Study Protocol

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1. **Title**: Efficacy of Supported Employment within the OIF/OEF Patient Aligned Care Team

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4. **Sponsor of the Study:** This is not a sponsored study. This study is investigator initiated and funded by the VA Rehabilitation Research and Development

5. **Research Setting:** Tuscaloosa VA Medical Center

6. **Purpose of the study including hypotheses to be tested:**

The purpose of this prospective, randomized, controlled study is to determine the efficacy of Individual Placement and Support (IPS) supported employment when delivered within a primary care Patient Aligned Care Team (PACT) serving Veterans of the Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn (OEF/OIF/OND) and all other Southwest Asia conflicts (since 1990 and after OND). Participants will be unemployed and have a diagnosis for mental illness, other than a serious mental illness (SMI; defined as schizophrenia, bipolar I, schizoaffective disorder).

Primary Hypothesis (H1): Compared to the group randomized to vocational treatment as usualTransition Work (TW), there will be a higher proportion of steady workers in the group of Veterans randomized to IPS delivered within the PACT. A steady worker is defined as holding a competitive job for ≥ 50% of the 12-mo follow-up (i.e. ≥26 wks).

Hypotheses (H2, H3): Over 12-months, compared to those randomized to TW, Veterans randomized to IPS delivered within the PACT will have greater improvement in quality of life (Quality of Life Inventory; H2), and greater improvement in self-esteem (Rosenberg Self Esteem Scale; H3).

Exploratory hypotheses: 1) Over a 12-mo follow-up, compared to those randomized to TW, Veterans randomized to IPS delivered within the PACT will have greater improvement in community reintegration (Community Reintegration of Service Members; CRIS; E1) and

greater improvement in psychiatric symptoms (Symptom Checklist-90-Revised; SCL-90-R; E2). 2) Over a 12-mo follow-up, compared to those randomized to TW, Veterans randomized to IPS delivered within the PACT will have significantly fewer crisis events and services that include ER visits, contacts with the legal system, homelessness, psychiatric inpatient utilization, addiction relapses, and suicidal behaviors (E3).

7. Background, including results of relevant research, gaps in the current knowledge:

The research is directly linked to the RR&D priority areas of improving vocational outcomes in Veterans of the Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn (OEF/OIF/OND) cohorts. Veterans returning from Iraq and Afghanistan wars often confront unemployment, as evidenced by 2013 unemployment rates of 9% for OIF/OEF/OND Veterans compared to 7.2% for nonveterans.[1] The traditional VA Transitional Work Program (TW) and other Compensated Work Therapy programs do not sufficiently meet the vocational rehabilitation needs of Veterans,[2] thus, leaving the majority of Veterans vulnerable to continued unemployment and a deteriorating trajectory. Over the past two decades, studies of Individual Placement and Support (IPS) supported employment involving persons with a serious mental illness (SMI; i.e. schizophrenia, schizoaffective, bipolar I disorder, and major depression with psychotic features) have yielded remarkably robust and consistent outcomes.[3-5] In the first study of IPS for Veterans with posttraumatic stress disorder (PTSD), 76% of the those randomized to IPS gain competitive employment, compared to 28% of those randomized to conventional VA vocational rehabilitation program.[6] These findings point to the efficacy of IPS across diagnostic categories. However, IPS has only been studied in mental health settings. Veterans who are returning from OEF/OIF/OND deployments often delay seeking treatment in a mental health setting for months or even years, thus, often delaying engagement in vocational rehabilitation.

The current methods of vocational rehabilitation used by VA do not sufficiently meet the employment rehabilitation needs of Veterans with disabilities.[2] For example, a VA Northeast Program Evaluation Center (NEPEC) study evaluating administrative data of 5,862 Veterans from 122 Compensated Work Therapy (CWT) programs, found that the rate of competitive employment at discharge was only 30% for Veterans with PTSD and 36% for those without PTSD, leaving the majority unemployed. Another VA study found that Veterans with PTSD involved in CWT were no more likely to be employed at 4 months follow-up compared to those who participated in a specialized PTSD treatment program. Based on the evidence that IPS enabled people with SMI to succeed in competitive employment, VHA chose to rollout IPS in 2005 to the 20% of CWT participants who have an SMI. In 2011, VHA also rolled out IPS to homeless Veterans. However, the majority of unemployed Veterans, i.e. those who are not SMI or homeless, are not eligible for IPS services.

Veterans' ability to obtain and maintain gainful employment is essential to successful reintegration into civilian life. OIF/OEF/OND Veterans often experience a potentially disabling medical or mental condition and simultaneously confront unemployment upon their military discharge. According to the VA Fiscal Year 2009 “Long Journey Home”

Report, 61% of Veterans entering specialized outpatient PTSD programs were not working, either due to inability to find work (27%), not looking (25%), retirement (26%), or 100% disability (22%).[7] Having a mental illness can substantially impede the Veterans' reintegration and ability to sustain employment. A cross-sectional study of 797 returning OEF-OIF Veterans, of whom 473 were employed,[8] found that a diagnosis of major depressive, PTSD, generalized anxiety, and panic disorders were all significantly associated with impairments in work functioning (mental-interpersonal demands, time management, and work output). These losses in productivity were on average four times higher than non-Veteran employees with no psychiatric disorder. In a study of female Veterans with PTSD (n=253), all three PTSD symptom clusters had significant independent associations with occupational impairment.[9] In a cross-sectional self-report survey of National Guard soldiers (n=4,034), higher rates of both depression and PTSD were associated with financial difficulties, job loss, unfavorable effects of their deployment on co-workers, and/or non-support of their military affiliation by employers. The rates of PTSD were doubled in those who had lost jobs compared to those who had not (27.8% *v.* 13.3% at 3 months and 47.7% *v.* 22.2% at 12 months).[10] In summary, the presence of a mental illness in Veterans is associated with significantly greater unemployment rates,[11] number of lost jobs, absenteeism,[12] financial difficulties,[13] deterioration in work functioning,[14] and losses in productivity and lower hourly wage, income, and occupational status.

Existing VHA Vocational Rehabilitation

Transitional Work Programs (TW): The long-standing approach to vocational rehabilitation in VHA is the ***"train-place" or "stepwise" model,*** founded on the assumption that the client benefits from some form of pre-vocational training or practice in a protected work setting prior to entering competitive work, e.g. skills training, sheltered workshops, transitional employment, and set-aside jobs. The rationale is that clients with a mental illness or disability are assumed to need a gradual introduction into regaining work capacity, because of their lack of skills, limited experience, and/or their sensitivity to stress in the competitive work environment. These programs assume that after gaining experience in a protected work setting, clients are more capable of succeeding in competitive employment. TW serves as the treatment-as-usual control intervention in this proposed study.

Individual Placement and Support

Supported Employment Programs: Supported employment (SE) is a ***"place-train" model*** of vocational rehabilitation.[15,16] This approach of seeking rapid placement into competitive employment, followed by specifically targeted job training and support, has been shown to be superior to pre-employment "train-place" approaches in persons with a serious mental illness (SMI) within a mental health treatment setting.[17-22] The rationale for a place-train SE model includes several important concepts.[23] SE evaluates and delivers the needed supports and work skills in the context of an intact competitive job. Secondly, the SE approach is very client-centered and for a competitive job that is in keeping with the interests and desires of the individual.[24-26] Third, SE is integrated within the mental health treatment team, which is not a defining factor of the TW. The SE specialist encourages the patient to maintain adherence to treatment plans so that they maintain their ability to work and stay on the trajectory of recovery and community integration.

Outcomes Associated with IPS Supported Employment

The specific manualized SE model evaluated in this study is called Individual Placement and Support (IPS).[27-29] The IPS model was first shown to be effective when IPS replaced a day treatment program for individuals with an SMI diagnosis.[30,31] Replication day treatment conversion studies and randomized controlled studies conducted in community mental health centers also demonstrated that IPS was effective in SMI populations.[32-34] In addition, the enhanced employment rates from implementation of IPS is durable over extended periods of time, as shown over a 10-year follow-up period.[35]

The long-term vocational and non-vocational trajectories of participants with a SMI in IPS are positive.[36] Participants reported enhanced self-esteem, relationships, and social activity. Longitudinal studies of the course of schizophrenia have often found modest correlations between employment and symptoms.[37] Secondary analyses of four IPS controlled trials in SMI groups examined the longitudinal impact of competitive employment on non-vocational outcomes by comparing those who work against those that did not work or worked very little[38-41] and all found some differences between working clients compared to nonworking clients resulting from a combination of worsening of symptoms for the non-working group and improvement in symptoms for the working group. In general, these studies suggest that a meaningful period of competitive employment is associated with improvement over time in symptom control, quality of life, self-esteem, and social functioning as compared to not working.

PRELIMINARY STUDIES

A Randomized Controlled Trial of Supported Employment Among Veterans With PTSD (Appendix; Davis et al Psychiatric Services 2012; funded by VA RR&D)

The PI and collaborators conducted the first single-site pilot study to examine the efficacy of IPS in a of Veterans with PTSD. Unemployed Veterans with PTSD were randomly assigned to IPS (n=42) or a VHA Vocational Rehabilitation Program (VRP) treatment as usual (n=43) and followed for 12 months. TW was the predominant VRP modality, although some incentive therapy was included. A total of 71 (84%) participants completed the study. Reasons for early exit were withdrawn consent (n=1), relocation (n=3), incarceration (n=2) in IPS group and lost to follow-up (n=2), relocation (n=5), and incarceration (n=1) in VRP. During the 12-month study, 76% of the IPS participants gained competitive employment, compared with 28% of the VRP participants ($p<.001$: number needed to treat=2.07). Veterans assigned to IPS also worked substantially more weeks than those assigned to VRP (42% versus 16% of the eligible weeks, respectively; $p<.001$) and earned higher 12-month income. Please refer to the publication in the Appendix for complete results. These findings are consistent with other IPS studies.[50] The IPS group achieved competitive employment significantly more quickly than the VRP group (log-rank $p<.001$). Most job acquisition occurred within the first 20 weeks. These findings are consistent with 9 IPS studies in SMI populations.[50] The outcome of whether or not the participant achieved competitive employment status was an excellent proxy for other occupational outcomes as demonstrated by correlations ranging from 0.53 to 0.79 between occupational outcomes. Additional analysis revealed that 40% (17 of 42) of IPS participants became steady workers, defined as holding a competitive job for $\geq$ 50% of the 52-week follow-up,

compared to 16% (7 of 43) of those in VRP (p=0.01). In conclusion, this study demonstrates feasibility and efficacy of IPS for Veterans with PTSD and demonstrates the ability of the investigators to conduct a randomized controlled trial.

Preliminary Findings of Employment Outcomes from a Recent Multisite, Randomized Controlled Trial of Supported Employment for Veterans with Posttraumatic Stress Disorder (PI; Funded by Department of Defense US Army Medical Research Acquisitions Activity

As follow-up to a recent single site pilot study of IPS, a multisite (3), randomized controlled trial of IPS in Veterans with PTSD has recently concluded. Unemployed Veterans with PTSD were randomly assigned to either IPS (N=48) or TW (N=46) and followed for 12 months. Compared with 33% of those who received TW, 52% of those receiving IPS gained competitive employment ($\chi 2$= 3.64, df=1, p=.056). The number needed to treat was 5.26. IPS participants worked in a competitive job an average of 23% of the eligible weeks and those assigned to TW worked an average of 13% of the eligible weeks (Mann-Whitney z test, p=0.10). The IPS group achieved competitive employment significantly more quickly than the TW group (log-rank $\chi 2$= 4.25, p=0.04). Due to the greater variability of a multi-site study, i.e. variations in IPS staffing and TW delivery, a larger sample size was needed to show more pronounced differences. **T**his study highlights that there is adequate equipoise between IPS and TW and further research is merited, especially for a broader population and in a new setting.

8. Potential benefits to the research subject and the knowledge to be gained:

Reintegration for recently deployed Veterans requires finding mainstream competitive employment that provides the Veteran with identity, structure, income, daily activity, friends, and other benefits. Without mainstream competitive employment, many Veterans become enveloped by preoccupation with symptoms, social isolation, economic instability, familial disintegration, substance abuse, legal problems, homelessness, and wayward lifestyles. Many Veterans need and want services that specifically target reintegration and functional recovery. **Recovery** is the goal of treatment and involves a multi-faceted process in which people with illnesses or disabilities move beyond preoccupation with illness, become hopeful about the future, and pursue their own journeys and goals. Recovery involves not only clinical and physical recovery, but also functional and social recovery which involves obtaining and maintaining valued societal roles and responsibilities, including employment, education, stable housing, and meaningful relationships with family, friends and the community. These domains of recovery contribute to an existential recovery, which is having the sense of hope, empowerment, agency, and spiritual well-being needed for a high quality of life.[44] Individuals with a SMI who gain steady employment report increased self-esteem, decreased psychiatric symptoms, reduced social disability, and overall greater quality of life.[45-48] For those who become steady workers, mental health treatment costs decline dramatically over the long term after adjusting for morbidity/needs.[49] In essence, employment helps people to escape from the disabled patient role, to experience a sense of purpose and accomplishment, and to establish a new identity as a working, contributing citizen. Whereas ***reduced or total loss of employability*** is the ultimate threshold that defines a disabling medical or mental illness, ***achieving and maintaining employment*** is one of the most significant goals in defining recovery. On this basis, this study targets this

critical health outcome, i.e. steady competitive employment, as its primary outcome of the interventions to be compared.

This study addresses gaps in knowledge and services, and provides the requisite data to guide VHA as to whether to expand the target population for IPS to all Veterans with a mental disorder and whether or not it is feasible to deliver IPS within the PACT. This expansion would require a major adaptation to CWT programming, and so clear substantial evidence is needed to support such a dramatic change. Given the large influx of returning (OIF/OEF/OND and all other Southwest Asia conflicts) Veterans seeking services and the potential chronic course that is predicted for many of them with a mental health issue, an improved employment and reintegration success rate will have a dramatic effect on the future functioning of this large cohort of young Veterans. An intervention, such as IPS, that directly addresses the occupational recovery of Veterans that can be delivered within the front door service of the PACT, has the potential to improve Veterans' personal income, clinical outcome, and quality of life, while offsetting VA disability costs and increasing the US income tax revenue. The outcomes of this study may lead to a shift in rehabilitation services within the VHA and improve the lives of thousands of Veterans who would otherwise have difficulty with reintegration.

In summary, the participant may benefit directly from the study (i.e. gain employment); however this benefit is not guaranteed. However, the outcomes of this study may lead to improved services for others based on the generalizable knowledge to be gained.

9. Definition of Population to which study is directed and justified

The target population for this study is men and women Veterans who previously served during the OEF/OIF/OND and all other Southwest Asia conflicts (since 1990). Participants will be unemployed and have a mental disorder other than an SMI. This population is justified based on the premise of the study which is planning to test the efficacy of IPS in a broader population of Veterans (i.e. not limit to a specific mental disorder) and is focused on the recent cohort of returning veterans since they are eligible for services in the Primary Care PACT at the Tuscaloosa VAMC, including the Transition Center, the Women's Clinic, and other primary care teams that operate under a PACT model and serve OIF/OEF/OND/Southwest Asia Veterans.

The Transition Center was originally the sole source of the recruitment, but the enrollment lagged far behind the timeline and did not provide adequate access to women Veterans. Thus, without impacting scientific merit, the study inclusion criteria is being expanded to other primary care teams that operate under a PACT model, such as the Women's Clinic, in order to allow better access to the study for women and OIF/OEF/OND/Southwest Asia Veterans who have timed out of the Transition Center (i.e. 5 years since discharge from the military). This strategy will help meet the enrollment period timeline and provide a more generalizable sample, with greater representation of demographics such as gender, age, and time since discharge from the military.

10. Number of Subjects that will be recruited for the study

Approximately 150 Veterans will be recruited in order to reach the target of 120 randomized participants (i.e. allowing for a 20% screen failure rate).

11. Inclusion Criteria:

- Age ≥ 19* (<19 years of age is the state of AL defined minor)
- Receiving primary care treatment in the TVAMC primary care clinics that operate under the PACT model, including the Transition Center and Women's Clinic, and that treats Veterans who served during OEF/OIF/OND and all other Southwest Asia conflicts
- Otherwise eligible for TVAMC TW services, in the event that the Veteran is randomized to TW
- DSM-5 diagnosis that is disabling or potentially disabling (i.e. depressive, bipolar II, anxiety, obsessive-compulsive, trauma- and stressor-related, dissociative, impulse- control, and substance related/addictive (other than caffeine and nicotine) disorder classifications), other than those listed as exclusionary, within past 90 days
- Currently unemployed, defined as not working in a competitive job for a wage or is under-employed (defined as: working less than 20 hours per week in a job that is low wage and is not in keeping with the Veteran's ability, aptitude, or skills)
- Expression of interest in competitive employment
- Willing and able to give informed consent.

Note: Veterans with history of mild traumatic brain injury (TBI) may be included in the study.

12. Exclusion Criteria

- Current diagnosis of (i) schizophrenia, (ii) schizoaffective, (iii) bipolar I disorder, or major depression with psychotic features, since these Veterans may receive IPS in mental health
- Diagnosis of dementia (evidenced in the medical record)
- Clinically significant unstable or severe medical condition, or terminal illness, that would contraindicate study participation or expose them to an undue risk of a significant adverse event
- Unlikely that participant can complete the study, e.g. expected deployment, incarceration, long-term hospitalization, or relocation from the vicinity of the TVAMC during the study period
- Active suicidal or homicidal ideation making it unsafe for Veteran to be included in study
- Current participation in another interventional trial.

13. Exit Criteria

Every effort will be made to retain the randomized participants in the study for the 12-month follow-up, regardless of employment status. However, participants will be exited if they specifically request study exit.

14. Justification for use of special subject populations who may present informed consent issues:

Special subject populations (i.e., prisoners, terminally ill, minors, and individuals with severe cognitive disorders) will not be included in this study. Subjects will exhibit an ability to make a choice for informed consent purposes as demonstrated on a general psychiatric interview and mental status exam. Subjects with cognitive impairment or dementia, such that they cannot provide truly informed consent will not be recruited. Subjects with legal incompetence will not be included in the study. Participants must have the decision-making capacity to provide their own autonomous informed consent. Therefore, special subject populations who may present informed consent issues are not included in the study and a surrogate consent is not needed.

15. Scientific and ethical justification for excluding classes (gender, race, etc) of persons who might benefit from the research

Both male and female subjects will be recruited. There will be no exclusion based on race or ethnicity. Subjects will be recruited without preference for gender, race, ethnicity or socio-economic status.

16. Appropriateness of Impact of Study design on risk.

The risk of participation in this prospective randomized research is very low and is fully discussed in the Risks section below. While the anticipated risks of this study are low, potential participants will be screened and have regular follow-up to decrease the chance of any adverse effect. Therefore, the risks of the study are outweighed by the benefits to subjects and the knowledge that may be reasonably expected to result from the study.

17. Description of procedures to be performed.

Following signed informed consent and HIPAA Authorization, baseline assessments are completed. Participants who meet eligibility criteria are randomized (1:1) to receive either IPS or TW. Randomization will use a permuted block design of randomly varying block sizes. Once assignment is made, the participant will be analyzed in that group regardless of future events or information, in accordance with the intent-to-treat principle. After randomization, the participant is assessed monthly for employment outcomes and every two months (month 2, 4, 6, 8, 10, and 12) for repeated measures assessments. The participant returns for post-study follow-up at month 16 (to allow for a 4 month transition from study treatment to usual clinical care and services).

INTERVENTIONS:

Overview of IPS and TW Treatment Regimens: Although the approaches between the two groups are very different, the goal of both IPS and TW inventions is the same, i.e. to obtain Competitive Employment and become a steady worker. The IPS intervention assists participants to directly search for and enter competitive jobs. The Veterans who are

randomized to IPS will not engage in TW set-aside jobs. In the TW intervention, the Veteran is placed in a time-limited set-aside job before seeking a competitive job.

Individual Placement and Support (IPS): The IPS manual entitled Supported Employment: Applying the Individual Placement and Support (IPS) Model to Help Clients Compete in the Workforce,[51] is provided to the IPS specialist for training and reference. The IPS model involves the following important domains: 1) *Competitive Employment:* The IPS intervention assists participants to directly enter into competitive jobs. 2) *Eligibility Based on Client Choice:* IPS embraces the notion of "zero exclusion." 3) *Integration of IPS and Treatment Team:* IPS programs are closely integrated with the treatment team, in this case the PACT. 5). *Personalized Benefits Counseling:* IPS specialists help Veterans obtain personalized, understandable, and accurate information about their VA, Social Security, Medicaid, and other government entitlements. *6) Rapid Job Search:* IPS specialists use a rapid job search approach to help Veterans obtain jobs directly, rather than providing lengthy pre-employment assessment, training, and counseling. *7) Systematic Job Development:* IPS specialists build an employer network based on Veterans' interests, developing relationships with local employers by making systematic contacts. *8) Time-Unlimited and Individualized Support:* IPS follow-along vocational supports are individualized and continued for as long as the Veteran wants and needs the support; however in the case for 12-months due to the time limits of the study.

VA Transitional Work Program (TW): TW involves the following domains*:* 1) *Time-limited Set-Aside Employment:* TW is a step-wise approach to job placement with initial short-term (i.e. 3 months) transitional work experiences in a brokered or set-aside work setting. 2) *Eligibility Criteria:* The eligibility criteria for VA TW programs vary; however, there are no strict entrance criteria for involvement in the TVAMC TW program. 3) *Limited Integration of TW and Clinical Services:* The TW specialist obtains clinical information from the provider upon referral; however, the TW specialist has little contact with the providers after initial referral is made. The TW specialist does not attend PACT treatment team meetings. 4) *Less Patient-Centered:* While the TW specialist treats all Veterans with respect and professionalism, the types of jobs provided by the TW are pre-arranged and thus, except for situations of happen stance, the set-aside jobs are less likely to have a meaningful relationship to the Veterans' preferences or career goals. 5) *Personalized Benefits Counseling:* As with IPS, the TW specialists help Veterans obtain personalized and accurate information about their VA, Social Security, Medicaid, and other government entitlements. 6) *Job Search:* The TW specialists provide variable and limited guidance for competitive job search, but these are typically conducted within the facility using internet resources. 7) *Limited Job Development:* The TW specialists do not engage in community based job development for a specific Veteran. 8) *Time Limited Support:* The TW specialist does not provide long-term follow-up vocational assistance after the first job is obtained and most often the time-limited follow-along supports are provided only during the time-limited transitional work experience.

NOTE: Although the intent of TW is to have the Veteran participate in a time-limited TW position, there is no guarantee for this provision due to various reasons such as Veteran preferences, availability of TW assignments prior to Veteran gaining a competitive job or losing interest in a TW assignment, or discharge from the TW program without having attended the TW assignment. Every effort will be made to ensure that all Veterans randomized to TW participate in a TW assignment at the local participating medical center.

If the Veteran does not participate in a TW assignment within the 12-month follow-up period, a reason for this will be noted at the end of or exit from the study.

Employment Diary: At least weekly, the Veteran records the following information for each week: worked in a job (yes/no); job title; same or new job; number of days worked; amount of wages earned; reasons for missed work; and reason for job terminations. This calendar method reduces recall errors. On a monthly basis, the Clinical Research Coordinator (CRC) contacts the participant (by phone or in person), and, with the aid of the Employment Diary, records the employment outcome and makes sure there is consistency between the participant's self-report and IPS/TW medical record notes.

Primary Outcome Measures and Rationale: The primary outcome will be achievement of a 'steady worker' status, defined as obtaining and maintaining competitive employment for at least 50% of the active follow-up period (i.e. ≥26 weeks). A week worked is defined as working for any period of time (i.e. part time or full time) during a Sunday to Saturday 7-day window. Competitive employment is defined as a job that pays at least minimum wage or is based on salary or commission, is based in community settings alongside others without disabilities, and is not reserved for people with disabilities (i.e. is not the set-aside job in the TW program). Day labor, e.g. pick-up cash-based odd jobs for yard work, babysitting, etc., and military drill are not counted as competitive employment. One can think of the steady worker primary outcome in terms of a clinical goal of "remission" rather than only meeting the criteria of "response." The study length of 12 months allows for the 3 to 4 month start-up time involved in each intervention prior to establishing competitive work and to allow enough time for an individual to establish steady work and achieve the secondary outcome goals.

The following assessments are completed at baseline:

Baseline Demographics and Military History: The Clinical Research Coordinator (CRC) collects **baseline /characteristics,** including age, gender, race, ethnicity, marital status, education level, and military history, including branch, period of service, combat exposure; **life status,** including housing, transportation, and family care burden status, VA and non-VA disability status, including claims/appeals pending, trauma history, and psychiatric history, including past and current treatment for PTSD; and **work history,** including length of current unemployment, past type of occupation(s), and longest duration of competitive work.

The MINI International Neuropsychiatric Interview (M.I.N.I.):[52] A structured clinician-administered interviews that assesses current and lifetime mental disorders, based on DSM-5.

The Cumulative Illness Rating Scale (CIRS):[53, 54] The CIRS is used to assess general medical conditions and provides a summary score that gives an index of baseline medical burden.

Ohio State University Traumatic Brain Injury Identification Method – Short Form (OSU TBI-IM):[55, 56] The OSU TBI-ID is an interviewer-administered questionnaire that captures the lifetime history of traumatic brain injury (TBI). The OSU TBI-ID gives a summary score that reflects the likelihood that consequences have resulted from lifetime exposure to TBI.

The following assessments are completed at baseline and every two month follow-up (except for the CRIS, which will be conducted at base, month 4, 8, 12 in order to reduce participant burden and improve retention, without affecting scientific method or planned analyses):

Self-Esteem Scale (RSES):[57] The RSES is a widely used, public domain, 10-item self-report Likert-type questionnaire that asks participants to indicate the degree of their agreement or disagreement with statements about their self-esteem and self-deprecation.[58,59, 60]

Quality of Life Inventory (QOLI):[61] The QOLI developed by Frisch[62] is a 32-item self-report measure of life satisfaction that takes approximately 5 to 10 minutes to complete. The Frisch QOLI recognizes social integration, which takes into account a persons' capacity to exercise connectedness and citizenship.[63]

Community Reintegration of Service Members (**CRIS)[64]** is a self-report instrument used to evaluate the Veteran's reintegration into the community. The correlations between the CRIS and the 36-Item Short Form Health Survey scales of role physical, role emotional, and social functioning were 0.44-0.80 and the CRIS has strong reliability, conceptual integrity, and construct validity. In pilot studies with 126 veterans, working subjects had better CRIS scores then unemployed subjects. Items on the CRIS cover 9 aspects of participation: (1) Learning and Applying Knowledge, (2) General Tasks and Demands, (3) Communication, (4) Mobility, (5) Self-care, (6) Domestic Life, (7) Interpersonal Relationships, (8) Major Life Areas, and (9) Community, Social and Civic Life. Subscale scores for 1) extent of participation, 2) perceived limitations, and 3) satisfaction with participation are calculated.[65]

Symptom Checklist-90-Revised (SCL-90-R)[66,67] is a 90-item self-report questionnaire that assesses nine constructs: somatization, obsessive-compulsive symptoms, interpersonal sensitivity, depression, anxiety, hostility, phobic-anxiety, paranoid ideation, and psychoticism. Coefficients of internal consistency range from 0.79 to 0.90 and test-retest stability is very good (r = 0.78 – 0.90). Some evidence supports the sensitivity of the SCL-90-R to changes due to treatment. The SCL-90-R is used as a measure of current status at baseline and outcome of psychopathology at each 2-month follow-up visit.

Inventory of Crisis Events: At baseline and at each 2-month follow-up visit, the CRC reviews the medical record, interviews the participant, and records all crisis events/interventions for the previous 2 months; which include VA and non-VA emergency room visits, contacts with the legal system, number of nights considered homelessness (i.e. residing on the street, in a shelter, or in a domiciliary), psychiatric inpatient admission days(s), and addiction relapse(s) (i.e. number of days spent in heavy drinking, using illicit substances, treatment(s) for detoxification, and/or admitted to an addictions rehabilitation treatment program. Suicidal behaviors are tracked by the Sheehan Suicidality Tracking Scale.

The Client Satisfaction Questionnaire-8 (CSQ-8)[68] is an 8-item assessment of global satisfaction with a specific treatment used to evaluate the participants' acceptance of and satisfaction with IPS and TW.

Safety Assessments: At the bimonthly follow-up visit, the participant is assessed for the occurrence of adverse events or serious adverse events, which includes the **Sheehan**

Suicidality Tracking Scale (SSTS).[69] The SSTS is an 8-item self-report scale that tracks treatment-emergent suicidal ideation and behaviors and is sensitive to change in frequency or intensity of suicidal thoughts or behaviors over time. The SSTS is reviewed by the CRC and positive endorsements are evaluated and handled by one of the investigators.

IPS Invention Fidelity Monitoring: The IPS fidelity monitor makes quarterly an on-site visit and conducts a 2-day fidelity monitoring (observes the IPS specialist in the field during job development and interaction with participants, interviews participants, interviews clinical treatment providers, interviews leadership, and reviews the VA electronic medical record). The IPS fidelity monitor evaluates the site using the 25-item Supported Employment Fidelity Scale. The IPS fidelity monitor provides feedback on the fidelity rating to the local site investigator to aid in working with the IPS specialists to ensure high quality of IPS services. The IPS fidelity monitor also evaluates the TW treatment arm using the same methods to ensure that the TW treatment arm is rated $\leq$55 on the Supported Employment Fidelity Scale (not supported employment). The Supported Employment Fidelity Scale is comprehensive, detailed, and research-based.[70, 71] Six of the 10 studies reported statistically significant measures of association between fidelity and employment outcome, and two others had results approaching statistical significance. More recently, the relationship between IPS fidelity and employment outcome using the 25-item IPS fidelity scale[72] has been shown to have predictive validity is similar for the original and revised scales. The research has found that the scale as a whole is a dependable tool for guiding effective IPS practice.[73]

18. Differentiation of "usual (Standard) Care" from Research Activities.

The PI or co-investigators are the individuals responsible for oversight of the relevant aspects of the research study which are different from usual care, including (a) providing and monitoring the IPS service, (b) explaining potential risks and benefits of the treatment or service (this task is also performed by the investigators and/or the CRCs during the informed consent process), (c) determining whether an adverse event results from usual care or research, (d) alerting the subject if there is a problem with the treatment or service (e.g., a newly discovered risk), and (e) documenting the subject's clinical course while receiving the treatment, as applicable. The TVAMC vocational rehabilitation program personnel are responsible for providing the usual care intervention (transitional work program), documenting the participants' progress during this treatment (CPRS), and the conducting the follow-up while the participant is in the TW program. The usual care for primary care and mental health treatment will be delivered by the TVAMC PACT providers and other mental health providers (non-research), as needed and appropriate depending on the participant's illness(es)/problems.

19. Enlisting Clinical Expertise, as needed

The PI has assembled a team of investigators and consultants who are expert in the focus of the study. Dr. Davis is experienced and expert in conducting clinical trials, making clinical diagnosis of mental disorders, and supervising IPS specialists/mentors/fidelity monitors. Richard Toscano is experienced and expert in delivery of IPS and IPS fidelity monitoring. The CRCs are experienced and expert in conducting clinical trials. Dr. Bartolucci is experienced and expert in biostatistics, specifically IPS outcomes. The investigators will review the adverse events and make required decisions to protect the

health of the study (e.g., stopping the subject's involvement in the study or determining when to notify the subject or the subject's health care provider of information that may affect the subject's health).

20. Description of the anticipated data and how the data will be analyzed

Descriptive statistics will summarize the socio-demographic and clinical characteristics of the sample at baseline. Continuous variables will be summarized by means, standard deviations, medians, and ranges. Categorical variables will be summarized by frequencies and rates. Although we expect randomization to produce equivalent groups, we will compare the two groups (IPS vs. TW) on baseline demographic and clinical characteristics, using t-tests for the continuous variables and chi-square tests for categorical variables. Although unlikely, these descriptive analyses may identify statistically significant group differences at baseline, which may warrant adjustment in outcome analyses, if the differences are large and also associated with the outcome variable. Research dropouts and completers will also be compared on baseline variables using similar procedures. These analyses will be under-powered, due to the low rate of expected attrition, and thus clinical, as much as statistical, significance will inform the generalizability (external validity) of the findings regarding the representativeness of the sample. Only baseline variables that are correlated at .30 or higher with the outcome (using a continuous measure of the primary outcome, which is number of weeks worked) will be included as covariates in subsequent analyses. Examples of potential covariates that may be correlated with outcome include age, disability status, length of unemployment, baseline severity of psychiatric symptoms, and concurrent diagnosis of addictions.

Primary Hypothesis (H1): Compared to the group randomized to TW, there will be a higher proportion of steady workers in the group of Veterans randomized to IPS delivered within the PACT.

Analysis of the Primary Hypothesis: Regardless of adherence to, or continuation in, treatment, all randomized participants will be included in the outcome analyses, based on the intent-to-treat principle. The proportion of steady workers will be compared initially by treatment group using Fisher's exact test at a two-tailed alpha-level of 0.05. A steady worker is defined as participant who holds a competitive job for at least 50% of the 12-month follow-up period (i.e., 26 or more of 52 weeks). A week scored as "worked" is one in which a competitive job was held for any number of hours or days during that week (Sunday through Saturday). A week scored as "not worked" is one in which there was no competitive job held, or there were no employment data (i.e., early exit or missing data). Following the analysis of the simple treatment effect, logistic regression models may be run in order to include covariates, either due to their association with the primary outcome (to increase power) or due to their suspected role as confounders (to adjust for selection bias).

Power Analysis for the Primary Hypothesis: We used Sample Power 3.0[74] to estimate the statistical power to test the primary hypothesis. The target sample size of 120 participants (60 per group) will provide 84% power to detect a 25% or greater absolute difference between groups in the percent of participants achieving 'steady worker' status (e.g., 40% in the IPS arm vs. 15% in the TW arm), at the .05 level of significance and assuming a 10% overall loss to follow-up. With 60 per group we can lower the power only

to 0.80 for two sided α=0.05 with a minimal detectable difference of at best 40% vs. 17%. Conclusions will need to be interpreted with this in mind.

Complementary Analyses to the Primary Outcome: In order to compare this study to other published studies of IPS, we will analyze other employment outcomes for the difference between groups. In each case, the PACT/IPS group is hypothesized to show greater gains than the TW group. These analyses include categorical outcomes (e.g., "yes vs. no" for obtaining competitive employment) and continuous outcomes (e.g., cumulative gross income, weeks worked in competitive job, and number of weeks to first competitive job). These outcomes will be correlated with the primary outcome and with each other, and thus these are not independent analyses, but they are useful in understanding the full picture of employment. Mean total number of weeks worked in a competitive job will be compared between groups using a t-test. Analysis of covariance will be used if covariates will be included in the model. The mean cumulative gross income of the two groups will be compared using a *t*-test (on raw or transformed data) or a non-parametric test, depending on the distribution of the income data; analysis of covariance may be used if inclusion of covariates is indicated. The group difference in the proportion of participants who obtain at least one competitive job will be examined using Fisher's exact test or logistic regression, as appropriate.

Background data in this paragraph are derived from the Davis et al[6] pilot study. The power for the categorical outcomes, using Fisher's exact test, is the same as for the primary outcome. Therefore, we will have ample power to detect a 36% difference in achieving any competitive employment, which was the difference found in the pilot study (66% in the IPS arm vs. 30% in the TW arm). In the same study, participants in the IPS group earned a mean of $9,264 (SD = 13,294) versus $2,601 (SD = 6,009) in the TW arm. Assuming a pooled standard deviation of $10,153, which yields an effect size of 0.65 based on comparing mean income between the two groups, the proposed study will have >90% power to detect a similar difference between groups, using a t-test and alpha = .05, two-tailed.

Analysis of Secondary Outcomes (self-esteem [H3] and quality of life [H2]): Self-esteem and quality of life will be assessed at baseline and every two months over the 12-mo. follow-up period, for a total seven repeated assessments. The effect of treatment on each of these outcome measures will be analyzed using a longitudinal mixed-effects regression model.[75,76] The dependent variable will be the outcome score at baseline and each follow-up time point. We plan to use covariance pattern by treating time as a categorical indicator variable and fitting the group means over time. Each follow-up visit (+/- 1 month visit window) will be categorized by a 2-month visit number. Any follow-up data collected outside of a study window will be assigned to the nearest uncompleted visit number. Any unscheduled visit that cannot be assigned a unique visit number will be excluded from the repeated measures analyses. Plots of the group means over time will inform choices concerning the possibility of piecewise models or models with higher-order time effects (e.g., quadratic time). We will specify the covariance structure of the repeated outcomes as unstructured initially, and then we will use model fit criteria (AIC and BIC) to determine if a systematic covariance structure should be specified (e.g., compound symmetry or autoregressive-1). In the initial models, the independent variable will be group (IPS vs. TW), and the dependent (outcome) variable will be either QOL or SE scores (at

seven time points). The group by time interaction will test for the treatment effect, as we expect the equivalent groups at baseline to diverge over the follow-up period, with the IPS group showing greater gains than the TW group. Mixed-effects regression methods assume that data are missing at random and use all available data to estimate the model parameters. In aggregate, there is one statistical model for the primary hypothesis, and there are two for the secondary hypotheses; therefore, there is no compelling reason to adjust the alpha level downward in order to avoid Type I errors. However to provide assurance and control for multiple comparisons, the sequentially rejective procedure of Hochberg will be also be conducted to determine statistical significance for the treatment comparisons for secondary outcomes using an overall Type I error of 5% (two-sided).[78]

Power for the Secondary Hypotheses: We used a specialized program[79] to estimate the power of mixed-effects regression analyses to test the secondary hypotheses. The following parameters were used: alpha = .05, two-tailed; seven points in time; power = 80%; the correlational among repeated assessments = .50; 60 participants per group at baseline; and 2% attrition at each follow-up assessment, for a total attrition of 12%. Given these parameters, we can detect a group by time interaction that has an endpoint effect size of .42 or greater.

Quality of Life [H2]: A randomized study of Vietnam veterans taking part in group psychotherapy for PTSD (CSP #420) reported change from baseline on the QOLI. The results (mean ± SD) were 0.02 ±2.0 for 203 female participants and -0.22 ±2.03 for 358 male participants.[80] Based on the above power analysis, and assuming a pooled standard deviation of 2.0, our study will need to yield an difference in change between the two groups of .84 on the QOLI to be statistically significant.

Self Esteem [H3]: Related to our expected treatment difference, a subgroup analysis of a randomized study of IPS showed a mean difference of 2.7 at 18 months on the Rosenberg Self-Esteem scale.[81] The subgroups were defined by cumulative earnings. One subgroup was composed of participants whose cumulative earnings in competitive jobs reached or exceeded the median for competitive earnings (n = 31, mean change from baseline on the Rosenberg Self-Esteem scale = -3.2). The other subgroup was participants who worked in either competitive or sheltered jobs, but whose cumulative earnings did not reach the median for either (n = 50, mean change from baseline on the Rosenberg Self-Esteem scale = -0.5). With a pooled standard deviation of 5.1, the effect size in this study was .53, which is greater than the minimum that we can detect with our study (.42).

Additional presentations of results: Both between-treatment condition and within-treatment condition effect sizes for primary and secondary outcomes will be presented: Cohen's *d* for mean quality of life and self-esteem and the number needed to treat (NNT) for rates of steady workers. An estimate of the 95% confidence interval will accompany each effect size in order to guide interpretation.[82] We will not claim a significant result unless the outcome analysis achieves a p value of $\leq$ .05. Effect sizes will not be used as precise point estimates. Effect sizes only guide interpretation of the clinical significance of the findings after statistical significance has been substantiated.

Analysis of Exploratory Outcomes [E1, E2, E3]: The exploratory outcome of crisis events/interventions will include VA and non-VA emergency room visits; contacts with the

legal system; number of nights homeless; psychiatric inpatient admission days; and addiction relapse(s). Each category of crisis events/interventions will be compared by treatment group using counts of total events/interventions and the proportion of participants who experience at least one intervention using statistics appropriate for count (poisson-family regression) or discrete (logistic regression) data, respectively. If there are few crisis interventions, Fisher's Exact Test will be used for comparing proportions between treatment groups. Differences in change between groups in community re-integration (CRIS [E1]), psychiatric symptoms (SCL-90-R [E2]), and suicidal behaviors (SSTS [E3]) will be analyzed as described for secondary outcome measures above.

Missing Data: Every effort will be made to assess each outcome for all participants, and the completeness of data gathering will be closely monitored. Because of this effort, we anticipate a small amount of missing data. Nevertheless, because missing observations have the potential to alter the results of analyses, we will examine whether the pattern of missing data is different between the two treatment arms. We will also examine the distribution of baseline covariates between those with and without missing outcome data. If there are no systematic differences between those with and without missing data, the data can be considered to be missing at random. If there are significant differences in dropout or missing data patterns between treatment arms, we will conduct sensitivity analyses to determine the impact of missing information on the treatment comparisons. Missing data are also minimized by use of computerized data collection system, which requires that an entire rating instrument be completed prior to advancing to the next one.

Minimizing Attrition: To minimize attrition from the study, the investigators will provide thorough pre-enrollment education for all prospective participants about the study objectives and procedures in order to confirm the participants' commitment to and feasibility for long-term follow-up. During the study, participant burden is kept to a minimum (i.e. small number of assessments and low frequency). For example, the CRIS is a very long instrument and was reduced in frequency from every two months to every four months in order to reduce participant burden. This may in turn improve retention. The investigators also will provide ongoing education during the study to reinforce the participants' commitment to long-term follow-up. If needed, the CRC will travel to a location in the community in order to make more convenient contact with the participants for assessments. To contend with the challenge of getting participants to return for assessments, we will provide compensation to help overcome transportation cost barriers or loss of wage due to missed work. In order to avoid reinforcing dropout or compliance with financial incentives, all participants who attend the follow-up visits receive payment, regardless of whether they continued in the treatment. The payments are not coercive given the relatively modest amount and the minimal risks involved in the assessments.

Demonstration of IPS Feasibility and Client Satisfaction within the PACT: We will demonstrate that IPS delivered within a PACT is feasible (defined as high IPS fidelity scores for ≥80% of the fidelity monitoring visits) and yields high Veteran satisfaction (defined as ≥80% of IPS participants rating $\geq$27 out of 32 points on the Client Satisfaction Questionnaire-8). These scores will be evaluated descriptively.

21. Risks (physical, psychological, social, and economic) and steps taken to minimize risks

Potential Psychological Risks: There are minimal psychological risks associated with this study due to the fact that participants remain under treatment for their underlying mental condition(s). Participants may experience transient anxiety or embarrassment during the clinical interviews when answering questions about their work, symptoms, self-esteem, or quality of life. Participants may feel that participation in the study is an invasion of their privacy. The study team minimizes these potential psychological risks by maintaining a pleasant and professional demeanor, conducting the interviews and physical assessments in a private clinical office, and allowing the participant to discuss these reactions and feelings if they occur. Participants are allowed to take breaks during the interviews and assessments, if needed, to avoid or minimize discomfort.

Potential Social and Economic Risks: Participation in a study may involve risk of feeling "labeled" or "stigmatized." Confidentiality safeguards will be strictly maintained to prevent such risks. A HIPAA authorization page informs the patient of the use of identifiable personal health information. The informed consent and HIPAA authorization details the provisions for protecting the confidentiality of research data. The methods used to obtain information about the participants include direct query and medical record review. Participation in the study may involve economic risk of missing work or having to pay for transportation. The study team works with the participant to minimize these inconveniences by seeing the participants outside their work hours and by minimizing clinical appointments to those necessary to adhere to the protocol. Also participants are seen in a timely fashion upon arrival and appointments are kept as short as possible to minimize inconvenience of attending appointments.

Psychological Risks:

The subject may feel that the interview process and completion of questionnaires are an invasion of privacy. The subject may experience nervousness, discomfort, of embarrassment during the assessments. If subject become upset during the assessment, the subject will meet with the study investigator or research coordinator to talk about his or her concerns and consider the need for a different treatment. The investigation team will make every effort to minimize the psychological risks by maintaining a pleasant and professional attitude and ensuring privacy during the visit. Additionally, the subjects are allowed to take breaks during the assessment or reschedule assessments for completion at a later time. The subject's psychological state, particularly in regard to suicidal ideation and agitation will be monitored at every study visit and the subject will be able to call the investigator or research assistant between visits if needed.

In the event participants experience extreme psychological distress secondary to participation, they will be encouraged to telephone the Principal Investigator (PI) or the Co-I's. In addition, they will have access to the VAMC treatment services. Any such adverse effects noted by any project personnel in response, or in potential response to any project intervention, assessment protocol, or study involvement will be immediately reported to the PI and Co-I's. Participants will also be given the PI's name and telephone number and the

on-site Study Coordinator's contact information. Moreover, if research or clinical staff believes that a participant is significantly distressed by participation, the PI will be notified and will contact the participant to assess distress and assure participant safety. If called by participants, the PI will attempt to address the participant's concerns and if indicated, set up an alternate appointment with the Veteran's designated provider.

Emergency Response: An investigator will be available 24 hours and 7 days per week for the subject to contact or be evaluated by in the event of a serious adverse event or emergency (see last page for phone numbers). In order to minimize risk of an emergency, his or her symptoms and side effects will be closely monitored at the research visits.

Physical Risks: Legal and Social Risks: No legal risks are anticipated during this study. An unlikely social risk associated with participating with this study would be invasion of privacy in the remote chance that there is a loss of data containing patient health information (PHI). These are research risks, not therapeutic risks. All clinical sites have standard operating procedures in place to guard against a privacy breach. The investigators and other research staff are aware of these policies and will adhere to the policies and regulations. Confidentiality safeguards will be strictly maintained throughout the study, including the use of a private office for assessments and the plan to keep all study documents in a locked office or on a computer with password protection. The subject's name will not be used in the data analysis, publications, or presentations of results.

Economic Risks: Participation in a study may result in the subject missing work during appointment times or having to pay for transportation to and from the facility. Every effort will be made to avoid this by our agreement to try and schedule the appointments around the subject's work schedule and limiting the frequency of visits to just those necessary for the protocol. The subject will be seen in a prompt and timely manner and appointments will be kept as short as possible. These are research risks, not therapeutic risks.

22. Describe in detail the provisions for managing adverse reactions and for monitoring data to ensure the safety of participants.

The local site investigator is responsible for following adverse event reporting requirements as outlined below in the protocol. These responsibilities include: 1) reviewing the accuracy and completeness of all adverse events reported, 2) compliance with IRB policies for reporting adverse events and/or serious adverse events, and 3) closely monitoring research participants at each follow-up visit for any new Adverse Events (AEs) or Serious Adverse Events (SAEs). Study participants are monitored at each research visit for AEs and SAEs. All AEs and SAEs are recorded on the appropriate event form(s). Active monitoring of AEs and SAEs begin as soon as the study participant is randomized and to 30 days post-study follow-up.

Adverse Event Definition and Monitoring

All adverse events that are related to the mental condition, the occupation, or the study intervention or procedures are recorded at each research assessment visit (description, severity, relationship to study intervention, date onset, date resolution). Adverse Events

(AEs) are collected using the CSP Global SOP 3.6 definitions. An adverse event is "any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research. An AE does not necessarily have to have a causal relationship with the research. **All adverse events related to mental disorder, an occupation, or study intervention or procedures will be collected.** Relatedness involves an assessment of the degree of causality (attributability) between the mental disorder, occupation, and/or study intervention and the adverse event. Investigators will provide an assessment of relatedness or attribution to PTSD, occupation, and/or the study intervention or procedures. All adverse events with a reasonable causal relationship to the mental condition, occupation, and/or the study intervention should be considered respectively "related". A definite relationship does not need to be established.

Serious Adverse Event Definition and Reporting

Serious Adverse Events (SAEs) are a subset of adverse events and are those defined by the CSP Global SOP 3.6., as an event that results in any of the following outcomes:

a. Death;
b. A life-threatening adverse event;
c. Inpatient hospitalization or prolongation of existing hospitalization;
d. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
e. A congenital anomaly/birth defect.
f. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based on appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

All serious adverse events are collected, including those related to and not related to the study intervention or procedure. Any suspected adverse events that are both serious and unexpected will be reported to the IRB. All SAEs require prompt notification by the local research team to the IRB within five (5) working days of the investigator being made aware of the event. The IRB will be responsible for evaluating all serious adverse events for participant safety concerns. All SAEs will be followed up at each study visit until the event is resolved or no further progress is expected.

Data Safety and Monitoring Board (DSMB): The DSMB provides independent monitoring of project safety, data gathering and analysis, as well as the overall performance of the clinical trial. The DSMB is charged with guiding the safe scientific and ethical conduct of projects. Information will be expected from each investigator regarding study implementation and ongoing project modifications. If at any time during the course of the study, the DSMB judges that risk to subjects outweighs the potential benefits, the DMC has the discretion and responsibility to recommend that the study be terminated. All unanticipated AEs, deaths, and SAEs due to the study procedures will be reported to the DMC. We agree to report all events as defined by VA-SAE guidance to the DSMB, regardless of whether the SAE appears to be related to the research within 48 hours (i.e.

two work days) after the time the investigator or study staff becomes aware of them. Reports for unanticipated events determined by either the investigator or DSMB to be possibly or definitely related to participation and reports of events resulting in death will be promptly forwarded to all regulatory agencies. In addition to safety monitoring, the DSMB will monitor data quality. The DSMB will receive a report on data quality and completeness. At a minimum, this will include an overview of the progress of subject intake; summary reports describing subject demographics; and a summary of data entry progress and query resolution. These reports will be used by the DSMB to evaluate the capacity of the data capture and processing to support scientifically valid analyses.

23. Planned procedure for obtaining informed consent

Prior to any study procedures being performed, the Institutional Review Board (IRB) approved informed consent will be obtained by research staff trained in informed consent procedures. Informed consent will be collected at the study research offices, in a private and interruption-free environment. Prior to entering the study, the potential participant will be provided with detailed information regarding the study's sponsor, purpose, procedures, potential risks and benefits, alternative treatment, compensation and other required elements. This will be done by a study team member and documented on a signed and dated informed consent form. A subject's willingness to take part in the study will be documented in the medical records. Potential subjects will be given ample time to consider the informed consent and may choose to involve family members and others in their decision. Potential subjects are informed that refusal to participate in a research study will in no way penalize them or change their eligibility for VA services, treatment, or disability payments. If a subject agrees to participate, his/her consent will be recorded on the VA Form 10-1086. Informed consent requires that the subject understand the details of the study, including its risks and benefits, and agrees without coercion to participation. The signed and dated consent Form will be distributed to: Subjects study file (original), subject (copy), subject file (copy). Persons with impaired decision-making capacity are excluded, so that surrogate consent will not be required. We do not anticipated that a potential participant will be unable to speak, read, or understand English.

24. Compensation for participation:

There is no cost to participate in this research study. To contend with the challenge of getting participants to return for follow-up assessments, we plan to provide compensation to help overcome any transportation cost barriers or loss of wage due to missed work. All participants are paid per follow-up visit. In order to avoid reinforcing dropout or compliance with financial incentives, all participants who attend these follow-up visits receive payment, regardless of whether they continued in the treatment or were an early exit for any reason. This modest payment adds incentive for participants to follow-up and secondarily covers the transportation cost in rural areas. The amounts are not coercive given the relatively modest payment and the fact that there are minimal risks involved in the assessments by means of interview and self-report (i.e. no invasive procedures, physical demands, or medications interventions are required in order to receive payment).

Participants will receive $60 for the first research clinic Baseline visit. When enrolled in the study and randomized, participants received $60 for each scheduled Study follow-up clinic visit completed. A total of $480 can be received from participating in the research study.

In cases where a face-to-face visit is done in lieu of a phone call or vice versa (a phone call is done in lieu of a face-to-face assessment), the current per-protocol payment schedule should still be followed.

That is, if a phone assessment is done instead of face-to-face (i.e., information is collected by phone, self-assessments will be mailed ahead of the visit to the participant at months 2, 4, 6, 8, and 12, instead of seeing the participant face-to-face), the participant should still be paid the $60 as per protocol payment schedule. Self-assessments can be taken over the phone in cases where the participant is hard to reach and there was not time to mail the self-assessments 2 weeks prior to the appointment.

Likewise, if a face-to-face visit is done in lieu of a phone call (i.e., the participant prefers to come in or the CRC meets the participant in a community setting for the convenience of the participant at months 1, 3, 5, 7, 9, and 11), would not receive additional money (these visit were not in-person visits), the participant will not be paid for this visit.

Participants will be paid within a reasonable time after each clinic visit you complete. Payment will be issued by electronic transfer of funds according to local medical center procedures. An Internal Revenue Service (IRS) Form 1099, which documents that the received income, will be generated using the participants' Social Security Number.

Participants will not be charged for any treatments or procedures that are part of this study. Veterans who are required to pay co-payments for medical care and services provided by VA, these copayments will continue to apply for medical care and services provided by VA that are not part of this study. There may be costs associated with transportation to the TVAMC or time away from work that will not be covered by your participation in this study. Veterans who are required to pay co-payments for medical care and services provided by VA, these copayments will continue to apply for medical care and services provided by VA that are not part of this study.

25. Plans for protection of patient privacy and confidentiality

To ensure confidentiality, a participant number will code all data and hard copy records will be kept in a locked cabinet in a locked room with access limited to the investigators and research staff assigned to this protocol (bldg. 3 research area, rooms 102, 103, 104, 106, 109, 114, 125, 132, 133, Building 137, 1st Floor, Room B1-102, and Building 38, Room 251). All interviews and clinical visit will be done in a private setting. All study documents will be kept in a locked office or in a computer with limited password access, in a secure area (network location VHATUAFPCIA/research/Davis PTSD Studies). Hospital medical records will document participation in the study and will be kept confidential in the VA CPRS. Patients' names will not be identified in the data analysis, publications or presentations of the research study.

Data entered in to a study database will be stored using the study subject identification code that does not identify the subject by name. The subject's social Security number will be linked with the subjects study identification number on a separate excel spreadsheet and in kept on a TVAMC computer on VA server and not sent to the biostatistician consultant. The link between each subject's identification code and their identifying information (SSN, name) will be maintained as required by the IRB and the TVAMC.

Certificate of Confidentiality:

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to stateor local authorities.

Retention of Records: Retention of Records: Records of this research study will be maintained in accordance with the new VHA's Records Control Schedule 10-1 (RCS) policies, section 7.6.

For a study such as this one (i.e. not FDA-regulated or Sponsored-study), the instructions state that the PI may destroy research records **6 years after the end of the fiscal year** after completion of the research project, but the investigator may retain longer if needed.

According to Disposition Authority Number DAA-0015-2015-0004-0032, research records maintained by the investigator that span the entire lifecycle of the project and the records required by regulations such as the investigator's regulatory file, include, but are not limited to: research protocol and all amended versions of the protocol; grant application; review committee correspondence (e.g., Institutional Review Board and Research & Development Committee) including documents approved by the review committees; correspondence with ORD, regulatory entities, sponsor and/or funding source, correspondence; case report forms and supporting data; informed consents, HIPAA; list of all subjects entered in the study and the cross-walk connecting the subjects name with the code used for each subject; subject compensation records; reports of adverse events, complaints and deviations from IRB-approved protocol; data analyses; codes and keys used to de- identify and re-identify subjects' PHI; reports (including, but not limited to, abstracts and other publications); research study correspondence not involving ORD, Office of Research

Oversight (ORO), sponsor, or funding source; • correspondence and written agreements with the funding source or sponsor, ORD and applicable oversight entities such as IRB, Research and Development (R&D) Committee, VA Office of Research and Oversight (ORO), VA Office of Human Research Protections (OHRP) and FDA; research study correspondence not involving ORD, Office of Research Oversight (ORO), sponsor, or funding source; signed and dated forms submitted to regulatory agencies; investigator's brochure; records related to the investigational drugs such as drug accountability records; monitoring and audit reports such as Data Safety Monitoring Board Reports and audits by oversight entities; documents related to budget and funding; other forms required by policy and regulation.

Note: If the PI leaves VA, all research records are retained by the VA facility where the research was conducted. If the grant is ongoing and the investigator leaves one VA facility to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility's research office. The investigator is not the grantee, nor does the investigator own the data.

Removal of Access to Study Data: Removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team (i.e. his or her research shared drive access will be terminated once they are no longer a researcher or research service employee).

Planned Procedures for Misuse, Loss or Theft of VA Sensitive Information: The investigators will comply with VHA policies on prompt reporting of loss, theft, or actual or suspected breaches involving sensitive information, along with any other privacy or security incident or complaint. The ISO will promptly determine whether an incident warrants further reporting and actions. At a minimum, the following should occur as soon as it is discovered that there has been a loss:

- Report the loss or theft to the VA security/police officers immediately
- During travel or at another institution, notify the security/police officers at the institution such as hotel security, university security, etc. as well as the police in the jurisdiction where the event occurred
- Obtain the case number and the name and badge number of the investigating officer(s). If possible, obtain a copy of the case report
- Any such event must also be reported to the IRB as an unexpected adverse event.
- **Immediately (within 1 hour of discovery)** phone and email a description of the event to the following persons:
    - The persons' immediate supervisor
    - The local Information Security Officer (ISO)
    - The Chief of Staff
    - The Medical Center Director
    - The Associate Chief of Staff for Research and Development
    - The Privacy Officer must be notified when there is any unauthorized use, loss, or disclosure of individually-identifiable patient information; so that it can be reported to Privacy Violation Tracking System (PVTS).

26. Plans for Information Security (in addition to section 25)

Study data will be collected and managed using VA Central REDCap (Research Electronic Data Capture), which is approved for use by the VA. VA central REDCap is a secure, web application. REDCap is a VA Intranet Web application and can only be accessed while logged into the VA Intranet. REDCap is a free, secure Web application that facilitates the collection and entry of research data. User-friendly electronic data capture (EDC) tools enable users to quickly develop surveys and databases from conception to production on the Web without additional software requirements. This tool helps researchers enter, store, and manage their project data in a systematic manner, and allows, closely supervised, ease of entry for participant self-assessments. REDCap is designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system is protected behind a login and Secure Sockets Layer (SSL) encryption. Data collection is customized for each study or clinical trial based on a study-specific data dictionary defined by the research team with guidance from the SCTR Informatics REDCap administrator. Once the project is set up in VA REDCap, permissions for database entry/access will be given through the VA REDCap administrative team and data entry will be done through the secure REDCap web application. Each addition or change to the database is tracked by login. More information is available at http://vaww.virec.research.va.gov/REDCap/Overview.htm. Sensitive research data will not leave the VA protected environment.

Permission to use, enter, or view the database will be granted through the VA REDCap administrator.

No data that will be stored in temporary files on a computer's hard drive.

There will be no use of mobile storage device. However, the investigators may store aggregate de-identified data (for example while working on a manuscript, presentation, poster, or report) on VA-issued laptops with FIPS-compliant encryption.

27. Methods used to identify and recruit patients.

At the time of initial IRB submission, the investigators will proactively request a HIPAA waiver for purposes of recruitment and screening and a waiver of informed consent for purposes of recruitment and screening. A multipronged approach for subject recruitment and sampling will be used. Importantly, there will be NO finder's fee or compensation to the referral sources for identifying potential subjects.

Participants are recruited from the outpatient TVAMC PACT, called the Transition Center, as they naturalistically present for treatment, are referred to the study, or make personal inquiry into the study. A HIPAA waiver for purposes of recruitment and pre-screening will be requested from the IRB so that IRB-approved letters or flyers can be posted and mailed to Veterans who receive primary care for the TVAMC Transition Center. Under this HIPAA waiver, the investigator and CRC may obtain personal identifying information, such as a list of names, social security numbers, and addresses of Veterans who receive treatment in the

Transition Center who have had contact with the local VA within the past five years. The clinical research coordinator will use this list to mail an IRB-approved letter or flyer to Veterans who live within a reasonable distance from the VA medical center that makes participation feasible, and to look in the VA medical record to pre-screen Veterans for the study (i.e. review the VA electronic medical record to determine if there are any obvious exclusionary criteria) prior to the Veteran signing informed consent.

Participants may also be recruited from the community, VA outpatient clinics, VA vocational rehabilitation programs, and VA domiciliary or residential programs, as they naturalistically present for treatment, are referred to the study, or make personal inquiry into the study. IRB-approved advertisements and flyers are also used as part of the recruitment strategy.

28. Safeguards to prevent coercion or undue influence for study subjects.

Patients will be given ample time to consider the informed consent document that explains the study procedures, risks, benefits, and alternatives. Patients may have as much time as needed (no time limit) to read and consider the risks and benefits of the study participation. Patients may elect to involve family members, significant others and primary treatment team in the decision on whether or not to participate in the study. Patients are informed that refusal to participate in research projects will not change their eligibility for VA services, treatment, of disability payments. In the patient has a legal guardian, that person will be involved in the informed consent process. No guarantees are made for symptoms improvement during the research study. Compensation is commensurate with time and inconvenience that is involved in completing the necessary research assessments and procedures.

29. Resources:

All investigators and research staff are qualified, trained, and experienced in clinical research or in the role for which they are responsible. They all have adequate offices space and adequate access to resources needed for the study.

30. Safeguards to protect the rights and welfare of mentally disabled and/or decisionally impaired subjects (vulnerable patient populations).

Protection of subjects from harm must be balanced against the potential for benefit to subjects themselves, and to other persons with their disorders, that may arise from research participation. Since new treatments must eventually be tested in persons suffering from the condition, a policy totally excluding vulnerable subjects from research would preclude the development of improved treatment for persons with mental disorders. This study specifically recruits veterans who are unemployed and who have a mental disorder, which may be considered as a vulnerable patient population. Vulnerable populations, i.e., prisoners, individuals with mental retardation, minors, persons with dementia or severe cognitive disorders, and persons deemed legally incompetent are not eligible for this study. Veterans are accustomed to taking and following direct orders, which requires a greater need for researcher to prevent coercion, either directly or indirectly. Potential subjects will be given ample time to read and consider the informed consent with other treatment options explained in the consent form. Family members, significant others, and primary treatment teams may also be involved

in the decision making process if the veteran wishes. They are also informed that declining participation in a study will not change their eligibility to VA services, treatment, disability or other VA benefits. Those individuals who are economically or educationally disadvantaged may be considered vulnerable. The VA population includes individuals in this category; however, the study keeps payments to participants at a minimum in order to avoid coercion based on economic hardship. In addition, the informed consent is written at a grade school level of education to minimize vulnerability to the educationally disadvantaged.

31. Plans for Adherence to VA Policies and Regulations Regarding Research Involving Controlled Drugs

Not applicable, since controlled drugs are not part of this study design.

32. Reuse of Data:

At this time there is no plan for data to be re-used in other studies.

33. Research at external sites and multi-site research in which the investigator is lead investigator.

Not applicable. This is a single-site study. The study will be conducted at the Tuscaloosa VA Medical Center in Tuscaloosa, 3701 Loop Road East Alabama 35401.

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