Protocol Number: CIRB 20-08

Work as a determinant of health: A pragmatic trial of enhanced cognitive behavioral therapy to bolster competitive work and wellness in veterans with serious mental illness (WORKWELL)

Funding Agency: HSR&D

Principal Investigator: Marina Kukla, Ph.D.

Version 4, 6/30/2022

Abstract

BACKGROUND: Work is a major social determinant of health. In people with serious mental illness (SMI), work is associated with better wellbeing, physical and mental health, quality of life, and may prevent the onset of disability. Among Veterans with SMI, work is a protective factor against suicide.

Most Veterans with SMI are unemployed and suffer substantially worse health and recovery across key domains. Despite quality VHA vocational services, such as supported employment (SE), two-thirds or more of Veterans who receive these services experience work dysfunction. A probable explanation lies in unsolved cognitive and behavioral barriers, such as low work-related self-efficacy, ineffective coping skills, little hope that work is attainable, poor work motivation and sense of self.

The Cognitive Behavioral Therapy for Work Success (CBTw) intervention was designed to target these problems and augment VHA SE services to synergistically improve work, as well as health and recovery, in Veterans with SMI. In an open trial pilot, CBTw was associated with significant increases in hours worked and wages earned and the majority of CBTw participants became steady workers. Veterans also experienced improvements in symptoms, recovery, and quality of life.

PROJECT GOALS: Using a randomized controlled trial (RCT) design over a 12-month study period at 3 VA SE programs, this project will 1) test the effects of CBTw on competitive work; 2) test the effects of CBTw on health and recovery outcomes; 3) Informed by the RE-AIM framework, conduct an implementation evaluation of CBTw to inform future wide scale roll-out of the intervention across the Veterans Health Administration (VHA).

OBJECTIVES:

Aim 1: Test the effects of CBTw + SE compared to a control of psychoeducation + SE on work.
Hypotheses: Participants in the CBTw+ SE arm will work significantly more total weeks in competitive jobs (primary study outcome) and will be more likely to become steady workers.

Aim 2: Test the effects of CBTw + SE on health and recovery.
Hypotheses: Participants in the CBTw + SE arm will have greater improvements on subjective recovery and health-related quality of life, and decreases in symptoms, suicidal ideation, and inpatient service utilization.

Aim 3: Conduct an evaluation of the implementation of CBTw using VA supported employment staff to deliver the intervention. Implementation evaluation will examine the following RE-AIM domains: Reach—number of Veterans who take part and complete CBTw. Effectiveness—examined in Aims 1 and 2. Adoption—factors that influence uptake by SE programs examined via interviews and during site visits. Implementation—fidelity to CBT model (collected during monthly assessments)-primary Aim 3 outcome; and key barriers and facilitators to CBTw implementation gauged via site visits and key informant staff interviews. Maintenance—factors that influence continued CBTw use across time examined through key informant staff interviews.

METHODS:

WORKWELL is a pragmatic, Hybrid 1 design RCT. CBTw will be tested at 3 SE sites—Roudebush VA Medical Center, the Edward J. Hines VA Medical Center, and the VA St. Louis Health Care System. 276 unemployed Veterans with SMI will be randomly assigned to receive CBTw plus regular supported employment services or a control of psychoeducation plus regular

supported employment services. Outcomes including total weeks worked in competitive jobs (primary study outcome), achievement of steady work, symptoms, recovery, health related quality of life, suicidal ideation, and service utilization will be assessed at posttreatment (12 weeks), 6 months (primary endpoint), and 9 months (to examine sustained effects). Competitive work outcomes will also be assessed at 12 months. Aim 1 and Aim 2 work and recovery outcomes will be analyzed using multilevel modeling to compare the intervention and control groups over time. CBTw implementation planning, training, and consultation will be provided to SE staff persons delivering the intervention. CBTw implementation outcomes will be analyzed using a rapid mixed methods approach.

List of Abbreviations

BDI-II: Beck Depression Inventory-II

CAPRI: Compensation and Pension Record Interchange

CBT: Cognitive Behavioral Therapy

CBTw: Cognitive Behavioral Therapy for Work Success Intervention

COFAM: Dr. Rollins and Dr. Salyers completed HSR&D IIR study, "Comparison of Fidelity Assessment Methods"

CDA: Career Development Award

CDW: Corporate Data Warehouse

CFIR: Consolidated Framework for Implementation Research

CPRS: Computerized Patient Record System

CTS-R: Cognitive Therapy Scale-Revised

CWT: Compensated Work Therapy

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

ERIC: Expert Recommendations for Implementing Change (resulted in a compilation of implementation strategies)

Hines: Edward Hines Jr. Hospital (study site)

HSR&D: Health Services Research and

Development ICC: Intraclass Correlation Coefficient

IMR: Illness Management and Recovery

IVIP: Indianapolis Vocational Intervention Program

MAR: Missing at Random

MCAR: Missing Completely at Random

MCS: SF-12 Mental Component Summary

NIMH: National Institute of Mental Health

PCS: SF-12 Physical Component Summary

PRISM: Expansion of RE-AIM implementation framework including inner and outer settings factors

PTSD: Post traumatic stress disorder

QUERI: Quality Enhancement Research Initiative

RA: Research Assistant

RAIN-MH: Dr. McGuire HSR&D funded study, "Evaluation of Recovery-oriented Acute INpatient Mental Healthcare"

RCT: Randomized Controlled Trial

RE-AIM: Implementation science framework intended to translate research findings into practice; includes domains of Reach, Effectiveness, Adoption, Implementation, Maintenance

RLR: Richard L. Roudebush VA Medical Center

St. Louis: St. Louis VA Health System (study site)

SE: Supported Employment

SF-12: 12-Item Short Form Health Survey

SMI: Serious Mental Illness

SWS: Satisfaction with Services Scale

TSES: Therapeutic and Supported Employment Services, VA Central Office

VA: Veterans Administration

VACO: Veterans Affairs Central Office

VHA: Veterans Health Administration

VISN: Veteran Integrated Service Networks

VistA: Veterans Health Information System and Technology Architecture

VRC: Vocational Rehabilitation Counselors

WORKWELL: Dr. Kukla proposed HSR&D study, “Work as a determinant of health: A pragmatic trial of enhanced cognitive behavioral therapy to bolster competitive work and wellness in veterans with serious mental illness”

Contents

Protocol Title: Work as a determinant of health: A pragmatic trial of enhanced cognitive behavioral therapy to bolster competitive work and wellness in veterans with serious mental illness (WORKWELL)

1.0 Study Personnel

1.1. Participating Sites:

Three VA sites, each from a different VISN, will participate in this study: Richard L. Roudebush VA Medical Center (RLR), Edward Hines Jr. Hospital (Hines), or the St. Louis VA Health System (St. Louis). The study PI will be stationed at RLR, and Local Site Investigators have been appointed at Hines and St. Louis. Start-up activities will occur concurrently at all sites.

1.2. Principal Investigator:

Marina Kukla, PhD
Contact Information: marina.kukla2@va.gov 317-988-3330
Facility: Richard L. Roudebush VA Medical Center, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

1.3. Co-Investigators:

Alan McGuire, PhD
Contact Information: alan.mcguire@va.gov 317-988-2725
Facility: Richard L. Roudebush VA Medical Center, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Teresa Damush, PhD
Contact Information: teresa.damush@va.gov 317-988-4277
Facility: Richard L. Roudebush VA Medical Center, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Paul Lysaker, PhD
Contact Information: paul.lysaker@va.gov 317-988-2546
Facility: Richard L. Roudebush VA Medical Center, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Angela Rollins, PhD
Contact Information: angela.rollins@va.gov 317-988-4789
Facility: Richard L. Roudebush VA Medical Center, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Wei Wu, PhD
Contact Information: wwu1@iu.edu 317-274-6945
Facility: Richard L. Roudebush VA Medical Center, 1481 W 10th St, Indianapolis, IN 46202
Affiliation Status: IPA

1.4. Local Site Investigators:

Kenneth Weber, MS, CRC, LCPC
Contact Information: kenneth.weber@va.gov 708-202-7897
Facility: Edward Hines Jr. VA Hospital, 5000 South 5th Avenue, Hines, IL 60141
Employee Status: 8/8th VA

Jessica Hatfield, MS
Contact Information: jessicahatfield@va.gov 314-652-4100 ext 65087
Facility: VA St. Louis HCS, Jefferson Barracks, 1 Jefferson Barracks Drive, St. Louis, MO 63125
Employee Status: 8/8th VA

2.0 Introduction

Among Veterans with serious mental illness (SMI), employment problems are pervasive. Over 1 million Veterans have a serious mental illness (SMI)[1], formally defined by SAMHSA and the VA as the presence of a mental disorder that substantially limits role functioning, including work[2], and encompasses diagnoses of major depression, bipolar disorder, posttraumatic stress disorder (PTSD), and schizophrenia-spectrum disorders[2]. Compared to unemployment of around 4.5% in the general Veteran population[3], over 75% of Veterans with SMI are unemployed.[4] In studies across groups, such as female Veterans[5], Veterans of Post-911 conflicts[6], and other combat eras[7], SMI is linked with worse work outcomes[5]. This problem is especially troubling because most people with SMI desire to work[8]; many search for a job with little success[4]. Even among the tens of thousands of Veterans with SMI who receive VHA employment services yearly, which focus on helping Veterans obtain community jobs, two-thirds or more continue to experience work deficits[9].

Employment problems in Veterans with SMI are costly at the personal and societal level. Unemployment in Veterans with SMI is associated with a higher risk of poverty and greater reliance on entitlements and the service system[10]. Veterans with SMI report greater financial troubles, more difficulties covering basic needs, and higher debt[11]. Overall, unemployment creates a deleterious feedback loop of poverty, declining mental status, and related problems, such as substance misuse[4]. Similarly, studies have highlighted that among Veterans with SMI, the problem of lack of participation in the workforce has major economic and well-being effects that persist into the future, if not adequately addressed[12].

Supported by public health research, employment is a major social determinant of health[13]. Employment dysfunction leads to poor health and wellness, including among those with SMI receiving quality employment services. In the general population, precarious employment has many chronic physical health effects[13] and is a major cause of distress and poor mental health[14]. Because people with SMI are particularly susceptible to the negative outcomes linked with unemployment, the effects are more damaging and include poor recovery, worsening illness trajectory, and more days of psychiatric hospitalization[13]. In addition, Veterans with SMI have more medical conditions[15] and experience deteriorating quality of life [16].These health problems also persist in unemployed persons with SMI who receive quality employment services[17].

Sustained work is associated with improvements in health and recovery in SMI, a Health Services Research and Development (HSR&D) priority. Across prospective studies, the health and wellness benefits of work in people with SMI who are receiving employment support include improved self-esteem and life satisfaction, a reduction in psychiatric symptoms, and fewer hospitalizations. In addition, studies of Veterans with SMI and broader meta-analysis evidence

indicates that work leads to major gains across health, quality of life, and wellness areas[20]. These health and recovery benefits are particularly strong when persons engage in steady, long-term competitive work[17,]. Competitive work refers to a regular community job open to anyone, and pays at least minimum wage[21].

Competitive employment also leads to lower healthcare utilization and lower service system costs. A study by Bush and colleagues[22] found that people with SMI who had received employment services and worked in competitive employment over 10 years had significantly reduced service utilization and mental health costs compared with persons who worked little or inconsistently. Similarly, young adults with SMI who work use fewer mental health services, take fewer medications, and are less reliant on disability entitlements[23]. Among this group, there is evidence that employment may delay or altogether prevent subsequent disability[24].

Aligning with a current major VA and HSR&D priority, employment is a protective factor against suicide, whereas unemployment leads to increased suicide risk. Meta-analytic evidence demonstrates that unemployment is associated with a significantly higher risk of suicide, a relationship that is particularly strong among people with mental illness[25]. A large study found that Veterans with recent suicidal ideation were more likely to have PTSD and report psychosocial barriers, including work problems. On the other hand, a sense of purpose, such as that found through career, was negatively associated with suicidal thoughts[26]. Similarly in a sample of Veterans with depression, compared to their employed counterparts; unemployed persons were more likely to have thoughts of self-harm[27].

Despite quality VHA employment services, employment dysfunction & poor wellness persist. To address work problems in Veterans with SMI, supported employment (SE) services have been widely implemented through VHA Therapeutic and Supported Employment Services (TSES), including 200 SE programs nationwide. VHA SE services are individualized and include a vocational assessment, rapid job search and placement in community jobs, collaboration with employers, and ongoing follow-along support after the job has been secured[28]. Supported by robust evidence[29], high quality SE services assist Veterans with SMI to find and keep competitive jobs in the community. However, SE programs have achieved only partial success in improving outcomes[29], as 67% or more of Veterans with SMI receiving SE remain unemployed. A further challenge is retention, as those with SMI who obtain jobs struggle to maintain employment long-term, even in the context of quality SE support[31]. Moreover, among many with SMI receiving SE services, these ongoing struggles to secure competitive work are linked with worse health and well-being outcomes across studies [e.g., 17].

SE services are not designed to address complex cognitive and behavioral work-related barriers. SE services effectively address common barriers such as skills deficits, resume building deficiencies, employer-related factors, legal involvement, navigation of job accommodations, and job search needs[32]. However, as demonstrated by an extant of literature and our prior work; these services incompletely address many key cognitive and behavioral factors that impact work success[33]. Specifically in people with SMI, including those receiving SE, many cognitive and behavioral factors have been identified as work barriers or linked with poor work outcomes: low work-related self-efficacy[34] and self-esteem[35], poor motivation, loss of hope that work is attainable [36], interpersonal problems[37], difficulties enacting coping on the job[38], and stress. Further, job tenure has been associated with one's perception of competence and efficacy on the job[39]. In this regard, work may present a threat to ones sense of self, resulting in lowered belief in ones ability to maintain a job[39].

In response, cognitive behavioral therapy (CBT) approaches have been suggested to augment SE services and address cognitive and behavioral barriers to competitive work success. A vast majority of CBT interventions do not focus on functioning as a primary target.

CBT is an empirically validated, recovery intervention recognized as a best practice in SMI care[41]. CBT is a standard component of VHA mental health services in treating anxiety, depression, bipolar disorder, PTSD, and schizophrenia. However, though traditional CBT interventions effectively treat psychiatric symptoms[42]; findings regarding the impact of CBT on functioning have been mixed and effect sizes are small[42]. One potential explanation for the lack of findings is that while CBT aims to restructure thoughts about symptoms and increase symptom coping; it does not directly address role functioning and hence may have less effectiveness in these areas. To address this gap, CBT interventions have begun to arise that emphasize correcting unhelpful cognitions and tailoring behavioral strategies directly pertinent to deficits in functioning.

Previous interventions combining CBT with rehabilitation practices have had positive results on role functioning in Veterans with SMI. A cognitive intervention focused on protected, time-limited noncompetitive work experiences had positive effects on work performance in people with chronic schizophrenia[43]. Further, CBT combined with social skills training has shown benefits beyond the effects of CBT or social skills training alone, improving skills mastery and interpersonal functioning in Veterans with SMI[44].

CBT approaches also improve health and wellness in Veterans. Cognitive behavioral interventions, either alone or in combination with other approaches, have been shown to improve physical health, mental health, quality of life, and related indicators of health in Veterans[45] and non-Veterans with SMI[46]. In addition, CBT approaches have shown benefits to improve physical health and functioning in Veterans with other chronic conditions, such as musculoskeletal pain[47].

Moreover, CBT directly builds upon existing VHA SE services. Featuring the provision of concrete individualized services to assist Veterans in acquiring strong fitting jobs, SE involves job assessment, resume support, rapid job development, collaboration with employers, and follow along support[28]. However, many Veterans with SMI in SE continue to falter in their work pursuits, due in part to unsolved personal issues, such as cognitive and behavioral obstacles[37]. The use of an empirically supported, tailored CBT approach tackles these barriers and builds upon SE by providing interventions that SE is not designed or intended to provide. CBT is also a strong fit with the structure and goals of SE, as demonstrated in past studies and in SE stakeholder accounts[33].

In summary, an enhanced CBT approach optimized to promote community work and wellness has great potential to increase meaningful functioning, improve health and recovery, and mitigate risk for negative outcomes, such as suicide, in Veterans with SMI receiving SE services.

3.0 Objectives

3.1. Study Purpose.

In partnership with the VA Office of Therapeutic and Supported Employment Services, the project is a pragmatic Hybrid 1 randomized controlled trial testing employment and recovery outcomes and examining implementation of CBTw at three VA SE programs in three VISNs—Richard L. Roudebush VA Medical Center, Edward Hines Jr. VA Hospital, and VA St. Louis Health Care System.

3.2. Specific Aims & Hypotheses.

Aim 1. Test the effects of CBTw + SE compared to a time and format matched active control of psychoeducation + SE on competitive work outcomes across the 9 month study period. A total of 276 unemployed Veterans with SMI will be randomized to CBTw + SE or the control arm of psychoeducation + SE. Assessed at posttreatment (12 weeks), 6 months (primary endpoint), 9 months and 12 months (to examine sustained effects), the primary outcome will be total weeks worked in competitive jobs. A secondary work outcome, achievement of steady competitive work (i.e. working at least 50% of the follow-up), will be compared between study arms across the 12 month follow up.

> Hypothesis 1: Compared to the control arm, participants in the CBTw + SE arm will work significantly more weeks and will be more likely to become steady workers.

Aim 2. Test the effects of CBTw + SE compared to the control arm of psychoeducation + SE on health and recovery at posttreatment (12 weeks), 6 month and 9 month follow up periods. The study will determine the effectiveness of CBTw to improve key health and recovery outcomes including health-related quality of life, suicidal ideation, subjective recovery, symptoms, and mental health service utilization.

> Hypothesis 2a: Compared to controls, participants in the CBTw + SE arm will have greater improvement on subjective recovery and health-related quality of life, and decreases in mental health symptoms, suicidal ideation, and inpatient service utilization.
>
> Hypothesis 2b: Greater participation in competitive work will predict improvements in these outcomes over time.

Aim 3. Guided by the RE-AIM implementation framework, conduct an implementation evaluation of CBTw to inform future wide scale roll-out of the intervention across the VHA. Existing Vocational Rehabilitation Counselors (VRCs) at the 3 VA SE programs will deliver CBTw, supported by an initial implementation strategy bundle—site tailored implementation planning, CBTw training, and weekly consultation including audit and feedback. Informed by the RE-AIM implementation framework, data will be collected and utilized to tailor implementation during the study, with assessment of the following RE-AIM domains:

(1) Reach—number of Veterans who take part and complete CBTw. (2) Effectiveness—examined in Aims 1 and 2. (3) Adoption—factors that influence uptake by SE programs examined via interviews and during site visits. (4) a. Implementation—fidelity to CBT model (collected during monthly assessments), the primary Aim 3 outcome; and b. key barriers and facilitators to CBTw implementation gauged via site visits and interviews. (5) Maintenance—factors that influence continued CBTw use across time examined through staff interviews.

3.3. Significance and impact on VA priorities & service mission to veterans.

Addressing national and HSR&D priorities, this project is a critical step toward enhancing employment and reducing poor health outcomes experienced by Veterans with mental health disorders, including PTSD. As discussed, Veterans with SMI, especially those who are unemployed, tend to have poor health and wellness. Targeting work, with its therapeutic benefits, is a novel way of improving these outcomes[20]. Systematic reviews and experts have also identified work interventions as an area of future development in order to directly bolster health and reduce such inequalities[60]. The WORKWELL study will fulfill this need and result in an intervention and implementation strategy prepared for uptake by SE programs across the VHA.

This study advances chief HSR&D and VA goals in the area of developing novel interventions to improve suicide prevention for at-risk Veteran groups. Given the strong links between work as both a protective factor among the employed and a risk factor for suicide among unemployed Veterans with SMI[26], combined with the evidence of the benefits of CBT on thoughts and actions of self-harm[61]; WORKWELL is an encouraging approach to tackle this critical issue among Veterans.

Underscored by our strong partnerships with national operational leaders, the CBTw intervention has high implementation and scalability potential. Pilot work indicates that CBTw appears initially feasible to implement, is acceptable and appropriate for Veterans with SMI, and is well supported by VHA SE personnel nationally. Importantly, this research is also strongly supported by national leaders in the VHA Therapeutic and Supported Employment Services (TSES) office. This project directly aligns with the TSES main priority to develop effective and feasible strategies to further enhance competitive work outcomes. This project is also a strong fit with the recent TSES transformation to provide services focused on improving recovery.
Indeed, if effectiveness is demonstrated and a feasible implementation strategy is finalized in WORKWELL, our operational partners are committed to broadly implementing CBTw.

4.0 Resources and Personnel

4.1. Richard L. Roudebush VAMC, Indianapolis, IN

Principal Investigator:

Marina Kukla, PhD
Contact Information: marina.kukla2@va.gov 317-988-3330
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Dr. Kukla will be responsible for the overall management of the study and will oversee delivery of the CBTw intervention and psychoeducation control intervention. Further, she will collaborate with study sites and site investigators, train vocational rehabilitation counselors delivering CBTw (Aim 3), provide ongoing consultation and implementation support throughout the study period, as well as implementation evaluation, e.g., site visits (Aim 3). In addition, Dr. Kukla will help oversee the training and supervision of research staff, oversee data management and entry, and will lead the research team in the preparation of progress reports, final reports, and publications. Lastly, Dr. Kukla will work with VA central office vocational leaders and operational partners to disseminate study findings and if appropriate, and work with partners to facilitate the a widescale roll-out of CBTw at VHA programs nationwide.

Co-Investigators:

Alan McGuire, PhD
Contact Information: alan.mcguire@va.gov 317-988-2725
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Dr. McGuire will oversee training of SE staff delivering psychoeducation, as well perform periodic psychoeducation fidelity assessments and provide psychoeducation

consultation during the study period. Dr. McGuire will also lend his expertise as part of the implementation support team, conducting site visits to provide pre-implementation planning and the implementation evaluation component, involving observations of CBTw and SE services, and interviews with key stakeholders (Aim 3). In addition, he will take part in mixed methods analysis and integration of data collected for the implementation evaluation.

Teresa Damush, PhD
Contact Information: teresa.damush@va.gov 317-988-4277
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

As a senior scientist and implementation expert, Dr. Damush will provide guidance to refinement of the implementation strategy that will occur throughout the primary study period and the Aim 3 implementation evaluation. In addition, she has conducted several multi-site studies and thus will provide key guidance on important issues and strategies regarding successful management and execution of a multi-site trial.

Paul Lysaker, PhD
Contact Information: paul.lysaker@va.gov 317-988-2546
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Dr. Lysaker's role will be three-fold: 1) He will provide subject matter expertise in cognitive behavioral interventions tailored to enhance vocational functioning in SMI; 2) He will provide guidance and expertise on issues related to clinical assessments in veterans with SMI; and 3) Dr. Lysaker will provide expertise as a licensed clinical psychologist in accordance with the data safety plan.

Angela Rollins, PhD
Contact Information: angela.rollins@va.gov 317-988-4789
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Dr. Rollins will coordinate and conduct CBTw fidelity assessment at all sites and work with Dr. Kukla to provide feedback to CBTw facilitators during weekly consultation meetings in order to ensure full adherence to the CBT model. Drawing from her unique background and experience in rapid qualitative and mixed methods analytic approaches, Dr. Rollins will also contribute to the Aim 3 implementation evaluation analysis.

Wei Wu, PhD
Contact Information: wwu1@iu.edu 317-274-6945
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Affiliation Status: IPA

Dr. Wu will guide the randomization process, oversee and supervise Indianapolis research assistants and data manager with regard to basic data management and cleaning, as well as rudimentary analysis (e.g., descriptives), conduct all primary analyses for Aim 1 and Aim 2, and assist with manuscript preparation.

Project Staff:

Project Coordinator: Nancy Henry, BA
Contact Information: nancy.henry2@va.gov 765-688-0677 *Facility:* Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202 *Affiliation Status:* IPA

As project coordinator, Ms. Henry will organize all processes required to receive IRB, R&D, and any other regulatory approvals for the project, as well as manage and coordinate multiple other research and administrative functions. In addition, she will coordinate and oversee all participant recruitment efforts at Roudebush and coordinate with the St. Louis and Hines VA sites. She will also supervise and oversee the informed consent process and the data collection team, coordinating with research assistants located onsite at Roudebush, Hines, and St. Louis.

Research Assistant (blinded): Miranda Connors, BS
Contact Information: Miranda.Connors@va.gov 317-988-2986
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Ms. Connors will have the primary responsibility of assisting Ms. Henry with participant recruitment and collecting research data from study participants located at the Roudebush VAMC, including informed consent procedures, baseline assessments, and all follow-up assessments. Second, Ms. Connors will enter all assessment data into the dataset. Third, Ms. Connors will perform administrative tasks, coordinate the research team and supervision meetings; in years 3 and 4 of the study, she will assist with data entry and cleaning. Fourth, as needed, Ms. Connors will assist Ms. Bobiles with transcription of staff stakeholder interviews during Year 4. Connors will be supervised by Henry for administrative purposes. Connors has a BS degree and has experience conducting research within our HSR&D Center and Research Service.

Research Assistant (unblinded): Jessica Carter, BS
Contact Information: Jessica.Carter1996@va.gov 317-988-2074
Facility: Richard L. Roudebush VAMC, 1481 W 10th St, Indianapolis, IN 46202
Employee Status: 8/8th VA

Ms. Carter will be responsible for basic data entry of assessment data into study databases and basic data cleaning. She will also be charged with clerical and administrative tasks, including reminder calls to participants for assessments and to attend (CBTw and psychoeducation, respectively) group sessions. Ms. Carter will also manage the Roudebush participant contact tracking sheet including all phone contacts,

sessions attended, assessment appointments, and contacts with vocational providers during the study. Lastly, Ms. Carter will be the primary transcriber of interview recordings from Aim 3-formative evaluation.

4.2. Edward Hines Jr. VA Hospital, Hines, IL:

Local Site Investigator: Kenneth Weber, MS, CRC, LCPC
Contact Information: kenneth.weber@va.gov 708-202-7897
Facility: Edward Hines Jr. VA Hospital, 5000 South 5th Avenue, Hines, IL 60141
Employee Status: 8/8th VA

Mr. Weber will serve as site investigator for this study, overseeing all study activities at Hines, coordinating with local study personnel (research assistant), and coordinating closely with Dr. Kukla and the study team. Further, Mr. Weber will oversee SE staff who are delivering CBTw and psychoeducation interventions, will take part in implementation support activities (e.g., pre-implementation, consultation, etc.), will assist with ensuring that recruitment targets are met, and will participate in the formative evaluation (i.e. provide feedback on the fit between CBTw and SE services). He will also utilize his prior research experience working with regulatory boards to ensure local study approvals and adherence to protocols.

4.3. VA St. Louis Health Care System, St. Louis, MO:

Local Site Investigator: Jessica Hatfield
Contact Information: jessicahatfield@va.gov 314-652-4100 ext 65087
Facility: VA St. Louis HCS, Jefferson Barracks, 1 Jefferson Barracks Drive, St. Louis, MO 63125
Employee Status: 8/8th VA

Ms. Hatfield will serve as site investigator, overseeing all study activities at St. Louis, coordinating with local study personnel (research assistant), and coordinating closely with Dr. Kukla and the study team. Further, Ms. Hatfield will help oversee SE staff who are delivering CBTw and psychoeducation interventions, will take part in implementation support activities (e.g., pre-implementation, consultation, etc.), will assist with ensuring that recruitment targets are met, and will participate in the formative evaluation (i.e. provide feedback on the fit between CBTw and SE services). She will also assist with the completion of site regulatory requirements and help ensure study approvals and proper adherence to protocols.

4.4. Contractors

No services will be performed by contractors

4.5. Data Agreements

No Memoranda of Understandings (MOUs), Data Use Agreements (DUAs), and/or CRADAs that are being entered into for this study.

5.1 Study Procedures

5.2 Study Design

5.2.1 Experimental Design

WORKWELL is a Hybrid 1 design, two arm RCT with 276 unemployed Veterans who have SMI and are receiving SE services at one of 3 VA sites: Richard L. Roudebush VA Medical Center (RLR), Edward Hines Jr. Hospital (Hines), or the St. Louis VA Health System (St. Louis). Participants will be assigned to one of two study arms: 1) the intervention arm consisting of the 12-week, group-based CBTw plus standard SE services; 2) a time and format matched active control arm consisting of psychoeducation plus standard SE services. The intervention period will last for 12 weeks after which time Veterans will be followed up for an additional 9 months (total of 3 follow-up assessments: posttreatment at 12 weeks, 6 months & 9 months). During the study, participants will receive all standard VA services. The primary outcome will be competitive work (Aim 1) and secondary outcomes of health and recovery will also be evaluated (Aim 2).

SE staff who deliver the CBTw intervention will take part in training led by the study team including education on CBTw content, practice of facilitation strategies, and customization of content to meet Veterans' needs. SE staff who deliver the psychoeducation intervention will take part in training that parallels this structure. Across the study, staff CBTw facilitators will take part in weekly consultation and monthly audit and feedback with study personnel.

Aim 3—Guided by RE-AIM, an evaluation of CBTw implementation will allow for ongoing refinement and finalization of an implementation approach (Aim 3). RE-AIM is an implementation science framework useful for directing the planning and evaluating of interventions, in order to expedite the translation of research into practice[49]. RE-AIM has been successfully utilized across studies[49], including multiple HSR&D hybrid 1 intervention studies[52].

RE-AIM includes 5 domains: degree of reach to the target population, effectiveness, or impact of the intervention, adoption by providers or settings, implementation or fidelity to an intervention model, and maintenance of the intervention across time[49]. WORKWELL will primarily focus on effectiveness (Aims 1 & 2) and implementation, assessed via staff fidelity to the CBT model (primary Aim 3 outcome). Barriers and facilitators that influence CBTw implementation, adoption, and maintenance in SE clinics will be examined via staff interviews.

5.2.2 Control, Intervention, & Standard of Care

Intervention: Cognitive Behavioral Therapy for Work Success (CBTw)

CBTw is a manualized intervention, tailored for unemployed Veterans with SMI who have competitive work goals. CBTw will be delivered by local VRCs in 12 weekly, one-hour sessions, in a group format with up to 8 participants per group. Once participants have been randomized into a group cohort, enrollment into that group is then closed. The cohort goes through the entire 12 session CBTw program together, promoting group cohesiveness, trust, and unity[56]. As displayed in Appendix 2, session content falls in five domains: 1) cognitive techniques to enhance healthy thinking pertaining to work; 2a) behavioral strategies to increase adaptive coping and problem solving in the context of emotions and stressors that impede work

functioning; 2b) behavioral strategies to facilitate effective interpersonal functioning on the job; 3) narrative exercises to enhance participants' sense of self as workers; and 4) the formation of an individualized work success plan tailored to address work barriers and capitalize on work-related strengths to facilitate long-term job success.

During CBTw group sessions, participants check in on their work progress, review homework, and review the session agenda. Next, session content is presented in an interactive way, allowing participants to apply material through didactic exercises, open discussions of their work-related experiences, and via the provision of feedback to one another. Participants are provided CBTw manuals containing session content to keep and bring to weekly sessions. These manuals also guide homework assignments and provide space for further narrative reflections, goal setting, application of cognitive restructuring, practice of coping strategies, and problem solving. In addition, in Session 6: "Coping with Work Stress and Anxiety," each participant is provided a PlayAway device, a listening device containing audio recordings of coping exercises (e.g., breathing); this is intended for use at home and on the job. Veterans will keep the PlayAway device after study participation.

CBTw sessions will be audio recorded for the purposes of audit and feedback fidelity review (Aim 3). If necessary, group will be held remotely according to local SOPs for remote groups, which are now being developed by local Service Line Leadership. In cases where group is conducted remotely, Veterans will receive a "Welcome Packet" which will include the CBTw Participant Manual (Appendix 2), the Veteran Self-Report Monthly Work Update Form (Appendix 8), and a copy of the Study Information Sheet. Veterans will receive the PlayAway device shortly before it is needed (utilized in a later module). This Welcome Packet, and the PlayAway device, will be mailed directly to the Veteran, or mailed to their local VR office if they so prefer or if they do not have an address where they can receive the packet. As described in the CBTw Manual, intervention providers will have to option to provide individual booster sessions for veterans who miss group sessions.

Control: Psychoeducation

The control arm will receive the 3 psychoeducation modules from the Illness Management and Recovery (IMR) program for adults with SMI (Appendix 4). Psychoeducation was chosen as the control because it is not work related and potential overlap with CBTw or SE services as usual is low. IMR is a well-respected intervention, and perceived credibility is high, increasing control group participant engagement and reducing attrition risk.

The control intervention will occur in cohort groups of up to 8 participants, led by local VRCs. Each psychoeducation module is presented across 4 sessions (total of 12 weekly group sessions, 1 hour in duration, mirroring the CBTw structure). Modules include "Practical Facts about Mental Illness," "The Stress Vulnerability Model," and "Understanding Relapse." Review evidence indicates that IMR is unrelated to better functioning in SMI[77] and, psychoeducation alone does not predict improvements in symptoms or functioning[78]. Psychoeducation training will be provided by Dr. McGuire, an IMR expert[79]. Furthermore, the CTS-R, a highly used fidelity measure for CBT interventions, will be used to examine fidelity in both the CBTw and psychoeducation conditions. The benchmark for low fidelity on the CTS-R (score of 3 or lower) will be used to ensure that drift in the control arm has not occurred. If necessary, group will be held remotely according to local SOPs for remote groups, which are now being developed by local Service Line Leadership. In cases where group is conducted remotely, Veterans will receive a "Welcome Packet" which will include the participant portions of the IMR Manual (Appendix 4), the Veteran Self-Report Monthly Work Update Form (Appendix 8), and a copy of the Study Information Sheet. This Welcome Packet will be mailed directly to the Veteran, or

mailed to their local VR office if they so prefer or if they do not have an address where they can receive the packet.

Standard Care: VHA Supported Employment (SE) Services

Participants in both study arms will receive standard SE services during the entire study period. SE services are individualized; vocational specialists meet one-on-one with Veterans and provide job assistance tailored to their needs and preferences. SE services are based on the evidence based Individual Placement and Support (IPS) model[28] that includes the following main tenets: a zero exclusion policy, a brief vocational assessment, rapid job search, job development, including dynamic engagement with employers in the community to identify and secure jobs, job carving (i.e. working with employers to create jobs based on veteran needs), integration with mental health services, benefits counseling, and follow-along support after job acquisition [75]. Further, VACO does periodic fidelity assessments to ensure quality at the 3 SE programs (all have good fidelity to IPS model). VISN learning communities supporting IPS implementation are also available.

5.2.3 Risk and Benefit Analysis

Potential Risks

Veterans

Potential risks for participating in the study are anticipated to be minimal. First, personal disclosure is always a part of CBT group interventions. Several prior studies, including our prior work developing and testing the CBTw intervention, have found that CBT group sessions are well tolerated and accepted by Veterans with SMI. In addition, this could be a potential risk for participants randomized to receive psychoeducation, but similarly is expected to be minimal. Furthermore, research strongly suggests that personal disclosure is an important component of the therapeutic group process, allowing for helpful and invaluable feedback from other persons in the group. Nonetheless, participants could experience some minor anxiety or distress in disclosing work difficulties and experiences in the group context.

Second, the loss of confidentiality is another possible but unlikely risk. Proper privacy and security procedures will be followed to protect against this risk, such as the de-identification of data and data storage using password protected VA servers; all sites will have access to RLR servers behind VA firewall. Any paper data collected will be stored in locked filing drawers in a locked office. Moreover, to further ensure the rights of participants and minimize potential risks, participants will be clearly informed that they may discontinue study participation at any point in time. No pharmacological therapies will be utilized in this study.

Key Informant Staff Persons-Interviews

Potential risks for SE key informants participating in Aim 3 interviews examining CBTw implementation may include feeling uncomfortable while talking with study staff. We have conducted several prior studies examining the implementation of programs within the VA utilizing staff interview methods that have minimized these risks. Key informant staff persons will also have the option of ending the interview or not answering any questions as they wish.

Staff delivering CBTw Intervention

SE staff persons who are delivering the CBTw intervention and taking part in the Aim 3 fidelity audit and feedback process may experience slight discomfort in response to evaluation and feedback during the CBTw fidelity assessment process. We have conducted several past

studies utilizing these implementation and evaluation methods, and our established processes have minimized these risks.

Adequacy of Protection From Risk

Protection Against Identified Risks

Prior to the start of research, study investigators will have completed required VA R&D committee training (i.e., VA's Cyber Security Awareness course and Overview of Good Clinical Practice and Human Subjects Protection course) as well as other required trainings by IRB. Research staff and all site investigators will complete all required VA R&D and IRB research trainings, such as Collaborative Institutional Training Initiative courses on responsible practice of research and protection against risk.

To protect against the potential loss of confidentiality, all electronic data will be, coded or de-identified to the extent possible, and stored on a secure, password-protected VA server. Any paper data will be kept in a locked cabinet in secure (locked) office space at each VA site until it can be scanned to a digital copy and the hard copy destroyed. Computerized files will be protected by the electronic firewall at the Roudebush VAMC and will be password protected (Roudebush servers behind VA firewall will be accessible to and used by study personnel at all sites, including Hines and St. Louis). Passwords are created according to guidelines set by the VA Office of Cyber and Information Security.

To protect against discomfort that may be experienced related to personal disclosure during CBTw and psychoeducation group sessions, participants will be explicitly informed that personal sharing is not mandatory, and they have the right not to disclose information and/or speak during groups at their discretion. This is a standard practice in psychotherapy and education-based groups in clinical and research contexts. Second, "group rules" will be laid out at the beginning of the CBTw and psychoeducation conditions during the first group session in which confidentiality and respect for the privacy of other Veterans will be discussed and agreed upon by all participants. Specifically, information discussed in the group will stay in the group and is not to be discussed with other persons outside of the group. Forming these "group rules" is also standard practice in research and clinical group therapy and psychoeducation settings.

During assessments, all participants will be instructed that they may refuse to answer any question that they are uncomfortable answering. In addition, participants may withdraw from the study at any time without any repercussions; participants will continue to receive all VA care and rehabilitation services (including supported employment) as usual, regardless of their study status.

If participants become distressed or experience a clinically significant increase in symptoms at any point during the study (e.g., during a CBTw or psychoeducation group session or assessment), facilitators will collaborate closely with Dr. Kukla, study PI,, as well as site investigators at St. Louis and Hines (SE managers- Ms. Hatfield and Mr. Weber) to quickly refer participants to their mental health clinic and mental health treatment coordinating clinician as appropriate. Because all Veterans will meet the inclusion criteria of SMI and functional impairment, they will have an assigned VA mental health treatment coordinator to arrange and directly provide mental health services on a same day basis. This procedure has been used extensively across mental health studies and studies of other vulnerable Veteran populations in the Roudebush VAMC and is standard across VA studies.

For participants who endorse suicidal thoughts on the Scale for Suicidal Ideation (administered at all assessment points—baseline, posttreatment-12 weeks, 6 month follow up, 9 month follow up), a similar protocol will be followed in which Dr. Kukla will be immediately notified and the participant will be connected with their onsite mental health treatment

coordinator that day. A further VA mandated suicidality screening will be conducted by Dr. Kukla (if the onsite mental health treatment coordinator is not immediately available to conduct the screening); if plan and/or intention for suicide are endorsed by the participant (indicating elevated risk for suicidal behavior), the onsite suicide risk prevention coordinator will be informed and connected with the participant immediately. Furthermore, if the participant is at imminent risk for self-harm, onsite staff will escort the participant to the medical center's emergency department (if onsite suicide prevention coordinator or mental health treatment coordinator are unavailable), or connect the participant with the Veteran's Crisis Line. We have effectively used these procedures in past studies at Roudebush, including studies involving multiple off-site clinics (See Drs. Kukla, McGuire, Lysaker, funded VA studies). All study personnel will be trained in this protocol.

Aim 3 qualitative interview recordings will be stored on VA approved recording devices and immediately uploaded to the VA server (behind VA firewall) and specifically, HSR&D CHIC server and the WORKWELL study folder. All study personnel at all sites will have access to the CHIC server and study folder.

Similarly, Aim 3 recordings of CBTw sessions for the purpose of fidelity audit will be stored on VA approved recording devices and immediately uploaded to the VA server (behind VA firewall) and specifically, HSR&D CHIC server and the WORKWELL study folder. All study personnel at all sites will have access to the CHIC server and study folder.

Potential Benefits of Research to Subjects and Others

The CBT for Work Success intervention to be rigorously tested in this project has potential widespread benefits to Veterans with serious mental illness. Specifically, potential benefits to participants include enhanced functioning, recovery and health, and socioeconomic outcomes, including increased competitive work success with potential long-term implications, such as longer periods worked, higher wages earned, more opportunities for career advancement, and a reduction in health disparities. Participants may also experience an increased understanding of the impact of their thoughts and feelings on work related behavior, greater work-related self-efficacy, more motivation, better self-esteem, and improved problem-solving ability and healthy coping. Overwhelmingly, these benefits outweigh any potential project risks.

5.3 Recruitment Methods

5.3.1 Number of Subject

Needed Veterans

276 total participants (138 per study arm) will be needed to ensure > 80% power for this two-arm trial, accounting for the clustering effect of CBTw group cohort and potential attrition of 13%[21]. The study sample will include around 50% minority participants, and 5% Hispanic; these figures are consistent with CBTw pilot studies which included 48% African American participants. These are also representative of the mean number of non-white Veterans served at RLR, Hines, and St. Louis. In FY18, 48.7% of Veterans at these facilities were non-white, 46.2% Caucasian, and 2.7% identified as Hispanic or Latino[30]. In the CBTw pilot studies, 10% women Veterans were recruited, consistent with gender distribution of Veterans served by the 3 study facilities (mean of 10.8% of Veterans identify as female in FY18)[30]. In WORKWELL, comparable numbers of women Veterans will be recruited. Data analyses will examine differences in outcomes based on gender and ethnicity, although these analyses may be underpowered to

detect significant differences.

Providers

Key Informant Staff Interviews: At each site, it is anticipated that approximately 5 key informal staff persons will participate in interviews occurring onsite or via phone (as needed); we will enroll a total of 15 staff for interviews.

Staff Persons Delivering Study Interventions: Up to 4 Vocational Rehabilitation Counselors (VRCs) will be enrolled from each study site, 1-2 to deliver the CBTw intervention and 1 to 2 to provide the psychoeducation control intervention. We plan to enroll up to 12 VRCs in total.

5.3.2 Identification and Recruitment of Subjects

Prior to recruitment, we will obtain Central IRB and Local VA R&D Committee approval at sites to conduct this proposed research

Veterans

At each site, we will consult with SE program staff and gain permission to recruit their patients (Veterans on their caseload who have SMI and are unemployed, those who they deem appropriate for the study). SE staff at each site will refer potentially eligible participants to the study. Recruitment may also include a review of administrative data to identify potentially eligible subjects. Study personnel will pull data from the Corporate Data Warehouse (CDW) using stop codes related to vocational rehab for each study site (i.e., 568, 574, and 535). Potential participants will be monitored for eligibility via chart review for presence of inclusion and exclusion criteria by study staff through VHA's Electronic Health Record (EHR) by way of JLV/CAPRI and/ or CPRS/VistAWeb. If a Veteran is deemed potentially eligible and expresses initial interest, they will be given a flyer, or have the flyer read to them by a program staff member, about the research study and be contacted by research staff for eligibility screening. If the Veteran is not able to be given or read the flyer by a program staff member, the research team will send the flyer via mail or email before they are contacted by research staff. During the eligibility screening process, study staff will confirm the diagnosis of an SMI, enrollment in SE services, and age 18 or older through a CAPRI/CPRS/JLV chart review. We used these procedures to successfully confirm SMI diagnosis during the CBTw pilot studies and believe it is the most appropriate approach for the proposed pragmatic trial. Though participants receiving SE will have a competitive work goal, study staff will also verify with the Veteran the presence of such a work goal. Participants who confirm that they would like to participate in the study will be scheduled for a pre-randomization baseline assessment with a(blinded) research assistant. At the start of the assessment, verbal informed consent will be obtained prior to further study involvement.

If needed, given the pragmatic study design and consistent with other HSR&D studies in our Center for Health Information and Communication; additional recruitment methods will be utilized, including self-referral by Veterans receiving SE services (who may have indirectly heard about the study).

Providers

Staff Persons Delivering Study Interventions

During initial start-up, the study team (Kukla and McGuire) will meet with SE staff and managers at sites, or remotely, to consult as sites determine the best approach to integrating CBTw in work flow, and develop procedures to support implementation (e.g., documentation procedures). The study team will also be available for consultation as sites select intervention facilitators from available and interested staff persons each SE program. Specifically, in consultation with SE program managers, SE staff persons who are vocational rehabilitation counselors (i.e. with expertise in rehabilitation counseling and in the provision of vocational services) will be chosen as intervention facilitators. During the study, these staff will participate in the CBTw consultation and audit and feedback process. At the beginning of their participation, they will be presented with a study information sheet and their consent will be implied by their participation as intervention facilitators.

Key Informant Staff Interviews

During day-long site-visits (may be conducted remotely), Drs. Kukla and McGuire will interview VRCs delivering CBTw (staff intervention facilitators) as well as SE managers, other SE staff, and service line leadership involved in the implementation process at their site. The interviews will focus on understanding reasons to uptake and continue CBTw, and ongoing barriers and facilitators to implementation (See Appendix 6).

Other Staff

During site visits, research personnel will observe procedures related to CBTw implementation. Staff present on the unit during the site visit may be identified for informal interactions to gather research data.

5.3.3 Recruitment Materials

Veterans: Informational Flyer

SE staff at participating sites will provide, or read, this flyer to Veterans who express interest in the research study groups, and will include information, such as study and PI contact information, that will allow Veterans to verify the authenticity of the research project before they are contacted by the study team by phone.

Providers: Site Visits

Ahead of site visits, the research team will provide an email template (Appendix 11) for SE managers to send to SE staff prior to site visits. These emails will inform staff that research personnel will be on site to observe unit operations related to implementation and to conduct interviews with available staff involved in the implementation process.

Providers: Key Informant Interviews

Ahead of site visits, the research team will provide an email template (Appendix 11) for SE managers to send to SE staff prior to site visits. These emails will inform staff that research personnel will be on site to observe unit operations related to implementation and to conduct interviews with available staff involved in the implementation process. A study information sheet regarding the interviews will be included for staff to review prior to the visit to ask any questions.

Staff Persons Delivering Study Interventions

The research team will provide information in person, or by phone/secure video conference to VRC staff persons who will be delivering study interventions and taking part in training, consultation, and audit and feedback processes involving monthly fidelity data collection. As noted, participation as intervention facilitators will be discussed with SE managers and potential interested staff, including all relevant implementation activities and expectations (facilitation of weekly groups, etc.).

5.3.4 Payments to Subjects

Veterans

Participants in both study arms will receive $20 for each completed outcome assessment (baseline, 12-week, 6 & 9 month only). After obtaining informed consent, the onsite RA will administer a baseline assessment to gather assessment data (see Sections D8a-c, Section E3d). Each assessment will take approximately 60 minutes. Participants will not be compensated for attendance in weekly group sessions (CBTw or psychoeducation,respectively). Participants will not be compensated for transportation costs.

Providers

In accordance with VA policy, VA staff will not receive payment for study participation.

5.4 Informed Consent Procedures

Veterans

We are requesting a waiver of informed consent for recruitment. Prior to recruitment, we will obtain Central IRB and Local VA R&D Committee approval at sites to conduct this proposed research. At each site, we will consult with SE staff and gain permission to recruit their patients (Veterans on their caseload who have SMI and are unemployed, those who they deem appropriate for the study). Next, SE staff will inform potential Veteran participants of the study. If those Veterans express interest, the SE staff person will provide or read the Veteran a study flyer.

Next, an onsite research assistant will use the electronic medical record to screen for inclusion criteria (SMI diagnosis and age 18 or older) of potential participants who have expressed interest in the study. If Veterans meet the SMI diagnosis and age inclusion criteria, the research assistant will then call these Veterans and screen for the other inclusion and exclusion criteria (confirm unemployed status, goal of competitive work, and no prior participation in a intervention CBT tailored for work). If all criteria are met, the RA will ask if the Veteran would like to participate in the study. Participants who confirm that they would like to participate in the study will be scheduled for a pre-randomization baseline assessment with the onsite (blinded) research assistant. At the start of the assessment, verbal informed consent will be obtained prior to further study involvement.

RA's, blinded to which group the participant is randomized to, will obtain verbal informed consent. All study group sessions will be audio recorded; all audio recordings will explicitly

capture the participants consent to be audio recorded. Audio recordings will be transcribed by research study personnel and deidentified. All individuals obtaining informed consent (RA's at local sites) and LSI's will be trained by the PI, Marina Kukla, on appropriate informed consent procedures. Travel funds have been designated for Dr. Kukla and other RLR personnel to travel to the local sites in order to provide training in informed consent procedures, as well as other study procedures. As deemed necessary, these trainings will be conducted virtually to minimize non-essential in-person interaction. At regularly scheduled team conference calls, the PI or Project Manager will periodically review informed consent procedures and address any questions or concerns. Moreover, all individuals obtaining informed consent and LSI's will have completed CITI Human Subjects Trainings for VA Human Subjects Research.

Providers

For all staff participating in the study, we will obtain any necessary approvals for their participation from service unions.

Staff Persons Delivering Study Interventions

As described above, in consultation with SE managers at each site, vocational rehabilitation counselors with interest in CBTw and psychoeducation will be chosen as intervention facilitators (up to 4 staff persons per study condition at each site). Separate staff persons will facilitate CBTw and psychoeducation interventions at each site. During the initial site visit, research personnel will discuss the role of intervention facilitators. Once consent is provided by staff, the initial training and intervention implementation will begin. All study group sessions will be audio recorded; all audio recordings will explicitly capture the participants consent to be audio recorded. Audio recordings will be transcribed by research study personnel and be deidentified.

Key Informant Interviews

Key informants who will take part in interviews (occurring at pre-implementation, early implementation, mid implementation, and late implementation) include staff delivering CBTw intervention, SE program managers, and other SE staff persons involved in CBTw implementation. Ahead of site visits, study personnel will email study information sheets (using VA encrypted email). The SIS will be further reviewed onsite (for onsite interviews) or over the phone (if interviews occur over the phone) with potential participants. Consent will be implied by participant/staff's participation in the interview. All interview will be audio recorded; all audio recordings will explicitly capture the participants consent to be audio recorded. Audio recordings will be transcribed by research study personnel and be deidentified.

5.5 Inclusion/Exclusion Criteria

5.5.1 Veterans

Inclusion criteria

1) Unemployment, defined as no current participation in a competitive job; 2) a competitive work goal; 3) Presence of a serious mental illness (required to receive SE services); 4) Receiving SE services; 5) Age 18 or older.

Exclusion criteria

1) Previous participation in CBT geared toward work; 2) Presence of a severe medical or cognitive impairment that will prevent participation in the study.

Details on Veteran inclusion criteria

Employment Status: Unemployment is defined as a lack of a competitive job at baseline. Veterans meeting inclusion criteria who hold noncompetitive jobs (e.g., transitional work experiences) are not considered competitively employed and will be eligible to participate in the study.

Competitive work denotes a job that it is open and available to everyone, not reserved exclusively for persons with disabilities; competitive jobs pay minimum wage or above. Casual labor, such as odd jobs, does not constitute competitive work[21]. Our prior research suggests that unemployed Veterans in SE often have competitive work goals that include finding a good job, maintaining a job over time, and increasing work hours and wages.

Enrollment in SE services: Participants must be formally enrolled in SE services at the sites described in Section D2, "Study Sites". Information regarding nature of these services is described in Section D5.

Diagnosis of serious mental illness & work impairment: To be eligible for the study, participants must have a lifetime diagnosis of a SMI including: affective disorders including major depression and bipolar disorders; schizophrenia spectrum disorders including schizophrenia and schizoaffective disorder; and PTSD. In accordance with the standard definition of SMI[2], no other diagnoses will be included. As noted, all participants will have a documented work impairment & SMI diagnosis in order to qualify for SE services at the three sites. SMI diagnosis will be further verified during the eligibility screening process.

Including Veterans with SMI

The inclusion of Veterans with SMI was chosen for 3 reasons: 1). These represent the average Veterans served nationally in VHA SE services; restricting to a narrow diagnostic group would not produce a generalizable understanding of the outcomes of CBTw in regular care[72]. 2) CBTw was designed for Veterans with SMI across the diagnoses that are included in WORKWELL. CBTw pilot findings demonstrate that these diagnostic groups did not significantly differ on outcomes at the follow-ups. Further, the developmental CBTw pilot found that the inclusion of Veterans with various SMI diagnoses was not a barrier; participants reported that the experience of vocational dysfunction was unifying[56]. 3). Maladaptive cognitive and behavioral factors that influence work functioning are consistent across SMIs[65] and are effectively addressed using CBT[73].

5.5.2 Staff

Inclusion criteria:

1) Key informants participating in interviews may be supported employment staff persons (frontline staff persons, SE manger, administrative staff, etc.) at a participating VA site. Staff persons delivering the interventions will be vocational rehabilitation counselors.

Exclusion criteria:

None

5.6 Study Evaluations

Data Collection Protocol for Study Aims 1 & 2

Conducted by onsite research assistants (RAs) blinded to arm assignment, outcomes assessments will take place at four time points: baseline, 12-weeks (posttreatment), 6 months, and 9 months. In addition, work outcomes will be collected monthly on Work Update Forms to lessen the burden of Veteran recall. This schedule will elucidate the trajectory of treatment effects over time, including early response and more sustained impacts on outcomes. Participants will receive $20 for each completed outcome assessment (baseline, 12-week, 6 & 9 month only). After obtaining informed consent, the onsite RA will administer a baseline assessment to gather assessment data. Each assessment will take approximately 60 minutes. All baseline assessments will take place in person; 12 week, 6 month, and 9 month assessments may be done in person (first consideration) or by phone.

The primary work outcome, total weeks worked in competitive jobs, will be collected monthly and analyzed at all assessment points with the primary endpoint being 6 months to allow adequate time for CBT skills to be practiced and solidified. The 12 month endpoint will examine whether there are sustained effects of CBTw and determine whether there are differences between the arms on achievement of steady competitive work (Aim 1). Health and recovery outcomes will be examined between the arms at all assessment points to understand the impact of CBTw; the relationship between weeks worked and these outcomes will also be examined at all assessment points (Aim 2). Work outcomes may be collected in person or by phone.

Aim 1 Competitive Work Outcome Measures: Collected Monthly

The competitive work outcomes are gold standard in VA work studies[80]. In Aim 1, the primary outcome is total weeks worked in competitive jobs. The secondary work outcome is steady competitive work status, defined as working at least 50% of the study period[81] (at least 19.5 weeks out of 38 weeks). Also standard procedure in work studies and used in CBTw pilots, work outcomes will be collected monthly by onsite RAs via Veteran self-report monthly work update form (Appendix 8), and verified with CAPRI/CPRS/JLV SE notes (i.e. SE staff notes will be reviewed for data regarding hours and weeks worked) and directly with SE staff using a data collection form
(Appendix 9), as needed. Additional verification layers will be used under any of the following conditions: monthly work update forms are not fully completed; conflicting or unclear information is reported (e.g., Veteran reported only working two days during a month when s/he is employed full time); Veterans report having difficulty recalling their work during the past month. Work outcomes may be collected in person or by phone.

Aim 2 Health and Recovery Outcomes: Collected at baseline, posttreatment, 6 & 9 months

Used in the CBTw pilot studies and across the SMI literature, subjective recovery pertinent to work will be measured using the Recovery Assessment Scale (RAS), a 41 item, self-report measure with higher scores indicating stronger recovery attitudes (scored on a 1 to 4 Likert scale); the RAS was developed and validated in people with SMI[82].

Psychiatric symptoms will be assessed using the adult version DSM-5 Level 1 Cross-Cutting Symptom Measure (CCSM), a 23-item, Likert response (scored on a 0 to 4 scale), self-rated instrument that assesses 13 domains that are important across SMI diagnoses (e.g., depression, anxiety, psychosis, mania, sleep problems, self-harm, substance use, etc.) with higher scores indicating more severe total symptoms. The CCSM has been found to have strong validity and reliability in SMI samples[83].

Health-related quality of life will be examined using the SF-12 comprised of the Physical Component Summary (PCS) and Mental Component Summary (MCS)[84]. The PCS and MCS are standardized with a mean of 50 and a standard deviation of 10, with higher scores indicating better health-related quality of life. The subscales have good reliability and are predictive of health outcomes in Veterans with chronic illness.

Suicidality will be assessed with the 21-item Scale for Suicidal Ideation (SSI)[85], an interviewer rated measure of a continuum of suicidal ideation, including thoughts, attitudes, plans, and behaviors. SSI items are scored on a 0 to 2 Likert scale, with higher scores indicating greater intensity of suicidal ideation. The SSI has strong psychometric properties in outpatients with psychiatric conditions[85].

Collected from a CAPRI/CPRS/JLV data pull, service utilization data will include days of psychiatric hospitalizations Lead by Mr. Larson, this service utilization data will be extracted from the Corporate Data Warehouse.

Other measures and covariates

Sociodemographic and background questionnaire (Appendix 10): Used broadly in previous work studies, a standard background and demographic questionnaire will probe gender, age, ethnicity, education, medical conditions, substance use[83], military history, residential status, disability entitlements, and legal history. Given its association with future work outcomes found in past studies[32], work history will be assessed via self-report, CAPRI/VCPRS/JLV chart review, and SE staff report for verification; these variables will include longest past competitive job, weeks worked and wages earned in the 6 and 9 months preceding baseline. Collected via CAPRI/CPRS/JLV chart review, time spent in SE services, operationally defined as the number of days receiving SE services, will be examined as a possible covariate. Session attendance for CBTw and psychoeducation will also be tracked.

Staff Participation: CBTw Implementation (Aim 3)

In order to ensure successful implementation of CBTw during WORKWELL and wide-scale uptake following its completion, an evaluation of this initial implementation strategy and barriers and facilitators of implementation will be conducted, guided by the RE-AIM framework.

Implementation Activities

Training (Months 1-3): Kukla, McGuire, and the project manager will conduct onsite or virtual trainings. VRCs delivering CBTw will attend a half-day CBTw workshop consisting of: 1) Education on CBTw content and application of cognitive, behavioral, and narrative strategies; 2) Mock practice of facilitation strategies; 3) Customization of CBTw content to meet unique needs of Veterans. Second, led by Dr. McGuire, psychoeducation facilitator training will follow a parallel structure. Third, other SE staff will be oriented to study procedures. Fourth, SE managers overseeing VRCs will receive training on how to provide supervision to ensure CBTw implementation.

Fidelity monitoring & feedback (~Monthly): Lead by Dr. Rollins, adherence to the CBT model will be assessed by the Cognitive Therapy Scale-Revised (CTS-R)[87]. All CBTw and psychoeducation sessions will be audio-recorded to rate fidelity. At each site, 3 sessions from each group cohort (i.e. 1 session out of every 4) will be randomly selected for rating (in the CBTw and psychoeducation arms). On a monthly basis, consultation lead by Kukla and Rollins, via tele or video, will include review of fidelity scores and recommendations to improve as needed. Psychoeducation facilitators will also be given fidelity feedback if they begin to drift toward CBT elements.

CBTw consultation (weekly) will be led by Kukla and the project manager via tele or video with VRC CBTw facilitators and SE program managers. Consultation will feature the CBTw Facilitator Guide (Appendix 3) that was piloted in earlier work[57]. In addition, strength based consultation will focus on Veteran case conceptualization, with an emphasis on understanding participants' recovery paths, applying CBTw strategies to fit goals and employment trajectories as they evolve over time, and problem solving obstacles.

Implementation Interviews & Site visits:

RE-AIM domains of implementation, adoption, and maintenance will be examined through semi-structured key stakeholders' interviews, lasting approximately 1 hour each. The interviews will also focus on understanding reasons to uptake and continue CBTw and important issues related to inner context and outer context (See Appendix 6). Interviews will also centrally focus on identifying barriers and facilitators to CBTw implementation within SE programs.
Interviews will be conducted in-person during periodic site-visits, or via phone/video, by Drs Kukla & McGuire. Site visits will take place at pre-implementation (1 month), early implementation (~Month 6), mid-implementation (first quarter-Year 2), and later implementation (first quarter-Year 3) will be conducted. During day-long visits, Drs. Kukla and McGuire will interview VRCs delivering CBTw, SE staff and managers, and make observations of CBTw processes. The implementation support team will keep detailed field notes recording activities conducted, barriers and facilitators encountered, and strategies utilized to address these. Site visitors will produce a written report that will provide a narrative summary of implementation strengths and weaknesses.

5.6 Data Analysis

Sample size and power

276 total participants (138 per study arm) will be needed to ensure > 80% power for this two-arm trial, accounting for the clustering effect of CBTw group cohort and potential attrition of 13%[21].

Analyses:

Study analyses will be conducted by study personnel associated with the Richard L. Roudebush VAMC, as noted in section 4.0, Resources and Personnel.

Preliminary Analyses:

Given the RCT design, characteristics of participants are expected to be balanced across the two study arms. Baseline characteristics and baseline clinical outcomes (e.g., symptoms) will be compared between the arms using the appropriate test (i.e., t-test, or Chi-square test). Variables found to significantly differ will be included as covariates in the primary

analyses. All primary analyses will also include time receiving SE services and site membership as covariates. The potential interaction effects of site with key predictors will also be included as predictors to account for the site effect. Lastly, attendance (the number of CBTw or psychoeducation sessions attended) and the association with the Aim 1 and Aim 2 outcomes will be examined.

Competitive Work Outcomes (Hypothesis 1)

For the outcome, total weeks worked in competitive jobs, three-level linear regression models will be used to test the effects of CBTw + SE compared to psychoeducation + SE over time, with predictors of study arm, arm by time interaction, site, and interaction between site and key predictors, covariates, as well as random effects to accommodate the potential non-independence due to repeated measures and group cohort effects[87]. The time effects could be linear or nonlinear; these possibilities will be examined by treating time as continuous or categorical. If the outcomes are not normally distributed, robust maximum likelihood estimation method will be used to correct the standard error estimates for nonmorality. In the case of excess of zeros for this outcome, hurdle negative binomial models, a reliable method to analyze zero inflated longitudinal data of this nature, will be utilized. For the binary outcome, steady competitive work status across the 12-month study period, two-level logistic regression model will be used with the same set of predictors as in the linear models, with random effects to accommodate the potential non-independence due to group cohort effects.

Health and Recovery Outcomes (Hypotheses 2a & 2b)

To test **Hypothesis 2a**, three-level linear regression models (i.e. mixed models) accounting for the nested nature of the data will be used to test the effects of CBTw + SE services compared to psychoeducation + SE on each of the continuous outcomes including recovery (RAS), health-related quality of life (PCS & MCS), symptoms (CCSM), and suicidality (SSI) over time. For the count outcome of service utilization, three level Poisson regressions will be used to examine group differences over time on number of days of inpatient hospitalization . If there is a problem of excess of zeros for utilization (e.g., no hospitalizations), hurdle negative binomial models will be used.

To test **Hypothesis 2b**, three-level linear regression models will examine the effects of work on health and recovery outcomes over time, with predictors of competitive weeks worked, time, weeks by time interaction, site membership and potential interaction between site and key predictors, potential covariates (i.e. controlling for baseline levels of health and recovery), as well as random effects to accommodate the potential non-independence due to repeated measures and group cohort effects.

Missing data: Aims 1 & 2

Missing data from Aims 1 and 2 will come in two different forms: missing by attrition and intermittent missing of observation. Using logistic regression, the effects of missing observations due to sample attrition will be examined by investigating the participant characteristics associated with dropout. If results reveal that data are missing completely at random (MCAR) or due to observed factors (MAR), the data will be analyzed using full information maximum likelihood, taking into account potential predictors for missingness. However, if the pattern of missing data is nonignorable; pattern-mixture models that includes variables defined by the participant's pattern of missing data will be used[89]. Sensitivity analyses also will be performed to examine how the result will change based on different assumptions about the missing data, such as the missing work period having no work, the mean amount of work as available data from earlier follow-up periods, or full employment.

Analyses & Integration of Mixed Methods Data (Aim 3-Implementation)

A deductive-inductive rapid qualitative analysis process will be used to facilitate the timely use of qualitative data to refine the implementation strategy[89], an approach appropriate for the description of implementation processes and environments[90]. Templated summaries of each data collection episode will be created, organizing quotes or observations by pre-established codes (the deductive component) pertaining to RE-AIM domains. Emergent themes in the data (the inductive component) will be captured through use of a grounded theory approach, allowing for discovery of themes not included in a priori codes[91]. Field notes will be written after site visit observations and staff interviews will bolster data not captured in immediate data summaries. An iterative process will occur, in which analysis will begin at the first observation and will inform direction of future data collection[91]. The team will then create a matrix summarizing data by code and collection episode. This will facilitate examination of variation across respondents, identify data gaps, and develop summaries of data mapping onto RE-AIM domains, as well as barriers and facilitators encountered[92].

5.7 Withdrawal of Subjects

To further ensure the rights of participants and minimize potential risks, participants will be clearly informed that they may withdraw from the study at any time without any repercussions; participants will continue to receive all VA care and rehabilitation services (including supported employment) as usual, regardless of their study status. Withdrawn participants will not be able to continue in audio recorded groups conducted for the purposes of this study nor complete outstanding assessments. If requested upon withdrawal, the participants' data will be removed from the study to the extent possible. If a participant wishes to withdraw, they will be directed to contact the research assistant at their site to provide a reason for withdrawal.

If during the course of the study the participant formally dis-enrolls in supported employment services, their participation in the study will be terminated. We do not anticipate these circumstances occurring often, as they have not occurred in any of our previous studies of CBTw.

6.0 Reporting

This study will have a Data Monitoring Committee. The details of this Committee and procedures for reporting are described in our Data Analysis Plan (Appendix 7). The appropriate local ISO(s) and PO(s) will be notified within one hour of the PI determining improper use or disclosure.

7.0 Privacy and Confidentiality

This study will collect and use, but not disclose, subjects' Protected Health Information (PHI). Data will not be banked. Biological specimens are not utilized in this study.

Prior to the start of research, study investigators will have completed required VA R&D committee training (i.e., VA's Cyber Security Awareness course and Overview of Good Clinical Practice and Human Subjects Protection course) as well as other required trainings by IRB. Research staff and all site investigators will complete all required VA R&D and IRB research trainings, such as Collaborative Institutional Training Initiative courses on responsible practice of research and protection against risk. If a study member is no longer a part of the research team,

their access to research study data will be removed.

To protect against the potential loss of confidentiality, all electronic data will be coded, or de-identified to the extent possible, and stored on a secure, password-protected VA server. A "key" file will connect participant names and contact information with their study ID number; this file will be kept on a secured server behind the VA firewall and only be accessible to study personnel. Any paper data collected will be kept in a locked cabinet in secure (locked) office space at each VA site, until it can be scanned to an electronic file and the hard copy destroyed. Computerized files will be protected by the electronic firewall at the Roudebush VAMC and will be password protected (Roudebush servers behind VA firewall will be accessible to and used by study personnel at all sites, including Hines and St. Louis). Passwords are created according to guidelines set by the VA Office of Cyber and Information Security. All research records will be retained in accordance with the VHA Records Control Schedule. Study records will be destroyed in accordance with VHA Records Control Schedule as written at the time of study closure and in accordance with any revision to VA RCS after that time.

To protect against discomfort that may be experienced related to personal disclosure during CBTw and psychoeducation group sessions, participants will be explicitly informed that personal sharing is not mandatory and they have the right not to disclose information and/or speak during groups at their discretion. This is a standard practice in psychotherapy and education-based groups in clinical and research contexts. Second, "group rules" will be laid out at the beginning of the CBTw and psychoeducation conditions during the first group session in which confidentiality and respect for the privacy of other veterans will be discussed and agreed upon by all participants. Specifically, information discussed in the group will stay in the group and is not to be discussed with other persons outside of the group. Forming these "group rules" is also standard practice in research and clinical group therapy and psychoeducation settings.

During assessments, all participants will be instructed that they may refuse to answer any question that they are uncomfortable answering. In addition, participants may withdraw from the study at any time without any repercussions; participants will continue to receive all VA care and rehabilitation services (including supported employment) as usual, regardless of their study status.

During key informant staff interviews (Aim 3), all staff participants will be instructed that they may refuse to answer any question they are uncomfortable answering and they may end the interview at any time.

8.0 Communication Plan

This project has multiple means of ensuring all study sites remain informed of current study events and changes. The study will utilize one project manager to oversee research assistants, other study personnel, and daily study procedures at all sites. Study team meetings will occur on a monthly basis to keep study sites informed of changes to the protocol, informed consent, the occurrence of Serious Adverse Events, Unanticipated Problems, and interim results. The project manager will lead weekly site calls via telephone will occur to discuss progress, plan, and troubleshoot with local site investigators and research staff at each site. Weekly consultation calls lead by Kukla (PI) will take place with CBTw intervention facilitators at each site. Moreover, the PI will make periodic visits to each site for training and data collection. These forms of contact will be used to ensure the study is conducted according to the IRB-approved protocol.

9.0 References

1. Trivedi RB, Post EP, Sun H, et al. Prevalence, comorbidity, and prognosis of mental health among US veterans. *American journal of public health.* 2015;105(12):2564-2569.
2. Definitions and terms relating to co-occurring disorders. In: (SAMHSA) SAaMHSA, ed. Rockville, MD2006.
3. USDL-18-0453 Employment Situation of Veterans Summary [press release]. United States Department of Labor, 03/22/2018 2018.
4. Zivin K, Bohnert AS, Mezuk B, et al. Employment status of patients in the VA health system: implications for mental health services. *Psychiatric Services.* 2011;62(1):35-38.
5. Hamilton AB, Williams L, Washington DL. Military and mental health correlates of unemployment in a national sample of women Veterans. *Medical care.* 2015;53:S32-S38.
6. Strong J, Ray K, Findley PA, Torres R, Pickett L, Byrne RJ. Psychosocial concerns of veterans of operation enduring freedom/operation iraqi freedom. *Health & social work.* 2014:hlu002.
7. Savoca E, Rosenheck R. The civilian labor market experiences of Vietnam-era veterans: the influence of psychiatric disorders. *The journal of mental health policy and economics.* 2000;3(4):199-207.
8. Frounfelker R, Teachout A, Bond GR, Drake RE. Criminal justice involvement of individuals with severe mental illness and supported employment outcomes. *Community Ment Health J.* 2011;47(6):737-741.
9. Abraham KM, Yosef M, Resnick SG, Zivin K. Competitive Employment Outcomes Among Veterans in VHA Therapeutic and Supported Employment Services Programs. *Psychiatric Services.* 2017:appi. ps. 201600412.
10. Danziger S, Frank RG, Meara E. Mental illness, work, and income support programs. *American Journal of Psychiatry.* 2009;166(4):398-404.
11. Elbogen EB, Johnson SC, Wagner HR, Newton VM, Beckham JC. Financial well-being and postdeployment adjustment among Iraq and Afghanistan war veterans. *Military medicine.* 2012;177(6):669-675.
12. Abraham KM, Ganoczy D, Yosef M, Resnick SG, Zivin K. Receipt of employment services among Veterans Health Administration users with psychiatric diagnoses. *Journal of rehabilitation research and development.* 2014;51(3):401.
13. Benach J, Vives A, Amable M, Vanroelen C, Tarafa G, Muntaner C. Precarious employment: understanding an emerging social determinant of health. *Annual review of public health.* 2014;35.
14. Paul KI, Moser K. Unemployment impairs mental health: Meta-analyses. *Journal of Vocational behavior.* 2009;74(3):264-282.

15. Kilbourne AM, Cornelius JR, Han X, et al. General-medical conditions in older patients with serious mental illness. *The American Journal of Geriatric Psychiatry.* 2005;13(3):250-254.

16. Twamley EW, Narvaez JM, Becker DR, Bartels SJ, Jeste DV. Supported employment for middle-aged and older people with schizophrenia. *American journal of psychiatric rehabilitation.* 2008;11(1):76-89.

17. Kukla M, Bond GR, Xie H. A prospective investigation of work and nonvocational outcomes in adults with severe mental illness. *The Journal of nervous and mental disease.* 2012;200(3):214-222.

18. Luciano A, Bond GR, Drake RE. Does employment alter the course and outcome of schizophrenia and other severe mental illnesses? A systematic review of longitudinal research. *Schizophrenia research.* 2014;159(2):312-321.

19. Luciano A, Metcalfe JD, Bond GR, et al. Hospitalization Risk Before and After Employment Among Adults With Schizophrenia, Bipolar Disorder, or Major Depression. *Psychiatric Services.* 2016:appi. ps. 201500343.

20. Van Rijn RM, Carlier BE, Schuring M, Burdorf A. Work as treatment? The effectiveness of re-employment programmes for unemployed persons with severe mental health problems on health and quality of life: a systematic review and meta-analysis. *Occup Environ Med.* 2016;73(4):275-279.

21. Davis LL, Kyriakides TC, Suris A, et al. Veterans Individual Placement and Support Towards Advancing Recovery: Methods and Baseline Clinical Characteristics of a Multisite Study. 2017.

22. Bush PW, Drake RE, Xie H, McHugo GJ, Haslett WR. The long-term impact of employment on mental health service use and costs for persons with severe mental illness. *Psychiatric Services.* 2015.

23. Drake RE, Xie H, Bond GR, McHugo GJ, Caton CL. Early psychosis and employment. *Schizophrenia research.* 2013;146(1):111-117.

24. Alvarez-Jimenez M, Gleeson J, Henry L, et al. Road to full recovery: longitudinal relationship between symptomatic remission and psychosocial recovery in first-episode psychosis over 7.5 years. *Psychological medicine.* 2012;42(03):595-606.

25. Milner A, Page A, Lamontagne AD. Cause and effect in studies on unemployment, mental health and suicide: a meta-analytic and conceptual review. *Psychological medicine.* 2014;44(5):909-917.

26. Pietrzak RH, Goldstein MB, Malley JC, Rivers AJ, Johnson DC, Southwick SM. Risk and protective factors associated with suicidal ideation in veterans of Operations Enduring Freedom and Iraqi Freedom. *Journal of affective disorders.* 2010;123(1):102-107.

27. May CN, Overholser JC, Ridley J, Raymond D. Passive suicidal ideation: A clinically relevant risk factor for suicide in treatment-seeking veterans. *Illness, Crisis & Loss.* 2015;23(3):261-277.

28. Bond GR, Drake RE. Making the case for IPS supported employment. *Administration and policy in mental health and mental health services research.* 2014;41(1):69-73.

29. Mueser KT, Drake RE, Bond GR. Recent advances in supported employment for people with serious mental illness. *Current Opinion in Psychiatry.* 2016;29(3):196-201.

30. *The Department of Veterans Affairs Compensated Work Therapy FY15 Interim Report: October 1, 2014-July 14, 2015.* Northeast Program Evaluation Center;2015.

31. Bond GR, Kukla M. Is job tenure brief in individual placement and support (IPS) employment programs? *Psychiatric Services.* 2011;62(8):950-953.

32. Campbell K, Bond GR, Drake RE, McHugo GJ, Xie H. Client predictors of employment outcomes in high-fidelity supported employment: a regression analysis. *The Journal of nervous and mental disease.* 2010;198(8):556-563.

33. Kukla M, McGuire AB, Salyers MP. Barriers and Facilitators Related to Work Success for Veterans in Supported Employment: A Nationwide Provider Survey. *Psychiatric Services.* 2016;67:412-417.

34. Zivin K, Yosef M, Levine DS, et al. Employment status, employment functioning, and barriers to employment among VA primary care patients. *Journal of affective disorders.* 2016;193:194-202.

35. Corbière M, Lanctôt N, Sanquirgo N, Lecomte T. Evaluation of self-esteem as a worker for people with severe mental disorders. *Journal of Vocational Rehabilitation.* 2009;30(2):87-98.

36. Waynor WR, Pratt CW. Barriers to vocational effectiveness in ACT: Staff perspectives. *Journal of the American Psychiatric Nurses Association.* 2011;17(1):72-79.

37. Kukla M, Bonfils KA, Salyers MP. Factors impacting work success in Veterans with mental health disorders: A Veteran-focused mixed methods pilot study. *Journal of Vocational Rehabilitation.* 2015;43(1):51-66.

38. Biegel DE, Stevenson LD, Beimers D, Ronis RJ, Boyle P. Predictors of competitive employment among consumers with co-occurring mental and substance use disorders. *Research on Social Work Practice.* 2009.

39. Williams AE, Fossey E, Corbière M, Paluch T, Harvey C. Work participation for people with severe mental illnesses: An integrative review of factors impacting job tenure. *Australian Occupational Therapy Journal.* 2016.

40. Drake RE, Bond GR. IPS supported employment: A 20-year update. *American Journal of Psychiatric Rehabilitation.* 2011;14:155-164.

41. Kreyenbuhl J, Buchanan RW, Dickerson FB, Dixon LB. The Schizophrenia Patient Outcomes Research Team (PORT): updated treatment recommendations 2009. *Schizophr Bull.* 2010;36(1):94-103.

42. Hofmann SG, Asnaani A, Vonk IJ, Sawyer AT, Fang A. The efficacy of cognitive behavioral therapy: a review of meta-analyses. *Cognitive therapy and research.* 2012;36(5):427-440.

43. Lysaker PH, Davis LW, Bryson GJ, Bell MD. Effects of cognitive behavioral therapy on work outcomes in vocational rehabilitation for participants with schizophrenia spectrum disorders. *Schizophr Res.* 2009;107(2-3):186-191.

44. Granholm E, Holden J, Link PC, McQuaid JR. Randomized clinical trial of cognitive behavioral social skills training for schizophrenia: Improvement in functioning and experiential negative symptoms. *Journal of consulting and clinical psychology.* 2014;82(6):1173.

45. Galovski TE, Monson C, Bruce SE, Resick PA. Does cognitive–behavioral therapy for PTSD improve perceived health and sleep impairment? *Journal of Traumatic Stress:*

Official Publication of The International Society for Traumatic Stress Studies. 2009;22(3):197-204.

46. Hofmann SG, Wu JQ, Boettcher H. Effect of cognitive-behavioral therapy for anxiety disorders on quality of life: a meta-analysis. *Journal of Consulting and Clinical Psychology.* 2014;82(3):375.

47. Stewart MO, Karlin BE, Murphy JL, et al. National dissemination of cognitive-behavioral therapy for chronic pain in veterans. *The Clinical journal of pain.* 2015;31(8):722-729.

48. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care.* 2012;50(3):217.

49. Glasgow RE, Harden SM, Gaglio B, et al. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice with a Twenty-Year Review. *Frontiers in Public Health.* 2019;7:64.

50. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implementation Science.* 2013;8(1):139.

51. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science.* 2015;10(1):21.

52. Matthias MS, Daggy J, Adams J, et al. Evaluation of a peer coach-led intervention to improve pain symptoms (ECLIPSE): Rationale, study design, methods, and sample characteristics. *Contemporary Clinical Trials.* 2019.

53. Kukla M, Rattray NA, Salyers MP. A mixed methods study examining work reintegration experiences from the perspectives of Veterans with mental health disorders. *Journal of Rehabilitation Research and Development.* 2015;52(4):477-490.

54. Kukla M, McGuire AB, Salyers MP. Rural and urban supported employment programs in the Veterans Health Administration: Comparison of barriers and facilitators to vocational achievement for veterans experiencing mental illnesses. *Psychiatric rehabilitation journal.* 2016;39(2):129.

55. Kukla M, Strasburger AM, Lysaker PH. A cognitive behavioral therapy intervention targeting competitive work outcomes for persons with mental illness. *Psychiatr Serv.* 2016;67(6):697.

56. Kukla M, Strasburger AM, Salyers MP, Rattray NA, Lysaker PH. Subjective experiences of the benefits and key elements of a cognitive behavioral therapy focused on community work outcomes in persons with mental illness. *Journal of Nervous and Mental Disease.* 2017;205(1):66-73.

57. Kukla M, Strasburger AM, Salyers MP, Rollins AL, Lysaker PH. A Pilot Test of Group Based Cognitive Behavioral Therapy to Augment Vocational Services for Persons With Serious Mental Illness: Feasibility and Competitive Work Outcomes. *The Journal of nervous and mental disease.* 2018;206(5):310-315.

58. Kukla M, Salyers MP, Strasburger AM, Johnson-Kwochka A, Amador E, Lysaker PH. Work-focused cognitive behavioral therapy to complement vocational services for people with mental illness: Pilot study outcomes across a 6-month posttreatment follow-up. *Psychiatric Rehabilitation Journal.* 2019.

59. Kukla M, McGuire AB, Strasburger AM, Belanger E, Bakken SK. Helping veterans achieve work: A Veterans Health Administration nationwide survey examining effective job development practices in the community. *Psychiatric rehabilitation journal.* 2018;41(2):103.

60. Bambra C, Gibson M, Sowden A, Wright K, Whitehead M, Petticrew M. Tackling the wider social determinants of health and health inequalities: evidence from systematic reviews. *Journal of Epidemiology & Community Health.* 2010;64(4):284-291.

61. Rudd MD, Bryan CJ, Wertenberger EG, et al. Brief cognitive-behavioral therapy effects on post-treatment suicide attempts in a military sample: results of a randomized clinical trial with 2-year follow-up. *American Journal of Psychiatry.* 2015;172(5):441-449.

62. Davis LL, Kyriakides TC, Suris AM, et al. Effect of evidence-based supported employment vs transitional work on achieving steady work among veterans with posttraumatic stress disorder: a randomized clinical trial. *JAMA psychiatry.* 2018;75(4):316-324.

63. Davidson L, Strauss JS. Sense of self in recovery from severe mental illness. *British Journal of medical psychology.* 1992;65(2):131-145.

64. Beck AT. *Depression: Clinical, experimental, and theoretical aspects.* University of Penn. Press; 1967.

65. Beck AT, Clark DA. An information processing model of anxiety: automatic and strategic processes. *Behav Res Ther.* 1997;35(1):49-58.

66. Beck AT, Rector NA, Stolar N, Grant P. *Schizophrenia: Cognitive theory, research, and therapy.* Guilford Press; 2011.

67. Skinner BF. *Science and human behavior.* Simon and Schuster; 1953.

68. Roberts GA. Narrative and severe mental illness: what place do stories have in an evidence-based world? *Advances in Psychiatric Treatment.* 2000;6(6):432-441.

69. Gallagher S. Self-narrative in schizophrenia. *The self in neuroscience and psychiatry.* 2003:336-357.

70. Lysaker PH, Ringer J, Maxwell C, McGuire A, Lecomte T. Personal narratives and recovery from schizophrenia. *Schizophr Res.* 2010;121(1-3):271-276.

71. Lysaker PH, Bryson GJ, Bell MD. Insight and work performance in schizophrenia. *J Nerv Ment Dis.* 2002;190(3):142-146.

72. Campbell K, Bond GR, Drake RE. Who benefits from supported employment: a meta-analytic study. *Schizophr Bull.* 2011;37(2):370-380.

73. Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioral therapy: a review of meta-analyses. *Clin Psychol Rev.* 2006;26(1):17-31.

74. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. *Journal of clinical epidemiology.* 1999;52(1):19-26.

75. Becker DR, Drake RE. *A working life: The individual placement and support (IPS) program.* New Hampshire-Dartmouth Psychiatric Research Center Concord, NH; 1993.

76. Garber-Epstein P, Zisman-Ilani Y, Levine S, Roe D. Comparative impact of professional mental health background on ratings of consumer outcome and fidelity in an illness management and recovery program. *Psychiatric rehabilitation journal.* 2013;36(4):236.

77. McGuire AB, Kukla M, Green A, Gilbride D, Mueser KT, Salyers MP. Illness management and recovery: A review of the literature. *Psychiatric Services.* 2013.

78. Lincoln TM, Wilhelm K, Nestoriuc Y. Effectiveness of psychoeducation for relapse, symptoms, knowledge, adherence and functioning in psychotic disorders: a meta-analysis. *Schizophrenia research.* 2007;96(1-3):232-245.

79. McGuire AB, White DA, White LM, Salyers MP. Implementation of Illness Management and Recovery in the Veterans Administration: An On-Line Survey. *Psy rehab journal.* 2013;36(4):264-271.

80. Ottomanelli L, Goetz LL, Suris A, et al. Effectiveness of supported employment for veterans with spinal cord injuries: results from a randomized multisite study. *Archives of physical medicine and rehabilitation.* 2012;93(5):740-747.

81. Bond GR, Campbell K, Drake RE. Standardizing measures in four domains of employment outcomes for individual placement and support. *Psychiatric Services.* 2012.

82. Corrigan PW, Giffort D, Rashid F, Leary M, Okeke I. Recovery as a psychological construct. *Community mental health journal.* 1999;35(3):231-239.

83. Narrow WE, Clarke DE, Kuramoto SJ, et al. DSM-5 field trials in the United States and Canada, Part III: development and reliability testing of a cross-cutting symptom assessment for DSM-5. *American Journal of Psychiatry.* 2013;170(1):71-82.

84. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical care.* 1996;34(3):220-233.

85. Beck AT, Brown GK, Steer RA. Psychometric characteristics of the Scale for Suicide Ideation with psychiatric outpatients. *Behaviour research and therapy.* 1997;35(11):1039-1046.

86. Muthén LK, Muthén BO. How to use a Monte Carlo study to decide on sample size and determine power. *Structural equation modeling.* 2002;9(4):599-620.

87. Milne D, Claydon T, Blackburn I-M, James I, Sheikh A. Rationale for a new measure of competence in therapy. *Behavioural and Cognitive Psychotherapy.* 2001;29(01):21-33.

88. Rapp CA, Goscha RJ, Fukui S. Enhanced consumer goal achievement through strengths-based group supervision. *Psychiatric rehabilitation journal.* 2015;38(3):268.

89. Beebe J. *Rapid assessment process: An introduction.* AltaMira Press; 2001.

90. Hamilton AB, Cohen AN, Glover DL, et al. Implementation of Evidence-Based Employment Services in Specialty Mental Health. *Health services research.*
2013;48(6pt2):2224-2244.

91. Charmaz K. *Constructing grounded theory: A practical guide through qualitative analysis.* London: Sage Publications; 2006.

92. Averill JB. Matrix analysis as a complementary analytic strategy in qualitative inquiry. *Qualitative Health Research.* 2002;12(6):855-866.

93. Stirman SW, Kimberly J, Cook N, Calloway A, Castro F, Charns M. The sustainability of new programs and innovations: a review of the empirical literature and recommendations for future research. *Implementation science.* 2012;7(1):17.

94. Lysaker PH, Davis LW, Bryson GJ, Bell MD. Effects of cognitive behavioral therapy on work outcomes in vocational rehabilitation for participants with schizophrenia spectrum disorders. *Schizophrenia research.* 2009;107(2):186-191.