventions that have been specifically designed to address functioning have shown promising results. One functional area of critical importance is work—a central goal of most veterans with (and without) mental illness. However, work functioning has received little empirical attention in the CBT domain. Despite research evidence suggesting that maladaptive thoughts about oneself and expectations about the ability to work interfere with work success (e.g., Hoffman et al., 2000; Kukla, Bonfils & Salyers, 2015; Kukla, McGuire, & Salyers, 2015), no CBT programs have been developed specifically targeting vocational themes with the goal of improving competitive work outcomes. Further, a recent paper outlined needed avenues of future study in the SE domain; Drake and Bond (2011) state that cognitive strategies may be a fruitful area to develop to help “nonresponder” consumers with mental illness who struggle with vocational dysfunction despite high quality vocational assistance. The goal of the current project is to address this gap and the serious problem of unemployment in veterans with mental illness by pilot testing the CBT for work success program (CBT_w) and assessing key employment outcomes before and after the intervention.

Overall Design:

Adult participants will take part in the 12 week CBT_w program. All participants will receive standard SE services during the study. The longitudinal design will consist of assessments of competitive employment outcomes, important psychosocial outcomes, and background and demographic variables at baseline and at two follow-up periods—immediately following the conclusion of the CBT_w program (12 week follow up point) and at a 6 month follow up. The 6 month follow up period is exploratory.

Setting and Participants:

Inclusion criteria is a diagnosis of any mental disorder as confirmed through medical record review; common diagnoses include schizophrenia, bipolar disorder, PTSD, personality disorders, anxiety disorders, and depressive disorders. Second, participants must be enrolled in VA supported employment services. Third, participants must also have an active goal of working in the community; participants can be currently working in the community or unemployed and searching for work. Both veterans seeking employment and those currently employed will be eligible for the pilot study in order to enhance the external validity of our findings. That is, people with mental illness commonly move in and out of job search and job maintenance phases over time and our findings will apply to the average veteran receiving SE services. In addition, including veterans in steady employment as well as those who are searching for a job (and may be experiencing more vocational instability) will reduce selection bias. In other words, we are not limiting our sample to only those veterans who are highest functioning with the greatest work ability.

Exclusion criteria is a major cognitive deficit or severe medical condition that would prevent participation in the intervention and/or community work.

Intervention:

The CBT_w program includes 12 sessions that are delivered in a weekly one-hour group format. Sessions focused on identifying and modifying maladaptive thoughts related to work, enhancing self efficacy and beliefs in one's ability to succeed at work, identifying and addressing personal barriers to work, and increasing beneficial coping strategies that can be applied across employment settings, including during the job search phase and working on the job. The intervention is tailored toward both employed and unemployed persons seeking community work. Session content includes the following modules: Introduction—Work goals and work story; CBT model and work; Thinking about work; Barriers to work; Coping with stress and anxiety; Coping with anger and difficult emotions; Communication at work; Dealing effectively with people at work; Managing work success; Personal work success plan.

Procedures:

Participants will be recruited from the SE program at the Roudebush VA Medical Center. Eligible participants will be approached by their SE vocational specialist who will inform them of the study; if veterans express interest in participating, they will be provided with a study information sheet further explaining details of the study and a member of the study team will call them to schedule a time for the baseline assessment; during this time, written informed consent will be obtained.

Baseline and follow-up assessments (post-intervention and 6 month follow-up) will be conducted by trained study personnel. Currently, several research assistants in our VAMC research service have been trained in interviewing veterans with mental

illness including completing standardized symptom and psychosocial rating scales. The assessments will take approximately 60-90 minutes and participants will be paid \$30 for each of the three assessments. Next, participants will be assigned to an CBT_w group. Once a cohort of eight veterans has been enrolled, we will begin a new CBT_w group.

CBT_w groups will occur weekly for 12 weeks and last for a duration of 60 minutes per session, taking place in one of two RVAMC locations. Participants will be provided with the CBT_w participant manual containing materials pertaining to each of the 12 modules. Each CBT_w group session will be conducted by two facilitators, Dr. Kukla (PI), a licensed clinical psychologist with extensive clinical and research expertise in CBT or the project manager, who has years of experience facilitating CBT interventions for veterans with mental illness (including the preliminary study of the adaptation of the CBT_w program) along with a pre-doctoral clinical psychology practicum students. Student facilitators will first be trained in the CBT_w program by Dr. Kukla. Lastly, periodic fidelity assessments will be conducted by a senior investigator and trained research staff to assess adherence to the general CBT model.

Study Measures:

Unless otherwise specified, study measures will be collected baseline and the 12-week follow up point (post intervention). Some measures will be assessed at the 6 month follow up; these are exploratory.

Background Characteristics. Collected at baseline only, participant background characteristics will include sex, age, ethnicity, mental health diagnosis, educational attainment, marital status, residential status, current work status (employed/unemployed), work history (i.e., weeks worked during the six months preceding the study), residential status, and legal history (i.e., number of felony convictions). We will collect this data through a combination of SE records, patient medical records (i.e., CPRS), and participant self-report.

Competitive Employment Outcomes. Competitive employment outcomes will be assessed at baseline and the follow up periods through participant self-report and supported employment records when available. These outcomes are standard in studies of employment in persons with mental illness and will include change in competitive employment defined as change in number of weeks worked in competitive jobs, comparing the baseline period (i.e. 6 months preceding baseline) and the 6 month follow up point. In addition, achievement of steady competitive employment will be assessed at the 6 month follow up point, defined as working at least 50% of the follow up period in a competitive job.

Work-related self-efficacy. Work related self-efficacy is defined as one's perceived ability and confidence to perform work activities. Given that the adapted CBT program will seek to improve these perceptions, we will measure this construct using the Work-Related Self-efficacy Scale (Waghorn et al., 2005). The 37-item self-report scale yields a total score on a 100-point scale, in which higher scores indicate stronger work related self-efficacy. Studies suggest that the scale has adequate to good reliability and validity in adults with mental illness living in the community (Harris et al., 2010).

Motivation to work: Motivation to work will be measured by the 18-item Work Extrinsic and Intrinsic Motivation Scale (WEIMS) based on self determination theory. The WEIMS is scored on a 1 to 7 Likert scale ('Does not correspond at all' to 'Corresponds exactly') with higher scores indicating higher levels of each domain of

motivation. The WEIMS has been shown to have strong predictive validity, correlating highly with work behaviors (e.g., Tremblay et al., 2009).

Work effectiveness & Work Productivity. The Work and Health Interview (Stewart et al., 2003) will assess work effectiveness and work productivity for participants who are currently working (unemployed participants will not complete these measures). Work effectiveness will be measured by one self-report item—"On days that you worked during the past 4 weeks, how effective were you in your job on average? Please tell me, on a scale of 0 to 100, where 0% means that you were not at all effective, and 100% means that you were completely effective, how effective would you say you have been on your job during the past 4 weeks?" Work productivity will be measured by 7 self-report items scored on a Likert scale ranging from 0, "none of the time" to 4, "all the time" (item example: "Work more slowly than usual?"). Participants will report on work productivity over the last two weeks. The Work and Health Interview has been used widely in patients with chronic conditions, demonstrating good psychometric properties.

Self-esteem: The Rosenberg self esteem scale, a 10-item Likert scale (1-strongly agree; 2-agree; 3-disagree; 4-strongly disagree) will examine self esteem (Rosenberg, 1965); higher scores on the RSES indicate higher levels of a unidimensional self-esteem construct. The RSES has been used extensively in samples of persons with and without mental illness and across various ethnic and cultural groups, demonstrating good reliability and validity (e.g. Link et al., 2014).

Quality of Life. Prior studies in the mental health domain have demonstrated that quality of life improves in response to CBT treatment, therefore, as discussed above with regard to symptoms, quality of life may be enhanced in response to CBT treatment, regardless of the impact on work outcomes. The Quality of Life Interview (QOLI; Lehman, 1988), developed specifically for a psychiatric population, will measure veteran quality of life. We will focus on the health domain of the QOLI. The QOLI has been shown to have very good reliability and validity in adult outpatients (Lehman, 1988; Lehman et al., 1993).

Subjective Recovery: Global perceived recovery will be assessed by the Recovery Assessment Scale (Corrigan et al., 1999), a 41 item scale designed to assess perceptions of recovery held by persons with mental illness. Because perceptions of recovery may be amenable to CBT and have been associated with key functional outcomes, including employment, it is appropriate to examine in this study. The self-report RAS is scored on a 1 to 5 Likert scale from 'strongly disagree' to 'strongly agree' (e.g., "I have a desire to succeed."). Higher scores indicate stronger held perceptions of personal recovery. The RAS has shown good test retest reliability, internal consistency, and criterion-related validity (Corrigan et al., 1999).

Psychiatric Symptoms. Symptoms are essential to assess in this study, as they are often the primary beneficiary of CBT intervention, demonstrating moderate to large effect sizes in randomized trials across numerous psychiatric conditions. Thus, it is possible that symptoms may improve in response to CBT treatment, regardless of change in employment status.

Psychiatric symptoms often present in schizophrenia-spectrum disorders will be assessed by the Positive and Negative Syndrome Scale (PANSS), which has been used extensively in studies of psychiatric rehabilitation and CBT. The PANSS (Kay et al., 1987) is comprised of 30 items scored on a 1 to 7 Likert scale, in which the total score is

obtained by adding up scores on all 30 items (total scores range from 30 to 240). The PANSS has five subscales identified via factor analytic studies including the Positive syndrome (6 items), Negative syndrome (8 items), Emotional discomfort (4 items), Hostility (4 items), and Cognitive (7 items). The PANSS has adequate reliability and validity (Kay et al., 1987).

In addition, we will assess depression and anxiety, two commonly occurring psychiatric conditions in veterans (Seal et al., 2007); depression and anxiety are linked with vocational dysfunction and have been demonstrated to respond well to CBT (e.g., Butler et al., 2006). Current levels of depression will be assessed using the Beck Depression Inventory, Second Edition (Beck, Steer, & Brown, 1996). The BDI-II contains 21 items that assess the various mood and bodily symptoms of depression; participants are asked to respond based on symptoms during the past two weeks. There are four response options for each item reflecting increasing severity of depression; the total score is obtained by summing up the scores on each item (0-3). The BDI-II is the gold standard tool to assess depression in both non-clinical and psychiatric populations and has been shown to have excellent reliability and validity across several prior studies (e.g., Yin & Fan, 2000).

Thirdly, symptoms of anxiety will be assessed using the Beck Anxiety Inventory (Beck & Steer, 1993). The BAI has 21 items, each describing a psychological or physiological symptom of anxiety (e.g., "Nervous") that respondents rate on a 0 to 3 Likert Scale ("not at all" to "severely") based on how much they have been bothered by the symptom within the past week. The BAI has been widely used to assess anxiety in adults with mental illness and has been demonstrated to have strong psychometric properties (e.g., Fydrich, Dowdall, & Chambless, 1992).

Privacy/Confidentiality Issues:

The possible risks to participants associated with participation of this study are a remote risk of loss of confidentiality and psychological risks. We will keep all research records private to the extent of the law. Original copies of assessment materials and digitally recorded CBT_w sessions will be kept in a locked file cabinet and on a secure server. The data will be maintained in a secured computer database in a password-protected computer, located in a limited access, locked room. Access to all data will be restricted to members of the evaluation team. Data will be kept for seven years according to state and federal regulations and destroyed at the end of that period. The other possible risk may be psychological risks associated with participation in the CBT_w group. We will try to minimize this potential psychological risk by informing subjects the CBT program and assessments are strictly voluntary and that they may drop out or quit at any time without any consequences. Participants may also skip or refuse to answer any questions that they would like.

Given the low anticipated risk of adverse events, special safety-monitoring procedures above and beyond those of the VA will be minimal. Participants will have access to the principal investigator's e-mail address and phone number and will be invited to inform the principal investigator of any concerns. All adverse events will be reported to the principal investigator who will be responsible for reporting them to IUPUI's IRB. Given that the pilot study proposed does not involve the use of experimental drugs or devices, reporting will be limited to the IRB and will not include the NIH OBA or the FDA. All procedures for safety monitoring required by the IRB will be observed.

Statistical Analysis Plan

Data will be analyzed using the Statistical Package for the Social Sciences (SPSS), version 24. First, frequency distributions and histograms will be generated to determine the normality of the sampling distribution and inspect for outliers. If the distribution is skewed, data transformations and the use of nonparametric tests in primary analyses will be considered. Secondly, descriptive statistics will be generated to characterize the demographic and background composition of the sample and levels of outcome variables at baseline and post-treatment (12 week follow up). This mean and standard deviation information obtained will be used for sample size calculation for a future expanded randomized trial.

Next, the primary study outcome of weeks worked during the baseline period (6 months preceding baseline) and the 6 months study period will be compared using dependent groups (paired samples) t-tests. Significance values for t-tests will be set at $p < .05$. The secondary work outcome, attainment of steady competitive work will be characterized using percentage of total participants achieving this benchmark. Because secondary outcomes are exploratory, these will be characterized using descriptive statistics, such as means and standard deviations.

Missing Data:

To address the issue of missing follow-up data, participants' baseline characteristics will be compared between those with and without missing data. We will also fit a logistic regression model to compare intervention and control participants with missing outcome data to determine whether missing data is completely at random. If not random, we will perform the analysis with complete cases, using LOCF imputation method. Multiple imputation techniques will be used to evaluate the robustness of our analysis for the main outcome.

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