21-11 Achieving Competitive Customized Employment through Specialized Services - Veterans: ACCESS-VETS
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Abstract

This randomized clinical trial will test the effectiveness of a customized employment (CE) intervention, Achieving Competitive Customized Employment through Specialized Services (ACCESS-Vets), to complement clinical services for Veterans and Service Members transitioning to Veteran status (hereafter referred to as Veterans) with spinal cord injury (SCI) and improve their employment outcomes.

Background: Restoring employment is an important rehabilitation goal for Veterans with SCI because employment impacts both quality of life (QOL) and longevity. Due to the medical complexity of SCI, however, these Veterans face unique employment barriers that are not adequately addressed by current Department of Veterans Affairs (VA) vocational services. Vocational services for Veterans with SCI need to address these employment barriers, which relate to physical health, finances, time for job search, and caregiver issues. Customized employment, an innovative strategy for tailoring vocational services to meet individual needs of people with complex disabilities, could be adapted for use in SCI rehabilitation. This research will evaluate a CE intervention to help Veterans with SCI discover their strengths, customize employment plans, and find competitive integrated employment in their communities. The proposed intervention, ACCESS, is a user-driven, standardized CE program delivered by a trained employment specialist and is effective for a non-clinical, community-based population of adults with disabilities. This research is needed to test ACCESS as a complement to clinical services for a clinically defined population and to assess the potential of CE for subsequent implementation in the VA.

Research Plan: The effectiveness of ACCESS-Vets will be tested with a randomized control trial of 100 Veterans with SCI. The study will have a rolling enrollment period with an intervention period of 30 months. ACCESS-Vets is typically completed in 8 months and includes the following elements: discovery, CE planning, job development, CE negotiation, and accommodations and job retention supports. Individual Placement and Support (IPS), otherwise known as evidence-based supported employment, will serve as an active control group consistent with treatment as usual. ACCESS-Vets and IPS will be compared on changes in employment attainment. We predict Veterans who participate in ACCESS-Vets will have a higher employment rate than Veterans who receive IPS. Among Veterans who attain employment, we predict those who receive ACCESS-Vets will report higher job satisfaction, wages, and retention. We predict Veterans who attain employment will demonstrate statistically significant improvements in self-sufficiency, QOL, and participation in life roles compared with those who do not attain employment. Finally, qualitative interviews with Veterans and their providers will identify strategies used in IPS and ACCESS-Vets for addressing barriers to employment and how practitioners adapt the ACCESS-Vets intervention for use in a VA clinical setting.

Significance: This study is responsive to Veterans' reported desire for individualized vocational rehabilitation services and to the Modernization Plan and the MISSION Act, which emphasize Veteran-centered, community-based approaches to care. The proposal goals align with the Transformation Plan of the Office of Mental Health and Suicide Prevention, which prioritizes evidence-informed, community-based employment

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services. Recognizing the rapid adoption of CE in state and federal agencies, VA is partnering with the Office of Disability and Employment Policy (U.S. Department of Labor) to introduce and train VA vocational staff on CE as a promising practice; however, integration of CE into standard VA clinical services has not yet been implemented. In support of VA efforts to assist Veterans to achieve competitive employment and reintegration into civilian life, this proposal will evaluate CE within the context of existing VA vocational services.

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List of Abbreviations

ACCESS-Vets	Achieving Competitive Customized Employment through Specialized Services - Veterans
AE	Adverse event
BQC	Benchmarks of Quality Checklist
CE	Customized employment
CWT	Compensated Work Therapy
H	Hypothesis
HIPAA	Health Insurance Portability and Accountability Act
HHMVAMC	Hunter Holmes McGuire VA Medical Center
ICF	Informed consent form
IRB	Institutional Review Board
IPS	Individual Placement and Support
ISO/PO	Information Security and Privacy Officers
JAHVHC	James A. Haley Veterans' Hospital & Clinics
MCAR	Missing completely at random
PHI	Personal health information
PI	Principal Investigator
PMM	Predictive mean matching
QOL	Quality of life
R&D	Research and Development Service
SAE	Serious adverse event
SCI	Spinal cord injury
SE	Supported Employment
TAU	Treatment as usual
VA	Department of Veterans Affairs
VAMC	Veterans Affairs Medical Center
VHA	Veterans Health Administration

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Protocol Title: Achieving Competitive Customized Employment through Specialized Services - Veterans: ACCESS-Vets

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  - Hunter Holmes McGuire VA Medical Center (HHMVAMC)

2.0 Introduction

Restoring employment is critical for Veterans with spinal cord injury (SCI). People with SCI view gainful employment as key to social reintegration.[1,2] Central to social participation, employment is a feature of overall functioning according to the International Classification of Functioning, Disability, and Health.[3] The employment rate for persons with SCI is approximately 35%.[4] In a recent study of a large national cohort of Veterans with SCI treated in the Veterans Health Administration (VHA), less than 10% were employed.[5] This rate of unemployment is alarming because it is associated with decreased quality of life (QOL)[6,7] and increased mortality, including suicide.[8] Employment improves QOL, well-being, and independence. Employed Veterans with SCI have greater social integration, productivity, and participation,[9] all highly valued outcomes for these Veterans.[1]

Current vocational services have modest outcomes. The VHA Vocational Rehabilitation Service provides recovery-oriented clinical services for Veterans with disabilities for whom the primary objective is competitive employment. In VHA, Compensated Work Therapy (CWT) programs offer Supported Employment (SE) and other vocational programs. In a recent study of CWT for Veterans with mental health disabilities (*N* = 38,199),[10] competitive employment outcomes were modest, but the highest rates resulted from emphasizing community employment, and low rates were associated with Veterans who had more than five general medical conditions, including SCI. Research is needed to assess modifiable factors in VHA vocational services and to evaluate effective private sector vocational services not available within VHA.[11] For Veterans with SCI, the Individual Placement and Support (IPS) model of SE,[12,13] which integrates vocational services into rehabilitation and health care, has had the best outcomes.[14–16] IPS includes rapid job search and job development guided by consumer preference, benefits counseling, and time-unlimited supports.[17] In two multi-center VHA studies of IPS for Veterans with SCI (Ottomanelli, PI), employment rates were 25-43%.[15,18] Although significantly better than usual care, these rates are lower than those for persons with mental health disabilities who receive IPS. After SCI, significant impairments likely contribute to a lower employment rate than other populations.

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Despite SE, Veterans with SCI take longer to locate and secure a job, and the majority do not obtain competitive employment.

Vocational services need modification based on unique barriers faced by Veterans with SCI. Information on potentially modifiable employment barriers is based on (1) cross-sectional studies of large data sets from civilian samples and our VA data and (2) prospective studies from our work implementing IPS SE in VHA SCI care.[19] The cross-sectional studies showed health and transportation are the most common barriers to employment after SCI. The prospective research[5 20–22] identified the following employment barriers: number of secondary medical conditions, poor health, and frequent rehospitalization. Our analysis (*N* = 1047) showed that, as the number of health conditions increases, likelihood of employment post-SCI decreases. In our previous study of IPS SE in SCI, longer hospitalization decreased likelihood of employment.[23] Transportation was a common barrier regardless of employment outcome, but those who did not become employed cited the following unique barriers: physical health, benefits, time, and caregiver issues.[24] Both groups identified two employment facilitators: (1) a vocational specialist providing individualized services and (2) vocational services integrated with SCI rehabilitation. To build on the success of IPS SE for SCI, modifications are needed to address unique barriers after SCI such as physical health burden, benefits concerns, and transportation needs. Rather than the current practice of rapid job search, in-depth exploration of Veterans' physical, environmental, and social contexts prior to job search may create a more Veteran-centric vocational plan that addresses their unique barriers and leads to jobs that meet their needs and preferences.

Customized Employment is an innovative strategy to address barriers. Customized Employment (CE), a new vocational intervention for people with complex disabilities[25] and the next evolution of SE,[26] is "a flexible process designed to personalize the employment relationship between a job seeker and an employer in a way that meets the needs of both."[27] It comprises additional customization of job responsibilities and the workplace environment[28] and a Discovery process that identifies individual interests, skills, and support needs prior to the job search. Personal networks and interpersonal relationships (social capital) leverage workforce connections and engage a natural support system. CE emphasizes employer engagement to match specific needs of targeted employers to Veterans' skills and talents and ensures provision of reasonable accommodations and any needed supports to perform job functions individually negotiated and developed."[29] The comprehensive process also integrates disability benefits analysis to identify appropriate work incentives and to enable informed decision making by the job seeker.

We propose to use the CE strategies of both employment matching (Discovery) and employment customization to help Veterans with SCI overcome employment barriers.

Customized Employment is being adopted in civilian sectors and introduced in VHA. *Competitive integrated employment* is defined as "full or part-time work at minimum wage or higher, with wages and benefits similar to those without disabilities

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performing the same work, and fully integrated with co-workers without disabilities."[30] For this outcome, CE is being adopted by civilian vocational rehabilitation programs nationwide due to recent legislation that specifies CE as a means to achieve competitive integrated employment[31] and because of real-world evidence that CE improves competitive integrated employment outcomes in people with complex disabilities.[32] In VHA, the Vocational Rehabilitation Service is exploring how CE could augment existing practices, particularly for hard-to-place populations such as persons with SCI or polytrauma (see Bakken letter). In VHA, planning has begun in partnership with the Department of Labor's Office of Disability Employment Policy to prepare VHA vocational staff to provide CE.

Novel CE elements could enhance current VHA vocational services. Discovery is the foundation of CE and distinguishes it from other employment interventions.[33] Qualitative interviewing and observation are used to discover a Veteran's strengths and employability by interacting with the Veteran, support systems, and communities to customize competitive integrated employment.[30] Hence, CE differs from current practices by: (1) engaging the jobseeker in Discovery prior to initiating job development, (2) aligning with qualitative research approaches, and (3) relying heavily on social capital to connect job seekers with employment opportunities. Engaging Veterans in their natural social contexts using these distinctive CE strategies could enhance employment outcomes for Veterans with complex disabilities who need more intensive and customized services to address their unique employment barriers.

Current literature supports CE as a promising practice. Real-world evidence and findings from controlled studies[32,34] demonstrate CE improves competitive integrated employment for adult civilians with disabilities. A literature review revealed 25 articles on CE from 2006-2013[35] and additional studies are ongoing. Although not all used experimental methods, all reported consistently positive outcomes. A retrospective study of CE reported 98% of adults with autism spectrum disorder and co-morbidities achieved competitive integrated employment jobs[40] and 77% had no prior work history. Type of jobs ranged from health care to hospitality to warehouse. In another study, 75% job retention at 6 months was reported and 66% at 1 year.[34,36–40] Chronological study results demonstrate improvement in outcomes over time as CE has become more standardized and replicable (Table 1).

Table 1. Summary of CE studies by study type, population, and outcome

Study	Method/ Study Type	Disability Type (S)	N	Age (Y)	Employed (%)
Wehman et al. (2016)[36]	Retrospective review	Autism (67% had co-morbidity)	64	19-59	98%
Staines et al. (2009)	Randomized clinical trial	Substance use disorder	135	18+	65%
Elinson et al. (2008)[37]	Secondary data	Cognitive, mental health/ psychiatric, physical	6555	Any	45%
Rogers et al. (2008)[41]	Demonstration	Cognitive, learning, mental health/ psychiatric	475	18-24	61%
Citron et al. (2008)[38]	Demonstration	Developmental, mental health/	198	18+	72%

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Table 1. Summary of CE studies by study type, population, and outcome

Study	Method/ Study Type	Disability Type (S)	N	Age (Y)	Employed (%)
		psychiatric, physical			
Luecking et al. (2008)[40]	Demonstration	Autism, cognitive, learning, mental health/psychiatric, physical	62	21+	89%
Luecking et al. (2006)[39]	Demonstration	Autism, cognitive, learning, mental health/psychiatric, physical	135	16-56	53%

For instance, the initial study by Luecking et al. (2006)[39] did not include the critical step of CE negotiation. In a randomized clinical trial, compared with standard vocational rehabilitation, CE significantly increased employment for outpatients with substance use disorders.[34] While that study had several areas of similarity with ACCESS (Achieving Competitive Customized Employment through Specialized Services), including a small case size and a strengths-based and community-based intervention, the target population was limited to people with substance use disorders with no co-morbid conditions. The study also lacked fidelity measures, which limits replicability. In an ongoing controlled trial that includes fidelity measurement, CE is increasing self-determination and promoting autonomy and community reintegration for adults with complex disabilities.[42] In summary, study findings support CE as a promising intervention that improves employment outcomes, however future studies will benefit from increased scientific and methodological rigor.

Critical gaps in the literature on CE need to be addressed in clinical settings. To build on the evidence base for CE, vocational researchers and implementation experts in the private sector and VHA state further research is needed. Based on a study of national CE experts and implementers, the Rehabilitation Research and Training Center on Employment of Persons with Physical Disabilities recommends further work is needed on specifying and defining the evidence-based practices of CE[33] by (1) Evaluating how Discovery could translate into provision of ongoing job supports after job acquisition to ensure job retention. (2) Determining how to train CE providers on the use of qualitative interviewing and participant observation skills and how to ensure fidelity when implementing CE. (3) Understanding how to facilitate the use of social networks (social capital) to improve employment outcome. These recommendations are consistent with the call for research among VHA vocational experts and researchers who state CE is one of the most promising directions in the field and warrants study within the VHA.[11,34,43–45] Specifically, future vocational research in VHA is recommended on (1) efficacy of CE with a range of target populations and (2) development and inclusion of fidelity measures assessed at the participant level. *Recent progress has been made toward developing expert consensus to standardize the intervention and moving toward fidelity measurement; however, this work has only focused on the one element of Discovery and not the full CE process.*[46]

To address these gaps, we will evaluate the effectiveness of CE in VHA for Veterans with complex medical disabilities. The proposed study examines the effects of a Veteran-driven CE intervention: Achieving Competitive Customized Employment

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through Specialized Services - Veterans (ACCESS-Vets) with SCI. A next step in developing evidence on CE, this research will evaluate whether it can be adapted for use with fidelity within VHA vocational services. Specifically, a mixed methods study will address knowledge gaps by obtaining data on (1) the CE process from Discovery through ongoing job supports and its impact on outcomes; (2) how standardized training in qualitative skills and well-specified benchmarks facilitate CE fidelity; and (3) how CE, including the use of social networks, reduces barriers to employment goals. Moreover, our study is innovative in examining CE within healthcare; we will determine whether collaboration between CE providers and VA rehabilitation teams strengthens CE practice and reduces or eliminates barriers to employment.

The proposed intervention: ACCESS-Vets. ACCESS is a CE model developed with National Institute of Mental Health funding (5R34MH111556-02, Smith, Dillahunt-Aspillaga, Co-PIs) for community dwelling adults with complex disabilities to improve competitive integrated employment outcomes. Based on popular CE models and stakeholder feedback, ACCESS was developed in response to a need to standardize the CE process to promote fidelity and replication. The model was informed by *The Essential Elements of Customized Employment for Universal Application* (2017), a document developed by leaders in the field and published by the National Workforce Innovation Technical Assistance Center. ACCESS includes the active treatment components of Discovery, CE Planning, Job Development and Negotiation, and Accommodations. However, ACCESS improves application of CE by standardizing how components are delivered via a package of tools, templates, and logs that promote consistent application of CE. This standardized process is supported by use of a fidelity instrument, the Benchmarks of Quality Checklist (BQC), a step-by-step guide for delivering CE. The fidelity measure was developed to: (1) facilitate training and guidance for CE providers who implement ACCESS; (2) promote adherence to the ACCESS model; and (3) document omissions, additions, and adaptations that occur during the implementation process. A BQC fidelity score is calculated after completion of each CE process element and at completion of the full CE process to determine whether acceptable levels of fidelity have been achieved during implementation. By standardizing the CE process and including fidelity measures, ACCESS lends itself to translation and adaptation to new settings such as VHA and SCI rehabilitation. While ACCESS standardizes how the CE process unfolds (i.e., the specific components and order of them), since it is a patient-centered intervention, the time spent and specific activities (e.g., where Discovery takes place, types of jobs developed) are individualized based on the needs and strengths of the job seeker.

3.0 Objectives

The purpose of the proposed study is to evaluate the effects of ACCESS-Vets (CE intervention) on employment outcomes of Veterans with SCI who have received or are currently receiving IPS (treatment as usual [TAU]). The short-term goal is to determine effectiveness of ACCESS-Vets for Veterans with SCI. The long-term goal is to obtain

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data to guide research on and adoption of ACCESS-Vets as part of evidence-informed VHA services to improve employment outcomes for Veterans with SCI.

The proposed 4-year, multi-site randomized clinical trial with concurrent mixed methods data collection will test ACCESS-Vets in a sample of Veterans with SCI. The specific aims are:

Aim 1: Determine the effectiveness of ACCESS-Vets in the VHA clinical setting.

> H1.1. The proportion of Veterans who attain employment will be greater for Veterans who receive ACCESS-Vets (CE Intervention) than Veterans who do not receive ACCESS-Vets (TAU) (Primary outcome).
>
> H1.2. Among Veterans who attain employment, those who receive ACCESS-Vets will report higher job satisfaction, wages, and retention (Secondary outcome).

Aim 2: Examine the impact of employment on QOL and participation.

> H2.1. Veterans who attain employment will demonstrate statistically significant improvements in self-sufficiency, QOL, and participation in life roles compared with those who do not achieve employment.
>
> (Secondary outcomes).
>
> Q2.1. How does employment-seeking and employment impact Veterans' QOL and participation?

Aim 3: Identify strategies used in IPS and ACCESS-Vets for addressing barriers to employment.

> Q3.1. As perceived by Veterans and their providers, how do IPS and ACCESS-Vets address barriers to employment?
>
> Q3.2. In what ways do practitioners adapt the ACCESS-Vets intervention for use in the VHA clinical setting?

Value to the VA. This project supports suicide prevention by focusing on a CE intervention to improve employment and reintegration. In alignment with the VA Modernization Plan and MISSION Act, ACCESS-Vets may empower and equip Veterans to take charge of their health and well-being. Currently, there is no empirical evidence to guide implementation of CE in VHA. This study will determine the value added by introducing standardized CE in VHA employment services for Veterans with complex disabilities and will provide data to guide future research and practice.

4.0 Resources and Personnel

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Site #1: James A. Haley Veterans' Hospital & Clinics, Tampa, FL

- **Principal Investigator** Lisa Ottomanelli, PhD; VA Employee: Dr. Ottomanelli will assume overall responsibility for administration of the grant, including overseeing the quantitative and qualitative components of the study, including data collection and analysis and day-to-day management. Dr. Ottomanelli will also lead in developing reports, publications, professional presentations, and other dissemination efforts. Will have access to PHI/PII.

- **Intervention Lead Trainer,** Tammy Smith, PhD; WOC Employee. Provides oversight for the ACCESS CE intervention including training study staff on the CE process and providing technical assistance throughout the intervention phase. This position assists in the interpretation of findings and dissemination of study results. Provides oversight for the intervention including training study staff on CE and refining the intervention. Participates in interpretation of findings and dissemination. Will have access to PHI/PII.

- **Technical Assistance Coach,** Christina Dillahunt-Aspillaga, PhD, CRC, CVE, CLCP; WOC Employee. Provides technical assistance and coaching for vocational and study staff and participates in interpretation of findings and dissemination Provides technical assistance and coaching for vocational and study staff and participates in interpretation of findings and dissemination. Will have access to PHI/PII.

- **Statistician**, Peter Toyinbo, PhD, CPH; VA Employee: Serves as the study statistician leading quantitative data collection, management, and analysis with the support of the quantitative data manager. Participates in writing manuscripts. Will not have access to PHI/PII.

- **Qualitative Lead Researcher**, Bridget Cotner, PhD; VA Employee: Leads the qualitative research component, supervises the qualitative data manager, and ensure all qualitative data collection activities, analysis, and findings inform the qualitative objective and overall study goals. Recruits and obtains informed consent from Veterans and providers for the qualitative interviews. Will have access to PHI/ PII.

- **Quantitative Data Manager**, Hari Venkatachalam, MPH CPH VA Employee: Serves as the quantitative data manger and will work with the study statistician to support data collection and analysis. May assist in recruitment, screening, informed consent, and administering questionnaires. Will have access to PHI/PII.

- **Project Manager/Qualitative Data Manager,** Areana Cruz M.S.Ed., WOC Employee: Provides administrative support to PI and Local Site Investigator including regulatory requirements and IRB. Works under the direction of the Lead Qualitative Researcher to conduct qualitative data collection and management. Recruits, screens, and obtains informed consent. Administers questionnaires and qualitative interviews. Will have access to PHI/PII.

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- **Vocational Rehabilitation Counselor (VRC),** VA Employee: Serves as the CE provider at the Tampa site. Delivers the intervention to Veterans with the direction of the Tampa Co-Is and in collaboration with VA clinical teams and under the guidance and support of the Tampa Site PI, Lead Intervention Trainer, and Technical Assistance Coach. May assist in recruitment, screening, and informed consent. Will have access to PHI/PII.

- **Local Site Investigator**, Julie Cessna Palas, PhD; VA Employee. Oversees day-to-day project activities including recruitment of Veterans with SCI, training the CE provider on working with Veterans with SCI and the clinical team, and facilitating integration of the intervention in the SCI Center. Provides guidance to the VRC on working closely with the rehabilitation teams at the SCI Center and training on management of SCI. Will have access to PHI/PII.

- **SCI Rehabilitation Team Lead**, Samantha Mendelson, MD; VA Employee. Expert on SCI who supports recruitment of Veterans with SCI and facilitating integration of the intervention in the SCI Center. Contributes to publications and dissemination of findings, specifically their clinical relevance and implications. Provides training on SCI management to the VRC. Will have access to PHI/PII.

Site #2: Hunter Holmes McGuire VA Medical Center

- **Local Site Investigator – Richmond**, Scott McDonald, PhD; VA Employee, Oversees day-to-day project activities with support of the project manager including recruitment of Veterans with SCI, training the CE provider on working with Veterans with SCI and the clinical team, and facilitating integration of the invention in the SCI center. Provides guidance to VRC on working closely with the rehabilitation teams at the in the SCI Center and training on management of SCI. Will have access to PHI/ PII.

- **SCI Rehabilitation Team Lead – Richmond**, Lance Goetz, MD; VA Employee: Contributes to publications and dissemination of findings, specifically their clinical relevance and implications. Will have access to PHI/PII.

- **Project Manager,** VA Employee: Provides administrative support including regulatory requirements and IRB. Works under the direction of the Local Site Investigator. Recruits, screens, and obtains informed consent. Administers questionnaires. Will have access to PHI/PII.

- **Vocational Rehabilitation Counselor (VRC)**: VA Employee: Serves as the CE provider at the Richmond site. Delivers the intervention to Veterans under the direction of the Richmond Co-Is and in collaboration with VA clinical teams and under the guidance and support of the Tampa Site PI, Lead Intervention Trainer, and the Technical Assistance Coach. May assist in recruitment, screening, and informed consent. Will have access to PHI/PII.

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Consultant

- **Customized Employment Consultant**: Serves as a national CE subject matter and content expert and will provide consultation on intervention refinement, CE provider training, and implementation. May participate in and provide guidance on dissemination of findings. Will not have access to PHI/PII.

5.0 Study Procedures

5.1 Study Design

Design. We will use a 4-year, 2-armed, multi-site randomized controlled study design with concurrent mixed methods data collection at two VAMCs (Tampa and Richmond) to compare ACCESS-Vets intervention with TAU, which is IPS. We will recruit a minimum of 100 persons with SCI who are Veterans or Military Service Members transitioning to Veteran status (hereafter referred to as Veterans) using rolling enrollment to ensure CE caseloads are within the recommended level for individualized community-based services. We expect most participants to complete the intervention in 8 months or less depending on their needs. Using the intent-to-treat approach, we will ensure that all enrolled Veterans who are assessed for baseline data and randomized into the study will have their employment status ascertained (primary outcome) and be included in the analysis. Intent-to-treat analysis will permit a real-world effectiveness study of ACCESS-Vets, which includes the ability of Veterans and clinicians to adhere to the intervention.[47] In addition, the dates of rolling enrollment and achievement of employment if any will be recorded to determine the time since employment. Given rolling enrollment, Fig. 1 depicts the study flow *for an individual participant from recruitment through the 12-month assessment.*

***Quantitative*: Aims 1 (H1.1, H1.2) and 2 (H2.1).** Assessment data will be collected from 100 Veterans via questionnaires and self-report surveys at the following four time points: baseline, 6, 9, and 12 months to assess primary and secondary outcomes. We will continue to collect data for the employed group until we will have 3 post-employment time points or until the data collection period ends (note: due to space limitations, post-employment assessments of secondary outcomes that may fall beyond 12 months are not included in Fig. 1).

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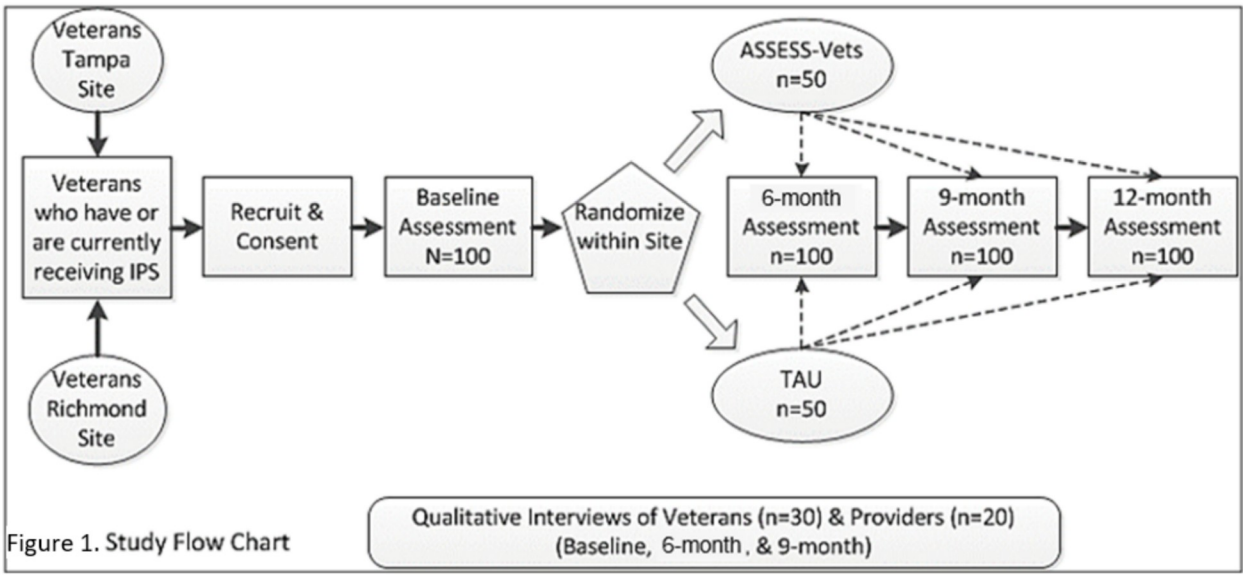


Figure 1. Study Flow Chart

***Qualitative*: Aim 2 (Q2.1) and Aim 3 (Q3.1 & Q3.2).** A sub-sample of 15 Veterans and 10 providers per site will be purposively selected for a 30- to 45-minute semi-structured telephone or video chat interview to evaluate CE and IPS experiences. Veterans will be interviewed at baseline and at 6 and 12 months after they start the intervention. Provider interviews will occur during the following 3 time periods: 0-9 months, 10-21 months, and 22-33 months after the study intervention period begins.

Intervention (Table 2). ACCESS will be adapted for use with Veterans with SCI (ACCESS-Vets) to achieve the primary outcome of competitive integrated employment defined as "full or part-time work at minimum wage or higher, with wages and benefits similar to those without disabilities performing the same work, and fully integrated with co-workers without disabilities" (Civic Impulse, 2015, p. 571). The primary adaptation will be integrating ACCESS into medical rehabilitation. Thus, the capacity of the SCI interdisciplinary care team will be leveraged to support addressing employment barriers. With this patient-centered intervention, users determine their own goals and proceed at their own pace.

Table 2. ACCESS-Vets (CE intervention)

CE Process Elements	Activities / Duration	Services	Veteran Product / Deliverable
Discovery	● Qualitative assessment of interests, skills, and support needs ● Up to 6 months	Community-based Discovery activities: home and neighbor-hood visits, conversational interviews, familiar and novel activities	Vocational Profile – a robust, narrative description of the Veteran that captures information learned through the Discovery process
CE Planning	● Action planning completed within 2 weeks of completing Discovery process ● 1-2 days	Person-centered planning meeting where team completes a series of structured activities to develop an action plan	Employment Blueprint – an action plan that bridges what is learned during Discovery with the employment outcome. Outlines steps to employment with timelines and person(s) responsible.

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Table 2. ACCESS-Vets (CE intervention)

CE Process Elements	Activities / Duration	Services	Veteran Product / Deliverable
Job Development	● Informational interviews and business tours to assess the needs of targeted businesses ● Up to 2 months	Development of tools to market the job seeker to potential employers. Interviews and business tours conducted with business owner or hiring authority to identify business needs.	Career Portfolio – a marketing tool with letters of recommendation, awards, degrees, certificates, and, if needed, a visual resume that utilizes photos and videos to demonstrate the Veteran doing essential functions of the job
CE Negotiation	● Customization of job to meet the needs of the employer through the skills of the Veteran ● Up to 2 months	Negotiation of elements of the job that may need to be modified to best utilize the talents/skills of the job seeker to meet the needs of the employer, e.g., job restructuring, job creation	Completed customized Employment Job Development and Negotiation form* (part of the ACCESS template package)
Accommodations and Job Retention Supports	● Environmental restructuring, training, and job supports to enhance Veteran success and job retention ● Up to 3 months	Retention services and supports individualized for reasonable accommodations. Supervisor and coworker training for development of natural support systems within the workplace	Environmental or interpersonal supports depending on job seeker abilities and job demands, e.g., elevated or modified workstation, flexible scheduling, or standing wheelchair

Individual Placement and Support (IPS). Delivered as part of SCI medical rehabilitation, IPS will serve as the comparison group. IPS is an evidenced-based practice of SE that helps persons with disabilities find and maintain integrated competitive employment. IPS follows eight standardized principles: zero exclusion, integrated services, rapid job search, competitive employment, worker preferences, systematic job development, benefits planning, and time-unlimited supports.

Timeline and duration of study (Table 3). Following an initial 6-month set-up and training period, the Spinal Cord Injury/Disorders Registry for Tampa and Richmond VAMCs will be filtered to identify patients meeting study inclusion criteria for SCI, age, and geographic location. Over 30 months, 100 Veterans with SCI will participate in study interventions and quantitative data collection (surveys and questionnaires). For a subset of 30 Veterans and 20 providers at the 2 sites (15 Veterans and 10 providers per site), we will conduct qualitative interviews on their experiences with the interventions.

Table 3. GANTT Chart of Study Benchmarks

	Year 1				Year 2				Year 3				Year 4			
Project Activity	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study Start-Up and CE Provider Training	■	■														
Rolling Recruitment and Screening			■	■	■	■	■	■	■	■						
Deliver ACCESS Intervention			■	■	■	■	■	■	■	■	■	■				

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Table 3. GANTT Chart of Study Benchmarks

Project Activity	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Data Collection (Quantitative, Qualitative)																
Transcription and Aim 3 Data Analysis																
Prepare and Stage Primary Data																
Primary Data Analysis																
Data Interpretation, Triangulation																
Finalize Data, Reports/Manuscripts																
Develop, Disseminate Materials																

Study population (Table 4). We expect to enroll 100 Veterans with SCI who have or are currently receiving IPS and 18 years of age or older and meet study eligibility criteria.

We expect to enroll 20 VA providers and stakeholders who meet study eligibility criteria to participate in qualitative data collection.

Women and minorities will be recruited into the study (Table 4). Both women and minorities are important to the Veteran community, and they will be given the same opportunity to participate as men and non-minorities. We expect about 7% of our sample to be women consistent with the Veteran SCI population. Additionally, we expect the number of minority participants to reflect their proportion in the Veteran SCI population who participated in our previous VA Rehabilitation Research and Development Service funded vocational studies. While these gender and ethnic ratios are ideal, if we are not achieving the desired ratio, we will continue to offer the study to all who meet inclusion criteria.

Table 4. Targeted/Planned Enrollment: Number and Type of Subjects

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino		10	10
Not Hispanic or Latino	7	83	90
Ethnic Category: Total of All Subjects *	7	93	100
Racial Categories			
American Indian/Alaska Native		2	2
Asian		2	2
Native Hawaiian or Other Pacific Islander		1	1
Black or African American	2	15	10
White	5	80	85
Racial Categories: Total of All Subjects *	7	93	100

Vulnerable populations. No children, prisoners, elderly, or persons with impaired decision making will be recruited as they are not the target population and would not be able to complete the assessments or treatments**.** While pregnant women will not be a

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targeted subgroup, they will not be excluded from the study as the study has no foreseeable physical risk and may have potential benefit for the woman.

Potential risks*.* The potential risks for participating in this study are no more than minimal. No pharmacological therapies are used in this study. This study will be reviewed for adherence to human subjects protection regulations by the Institutional Review Board (IRB) and the local VA Research and Development Service (R&D) Committees.

Subjects will be issued a coded identifier, which will be known only to the PI, lead qualitative researcher, project manager, and data manager. Electronic records including the documentation of the verbal informed consent obtained by phone (see form 112B Request for Waiver of Documentation of Informed Consent included in package) will be kept behind the VA firewall and any paper records will be retained in locked files in the PI's or study team member's office at the JAHVHC. All computer data will be encrypted to protect patient confidentiality. Health Insurance Portability and Accountability Act (HIPAA) regulations will be strictly adhered to. Data will be secured on a networked computer system behind VA firewalls, and access will be restricted and password protected.

Adequacy of protection from risk. Participants will be assured that their participation is voluntary, and they can choose not to answer any question. Participants will also be assured that they can choose not to participate in the study at any time. There is an intervention being offered in this study; there are no alternative options available for participants beyond standard of care treatment.

The proposed study poses no more than minimal risk to participants as this intervention is psychosocial in nature with non-intrusive data collection. There is a risk that some participants may:

1. Feel uncomfortable reporting about their comorbid condition symptoms.
2. Experience emotional and/or physical discomfort while engaging in the vocational activities.
3. Experience agitation/distress during the intervention and/or data collection.

Unauthorized access to data is also a risk in all research studies. Based on our prior research, it is unlikely that these adverse events will occur, however we will implement several protective strategies to protect participants and their data.

Should any behavioral or relationship issues arise during treatment, participants will have information to contact their providers and the research team for support. The research team will follow up directly with Veterans' identified provider (at onset of participation) to ensure the Veterans have mental health support. All unanticipated incidents will be documented and reported in alignment with VA and IRB regulations.

Since the study is utilizing a non-invasive CE intervention and social-behavioral methods approach including surveys and telephone or video chat interviews, it is unlikely that recruiting participants in the described activities will cause an "adverse event" among the study population. However, it is possible that a Veteran participant will

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become agitated or experience an adverse emotional/psychological response during the intervention and/or the data reporting process. In the event of an adverse event, the project manager and PI will follow regulated protocol. Then they will follow procedure to report the adverse event to the IRB. In anticipation of the unlikely event that a participant might become agitated or distressed during the intervention or data collection, each participant will be provided: (1) the contact information of the Veteran's provider (collected at onset of study participation for referral as appropriate (i.e., mental health), if indicated; (2) the PI's contact information; and (3) the national crisis hotline number for Veterans. The participant may be formally excluded from further participation to ensure the individual's safety.

We are including an established process for responding to adverse events, in which the designated team member immediately contacts the designated primary care provider for the participant to report the incident and request immediate follow-up. In cases of mental health or other potential serious issues, study staff also contact the site investigator who is a neuropsychologist on the team and follow up with the primary provider and/or patient to provide support for responding to the adverse event until resolved. After following up with the participant, a final follow up call will be made to the neuropsychologist to document the plan put in place by the primary provider and clinical psychologist.

Potential benefits of research to subjects and others. Participants may receive direct benefit from participating in this study because of engaging in the proposed intervention. Potential benefits of this research to participants include:

1. Obtaining a paying job in the community and earning a competitive wage from employment.
2. Experiencing improvements in QOL and social participation. Employment is associated with improved QOL and participation in life roles.
3. Veterans in the future may benefit if the intervention is found to be effective in improving rehabilitation outcomes and subsequently disseminated to Veterans and their providers throughout the VA system.

Importance of knowledge to be gained. Advancing the science of implementing CE services in the VA system of care for Veterans and their providers is an important aspect of providing Veteran-centered care. VHA recognizes the need to develop a holistic approach to create a patient-centered experience for Veterans with complex disabilities such as SCI. These data will support the development of a Veteran-centric employment intervention for Veterans and their providers within the VHA. This study will determine the value added by introducing standardized CE in VHA services for Veterans with complex disabilities and will guide future research and practice.

Data and safety monitoring plan. Risk of harm from this study is no more than minimal. The PI will be responsible for monitoring the safety and efficacy of the study, executing the data and safety monitoring plan, and complying with the reporting requirements. The PI and project manager will provide a summary as part of the grant's progress report. The report will include each participant's socio-demographic

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characteristics, expected versus actual recruitment rate, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events, and any actions or changes with respect to the protocol.

The research team will be trained in protecting the safety of the study participants and the scientific credibility of the project. Integrity of the data collection is strengthened by the team's use of the Qualtrics platform. The Qualtrics platform allows for various data validation techniques, such as prompts for missing responses, and techniques for assigning specific response types for questions. This will allow the research team to collect high quality data. This electronic platform, therefore, ensures the integrity of collected data to a higher degree than data collected through traditional paper methods. The participant also will be able to directly input their desired responses into the Qualtrics platform, which removes the possibility of interviewer biases and misclassification. Periodic review of the quantitative data, and preliminary analyses of the data will also ensure the highest quality of the collected data. (for additional detail see sections 7.0 and 8.0)

The team includes PI, LSI, and co-Investigators who are VA clinical staff and experts in SCI to provide clinical expertise and recruitment support at Tampa and Richmond. The team will coordinate to respond to any individual participant needs that may present throughout the study.

5.2 Recruitment Methods

Aims 1-3: Veteran Recruitment. Veterans may be identified for recruitment into the study by (1) providers, (2) research staff, or (3) self-referral.

The SCI registry and electronic health record (CPRS, Joint Legacy Viewer [JVL], and Vista – including upcoming clinic appointment information) will be utilized to identify Veterans with SCI who live within the two study sites' geographical regions and appear to meet study inclusion criteria and provide them with information about the study by mail and during in-person or telehealth visits at the VA hospital and clinics outlined below.

Study Staff will use the SCI registry and the electronic health record to identify Veterans with SCI who live within the two study sites' geographical regions. The identified Veterans will be sent an IRB-approved recruitment letter via mail (note external envelope will not include study specific information to identify the Veteran as a potential research subject) or Microsoft AZURE e-mail with detailed information about the study. Veterans will also be mailed a separate "opt-out" response card following the letter. Veterans may mail back the "opt-out" card if they do not want to participate and do not want to be contacted by study staff. We expect to mail IRB approved recruitment letters to the Veterans on the SCI/D registries at Tampa and Richmond. Approximately 2400 Veterans are currently on the registry at Tampa and Richmond. The medical record will be reviewed for other inclusion and exclusion criteria for those Veterans who do not contact the study staff, prior to following up with a phone call. We expect to

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screen more than double the number of participants in order to achieve our sample size. Thus, we expect to examine about 400 charts and conduct 200 phone screens. Microsoft AZURE is a VA-approved encrypted e-email tool (AZURE RMS). The letter will provide study information including an IRB-approved recruitment flyer, study information sheet, and a telephone number the Veteran can call if s/he would like to be considered for the study. Veterans interested in taking part in the study will contact study staff, who will review the Veteran's medical record and discuss the study and inclusion criteria with the Veteran. The study team member will also call participants who have not called two weeks after receiving the letter e-mailed to them. Once contact is made with potential participant, no further calls will be attempted unless initiated by a potential participant. No more than three attempts will be made to contact the Veteran.

Providers in the SCI Center or CWT Program who treat Veterans with SCI will refer interested Veterans to the study. If the Veteran agrees, the provider will communicate via phone, in-person, encrypted email, or secure messaging to the study team with the Veterans information or co-sign the study staff on the Veteran's note in the electronic medical record indicating that the Veteran would like to be considered for the study. The study staff will follow-up with a phone call or meet with the Veteran in clinic or a location of the Veteran's choosing. If the Veteran believes he/she may qualify for the study and is interested, an appointment will be made for an informed consent appointment. Then the steps for obtaining informed consent will be followed. In cases where a provider is not available to introduce the study to patients during their appointment, study staff may also provide study information to patient who present to the VA hospital or clinics for healthcare.

Veterans can call study staff directly as IRB approved materials (e.g., study flyers, PowerPoint slides/videos) will be distributed in patient waiting areas and posted throughout VA hospital and clinics including VA-approved social media (Facebook, YouTube, and Twitter). Veterans may also hear about the study from other Veterans.

Study staff will discuss the study treatment and eligibility requirements with the interested participant over the telephone, telehealth, or in-person. If the Veteran believes s/he may qualify for the study, an appointment will be made for screening and to obtain informed consent.

Aims 2 and 3: Provider Recruitment. A purposive sample of providers who serve Veterans with SCI and are knowledgeable about the vocational interventions may be identified for recruitment into the study by (1) research staff (Site Co-Investigators, vocational providers), (2) other providers, or (3) self-referral.

- Research staff, including Site Co-Investigators and vocational providers, may recommend providers who serve Veterans with SCI;
- Providers may suggest other providers to recruit; and
- Providers can self-refer if they hear about the study from other providers.

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Research staff will send providers an IRB-approved Microsoft email with detailed information about the study and will follow up with a phone call 3-5 days after the initial email. A second and third follow up phone call and/or email will occur one week after each other. Up to 3 follow up attempts will be made. If the provider is interested, the research staff will discuss the study requirements and the steps for obtaining informed consent will be followed.

Recruitment materials. The study team is submitting recruitment letters, emails, and flyers for IRB approval prior to use.

5.3 Informed Consent Procedures

Waiver of HIPAA authorization. A waiver of HIPAA authorization will be requested. This will allow study staff to examine electronic medical records of potential participants for screening purposes. This waiver will allow more efficient screening by ensuring that participants meet basic criteria prior to contact from study staff.

HIPAA authorization waiver will be for all enrolled participants. The health information to be disclosed presents no more than minimal risk to the privacy of the participants. Personal health information (PHI) is required for creation of a vocational profile and participation in CE. The study team will protect PHI in accordance with VA guidelines and will destroy identifiers at the earliest opportunity.

Waiver of informed consent documentation. Study procedures (including interviews and surveys) will be completed remotely via telephone or videoconferencing except in instances where the participant expresses the desire and willingness to present in person and data collection or the intervention can be conducted with appropriate COVID-related safety measures (social distancing, masks, and other procedures as designated by the respective VA medical facilities policies and procedures). In lieu of a signed ICF, we will be asking for verbal consent during our screening process. Once we have obtained verbal consent, we will document that the subject has consented in our records. Verbal consent documentation will be more appropriate because we may not have in-person interactions with the subjects. We will avoid any potential risk of breech of PHI by not transmitting ICFs. A study information sheet will be sent by postal service or email to the participant after being read verbally to the participant by telephone. Participants will have time to review information and ask questions prior to giving consent.

The PI, Co-Investigator/site PI, and project managers may complete the screens or informed consent process. All study staff will complete human subject protection training prior to start of study procedures in order to understand how to properly provide study information and behave during the informed consent process. Scripting for informed consent will be provided by the PI. Study staff will be trained using the scripting to

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ensure consistency in informed consent. Informed consent for providers will be conducted in the same manner.

5.4 Inclusion/Exclusion Criteria

Inclusion criteria

- Veterans or Military Service Members transitioning to Veteran status
- English-speaking Veterans
- 18 years or older
- Want to find work in their community
- Have received or are currently receiving IPS

Exclusion criteria

- Living more than a two hours' drive from the VAMC
- Progressive spinal cord disorder or terminal diagnosis, e.g., multiple sclerosis
- Moderate to severe traumatic brain injury or Rancho Level of 6 or less on discharge from acute rehabilitation
- Diagnosis of or documented treatment for psychosis in previous 6 months
- Untreated substance use disorder
- Visual, hearing, or cognitive impairment preventing consent or ability to participate in essential elements of the intervention

VA provider inclusion criteria

- CE providers and other clinical providers on the SCI interdisciplinary team and other stakeholders.

VA provider exclusion criteria

- Providers who do not meet inclusion criteria

5.5 Study Evaluations (Table 5)

This study will involve (1) collection of quantitative data through the collection of repeated measures through electronic survey collection at baseline and 3

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subsequent timepoints (Appendix 1), (2) collection of qualitative data through interviews with Veterans and providers (Appendix 2), and (3) collection of fidelity measures (Appendix 3).

Table 5. Data Collection Constructs and Measures

Aim	Construct	Measure	Participant/ Respondent	Participant Time Burden (minutes)	Administered Time Point (mo from baseline)			
					B	6	9	12
Quantitative								
1	Demographics, injury, and health conditions assessment	Participant survey	Veteran	15-20	X			
1	Work and vocational history	Background questionnaires	Veteran	15	X			
1	Employment & Job seeking	COVID-19 employment impact	Veteran	5	X	X	X	X
1 H.1.1	Employment - Primary Outcome	Employment questionnaire	Veteran	15		X	X	X
1 H.1.2	Employment - Satisfaction, wages, retention	Employee satisfaction survey	Veteran	15		X	X	X
2 H.2.1	**QOL -** Social and physical functioning – participation **QOL –** Positive psychological variables and emotional states	Spinal Cord Injury-Quality of Life (SCI-QOL) Scales	Veteran	10	X	X	X	X
2 H.2.1	Self- sufficiency	Employment Hope Scale (EHS)	Veteran	15-20	X	X	X	X
		Perceived Barrier Scale (PEBS)	Veteran	15-20	X	X	X	X
Qualitative								
2 Q2.2	Quality of life and participation	Qualitative Interviews	Veteran and Provider*	30-45	X	X		X
3 Q3.1	Employment Barriers	Employment questionnaire (open-ended questions)	Veteran	15		X	X	X
		Qualitative Interviews	Veteran and Provider*	30-45	X	X		X
3 Q3.2	Adaption of intervention	Qualitative Interviews	SCI Provider*	15	*	*	*	*
		Benchmarks of Quality Checklist (BQC)	CE Practitioner			X	X	
Fidelity and Adherence to Model Indicators								
	Fidelity to CE Model	BQC	CE practitioners		Every 6 months			
	Fidelity to IPS Model	IPS Fidelity Scale	CWT		Every 6			

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Table 5. Data Collection Constructs and Measures

Aim	Construct	Measure	Participant/ Respondent	Participant Time Burden (minutes)	Administered Time Point (mo from baseline)			
					B	6	9	12
			program managers and mentor trainers		months			
*For Providers: After the intervention begins, interviews will occur during the following 3 time periods: 0- 9 months, 10-21 months, and 22-33 months.								

Aim 1. To determine the effectiveness of Access-VETS, we will employ the following measures:

1. Participant Baseline Survey: This series of demographic questions is designed to determine potential moderators of the intervention, and includes questions regarding Veterans' injury and health conditions to determine baseline health conditions and possible comorbidities.
2. Participant Baseline Work and Vocational History: A series of questions to determine baseline conditions for employment attainment conditions prior to the administration of the intervention. This instrument will include questions about educational, vocational, and employment history and current benefits and residence.
3. Employment Questionnaire and Employee Satisfaction Survey: These will assess Competitive Integrated Employment outcome measures, and Veterans will self-report on job satisfaction, wages and retention.

Aim 2. To determine the impact of the Access-VETS and employment on global health and QOL, we will employ the following measures:

1. Spinal Cord Injury-Quality of Life (SCI-QOL) Scales: Assesses the Veterans' ability to participate in social roles and activities, satisfaction with those roles and activities, self-efficacy, independence, self-esteem, emotional well-being, and self-perceptions.
2. Employment Hope Scales (EHS): Measures psychological empowerment, futuristic self-motivation, utilization of skills and resources, and goal-orientation for career attainment.
3. Perceived Barriers Scales (PEBS): Obtains information on self-reported barriers and limitations to employment.

Aim 3. To identify the domains and taxonomy of participant CE experiences:

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1. Qualitative Interviews: Telephone or video chat interviews asking questions about the perceived value of the intervention in addressing QOL and participation.
2. Benchmarks of Quality Checklist (BQC): Structured notes completed by CE providers on ACCESS omissions, modifications, and adaptations.
3. Employment questionnaire: Open-ended questions on accommodations, supports, transportation, and barriers at work.

Fidelity. The following instruments will be administered to CE practitioners:

1. Benchmarks of Quality Checklist (BQC): Obtains data on fidelity to the CE model by collecting completion of each of the four CE elements: Discovery, CE Planning, Job Development, and CE Negotiation.
2. IPS Fidelity Scale: Obtains data on adherence to the IPS model in the domains of staffing, organization, and services.

Compensation. Veteran participants will be compensated for their time spent completing the study assessments. Consistent with other funded Tampa studies, each Veteran participant will receive $20 each for completion of study questionnaires at up to 3 data collection points (baseline, month 6, and month 9), hence total payment will range from $20 to $60. Veterans will receive separate stipends via mail for their time. VA providers who complete qualitative interviews will not receive any compensation.

5.6 Data Analysis

Sample size determination – Aim 1

Quantitative. We calculated the sample size required for this study based on the analysis planned for Aim 1. Aim 1 tests the difference in proportions of employment between the two treatment arms of this study: (1) the ACCESS-Vets cohort and (2) the TAU cohort. We plan to include all randomized Veterans in the analysis by missing data imputation and therefore will ignore attrition in all our power analyses.

Our work in previous studies has shown IPS employment rates between 25% and 43%. Therefore, we assume a probability of employment of 37% for the TAU cohort. Unpublished results of the ACCESS program have shown success rates of over 75%. We anticipate the ACCESS-Vets program in this study will have a more conservative rate of 65% employment, but it is uncertain when the employment rates will diverge between the two cohorts, ACCESS-Vets and TAU. A sample size of 100 subjects (50 per treatment arm) will provide 80.9% power (2-sided type I error rate of 0.05) to detect a difference in proportions of 0.28 (i.e., 0.65-0.37). Using effect sizes and notations from Cohen (1988),[48] the difference of proportion test with N=100 and alpha = 0.05 will allow us to detect a moderate standardized effects size of 0.4 when power = 0.8.

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***Power calculation for H1.2*.** For the subsample that attains employment, we estimate 32 members of the ACCESS-Vets cohort (i.e., 50 initial participants * 0.65 conservative employment rate) and 18 members in the TAU cohort (i.e., 50 initial participants * 0.37 IPS employment rate). For our design with 4 repeated measurements, we assume an AR (1) covariance structure, 1.0 standard deviation of a single observation, $\alpha = 0.05$, and correlation between observations on the same subject ranging from 0.3 to 0.5. In a time-averaged difference power analysis, we expect to achieve 80% power to detect a minimum standardized difference between 0.5 and 0.6 (medium effects size).

***Power calculation for H2.1*.** With the assumption that 50% of the total sample will be employed (32+18) by the end of the study, we performed power analysis for longitudinal linear mixed-effects models. Since we have multiple outcomes with potentially different and unknown parameters, we accepted the application's default value of 0.5 for the amount of baseline variance at the subject level and 0.03 for the ratio of the random slope variance to the within-subject variance. N=100 achieves 83% power to detect a medium Cohen's d effects size 0.6.

***Screen failures*.** We expect to mail IRB-approved recruitment letters to the 2400 Veterans on the SCI/D registries at Tampa and Richmond. Working with the SCI interdisciplinary team we will screen or review charts of those coming in for annual SCI evaluations or admitted for rehabilitation. We expect to screen more than double the number of participants in order to achieve our sample size. Thus, we expect to examine about 400 charts and conduct 200 phone screens to meet the final sample size of 100 participants.

Study discontinuations / loss to follow up. Although, based on a previous IPS study, we had an approximate 20% dropout rate, we did not factor this into the sample size calculation. This is because our intention-to-treat approach requires us to follow-up and analyze all 100 participants randomized at baseline and to impute missing values if any.

Qualitative – Q2.1, Q3.1 &Q3.2. For these aims, the sample size relies on the quality and richness of information obtained.[49] Conceptual saturation is the goal of qualitative research and depends on data for interpretation. Saturation has been noted to occur within the first 12 interviews.[49,50] Our team has extensive experience in evaluating employment interventions. We plan to have 30 Veterans and 20 providers participate at the 2 sites (15 Veterans and 10 providers per site).

Quantitative analysis plan – Hypotheses: Aim 1 (H1.1 & H1.2) and Aim 2 (H2.1). Cross tabulations will be used to compare variables across groups. Continuous baseline variables will by compared by use of Student's t-tests or Wilcoxon tests (depending on distributional properties); categorical variables will be compared by chi-square tests. Similarly, contact time assessed post baseline will be tested for group difference and included as covariates in the multivariable models. Fig. 2 describes the different group comparisons to be performed for each outcome.

For the primary hypothesis (**H1.1**), a chi-square test of difference in proportions will be used to compare rates of competitive integrated employment between the ACCESS-Vets and TAU groups by 6, 9, and 12 months post baseline.

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H1.2: The analyses here will use data from all Veterans who attain employment. The outcomes consist of repeated assessments at 6, 9, and 12 months post-employment. Retention will be calculated as the number of weeks of employment. We will test whether ACCESS-Vets results in higher job satisfaction, wages, and retention than TAU by 6, 9, and 12 months post-employment. We will do this by comparing group means and frequencies separately for job satisfaction using t-test and, for wages and retention proportions, using chi-square test. **H2.1:** Employment vs. no employment will be compared for the whole sample. The outcomes consist of repeated assessments at 6, 9, and 12 months post-baseline for no-employment group and post-employment for employment group, thus allowing us to assess the effects of employment. To test whether the employed group shows greater improvement over time than the no-employment group on each continuous outcome (self-sufficiency and QOL), we will fit linear growth models specifying random intercept and slope. The model will account for variation in outcome and rate of change that could be explained by interpersonal difference. The model will include an employment*time interaction to assess whether the change in outcomes over time differs by employment status; and also include an intervention*time interaction to assess whether the change in outcomes over time differs by intervention status. To better understand the significant difference, graphs will be used as a visual aid to compare estimated trajectories between intervention groups and between employment groups.

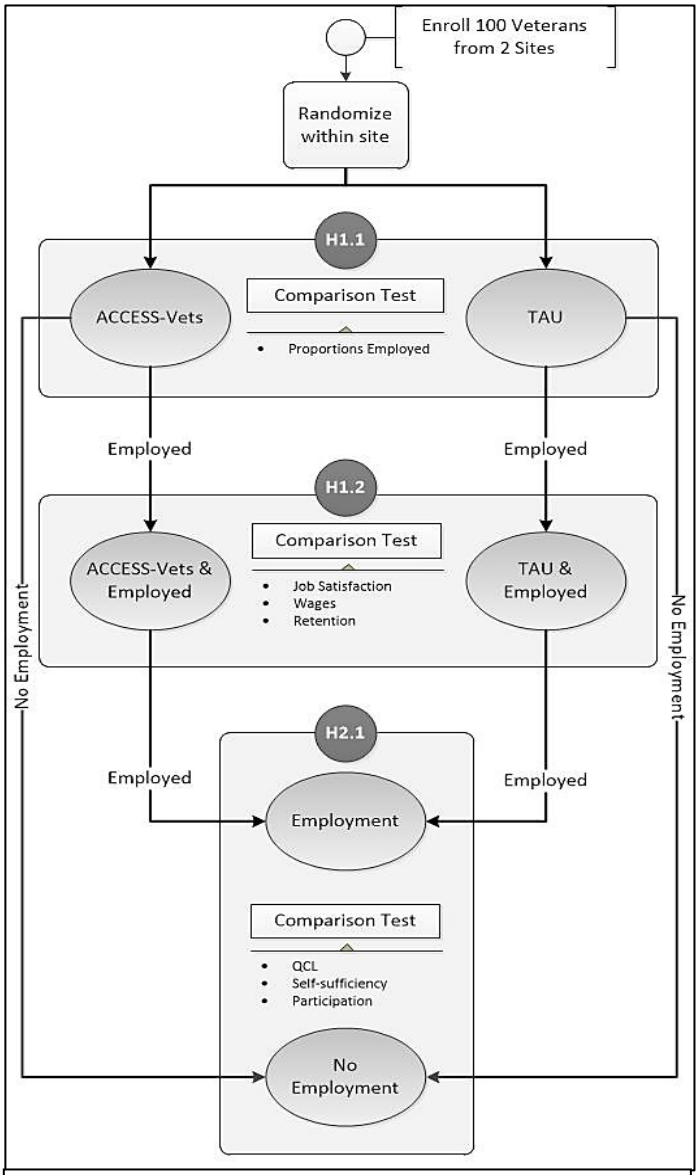


Figure 2. Binary group comparisons proposed for hypothesis testing.

Missing data. Given our intention-to-treat approach we plan to impute any missing data. As some missing data on outcomes are inevitable, we will first assess the extent of missingness by tabulating how many Veterans are in the study at each time-point. Next, we will explore the missing mechanisms by graphing separately each outcome over time stratified by intervention group (panels) and dropout time category (within panel). If the dropout category trajectories are similar within and across intervention group panels, we can assume missing completely at random (MCAR), i.e., drop out is not related to the outcome, intervention assignment, or other covariates, in which case our

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observed data are sufficient to correct the missing data. Otherwise, a substantial difference in trajectory patterns will suggest that data are not MCAR. For example, if Veterans with a certain level of outcome at baseline or with a certain rate of change in the outcome over time are more likely to drop out, this will suggest missing not at random, i.e., dropout is related to the level of outcome. With other methods, we will also compare Veterans who drop out versus those who do not on each outcome, intervention group, and baseline variables by using cross tabulations with correlation tests (Cramer's V, point-biserial), t-tests or chi-square tests as appropriate. Statistically and clinically important differences between the two dropout categories on any variables will further confirm that data are not MCAR. A correlation below 0.4 or a missing data rate below 25% suggests that the form of the missing data mechanism may not strongly determine which model parameters are affected.[51] We anticipate no missing data on the pre-randomization baseline assessments and that any Veteran who drops out will have missing data on all outcomes at the same time point simultaneously, so one imputation exercise for the primary outcome should replace all missing data. Missing outcome values will be imputed using multiple imputation with chained equations (MICE). Using subjects with complete data, we will identify which covariates are most predictive of outcome status at 6, 9, and 12 months. We postulate that baseline value for any outcome will be strongly predictive of subsequent measurements; thus, we anticipate this variable (in addition to unknown others) will be used in multiple imputation of outcomes with missing values. Results from complete case and imputed datasets will be compared for consistency and as a sensitivity analysis. The predictive mean matching (PMM) option of the method of multiple imputation with chained equations as implemented in the R package mice will be used to provide a semi-parametric approach to imputation that does not assume normal distribution for the predictive distribution. The PMM (a.k.a. FCS-P) tended to perform rather poorly with smaller samples (N<100) particularly when missing data rate is >20%.[52] Therefore, to obtain unbiased parameter estimates by the PMM, given our N=100, we will decrease the size of the donor pool option from the default k=5 to k=3.[53] The baseline variables found to influence missing data (correlation exceeds 0.4 level) will be included as auxiliary variables for the PMM.

Qualitative analysis plan – Research Questions: Aim 2 (Q2.1) and Aim 3 (Q3.1 and Q3.2). Interview transcript data will be managed using descriptive content analytical methods to identify domains and taxonomies of participant CE experiences.[44] Categories will be compared and contrasted, and relationships identified. As coding schemas are developed to create domains and taxonomies, data samples will be extracted and coded by research team members (Lead Qualitative Researcher and Qualitative Data Manager) and evaluated for inter-rater reliability and credibility. Descriptive and comparative matrices, which identify patterns of regularities (shared) and inconsistencies (unique or varied) will then be constructed for Veterans and providers. Comparative matrices enable identification of the most relevant, shared, and perhaps representative components and, thereby, enhances the potential representation of the findings. Finally, a complex cross-case data matrix will be developed to summarize the significant taxonomic outcome structures identified within and between Veterans. This process of descriptive and comparative matrix analysis will enable detection of most salient and representative components identified by Veterans

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and providers. This analysis will examine site variations in adapting the intervention for use in VHA.

The qualitative scientists led by the Lead Qualitative Researcher Co-I will code CE providers' structured notes provided in the open-response column of the CE component benchmarks from each checklist and the employment questionnaire. The Lead Intervention Trainer will randomly check 10% of the checklists to ensure high inter-rater reliability. Matrix analysis, a rapid assessment approach, will be used to identify and summarize themes from open-ended responses. The qualitative scientists will (1) transfer coded open responses to an Excel matrix; (2) categorize responses under domain names applying a priori codes and those that emerged from the data; (3) review codes and establish consensus among the research team; and (4) analyze and summarize codes to identify key themes, variations, and information gaps.

Quantitative Data Analysis Methodology. Quantitative data will be analyzed by our data manager and statistician. All analyses will be performed behind the VA firewall on electronic devices approved by JAHVH (see Privacy and Confidentiality section below for details). The following statistical data packages will be used:

- SPSS: Quantitative Data will be managed using IBM SPSS statistical analysis packages. Available at: https://www.ibm.com/products/spss-statistics (Accessed: 14th January 2021).
- SAS: Quantitative Data will be managed using SAS statistical software suite. Available at: https://www.sas.com/en_us/software/stat.html (Accessed: 14th January 2021).
- R: Quantitative data analysis will be performed using R: The R Project for Statistical Computing (r-project.org). Available at: https://www.r-project.org.

Qualitative Data Analysis Methodology. Qualitative data will be analyzed by our Lead Qualitative Researcher using the following software package: **ATLAS.ti v.8.4**. Qualitative Data managed using Atlas.ti (available at: https://atlasti.com/; accessed: 14th January 2021). Akin to handling quantitative data, all qualitative data analyses will be performed behind the VA firewall on electronic devices approved by JAHVHC (see Privacy and Confidentiality section below for details).

We plan to use Alpha Transcription and/or VA Microsoft Teams to transcribe stakeholder interviews. Alpha transcription is an external transcription company based in Manassas, Virginia that has handled secure transcription for multiple VA and government projects. When using Alpha Transcription, the qualitative researchers will complete transcription via transmission of audio recordings through a secure drive and transcripts will be returned deidentified. When using Microsoft Teams, the qualitative researchers will use the VA licensed Microsoft Teams recording and transcription features.

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5.7 Withdrawal of Subjects by Study Team or Participant

The study team may terminate a participant from the study intervention if no participation has occurred for a period of 8 weeks or for any circumstance which, in the judgment of the investigators, makes further meaningful participation unlikely. If a participant is enrolled as an outpatient and requires inpatient admission for a complication such as a pressure ulcer or other prolonged condition that precludes their active participation for a prolonged period, they will be withdrawn by their study team. Similarly, participants enrolled as outpatients who develop new skin breakdown and have activity restrictions (such as limited time in wheelchair or sitting) might need to be withdrawn for the same reason. The judgment of the clinician is required, as not all skin breakdown will preclude participation. Common sequelae of SCI such as urinary tract infection or pneumonia, which may or may not require hospitalization, might not require withdrawal as they tend to be shorter illnesses. Admission for elective procedures would not preclude participation. The decision to withdraw a participant will be made by the study PI and Local Site Investigator in consultation with the study team and the attending SCI physician.

If the participant develops a new psychiatric problem, (e.g., reports suicidal or homicidal intent and needs a higher level of clinical care), s/he will be terminated from the treatment phase of the study. Additionally, if new information determines the procedures might hurt a participant, we will discontinue the treatment sessions.

If a participant wishes to withdraw consent or is terminated from the project for some reason, the following steps will be followed:

1. Data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. This is documented in the ICF.

2. The PI may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection after his/her withdrawal from the interventional portion of the study. Under this circumstance, study staff will provide education about the difference between study-related interventions and continued follow-up of associated clinical outcome information, such as the posttreatment assessment and psychotherapy notes collected via chart review, and will address the maintenance of privacy and confidentiality of the participant's information. The ICF states the participant can complete follow up assessments even if s/he would like to withdrawal from the therapy sessions.

3. If a participant withdraws from the interventional portion of the study and does not want to be a part of the continued follow-up of associated clinical outcome information, the participant’s medical record or other confidential records requiring the participant’s consent will not be accessed. However, study data related to the participant collected prior to the participant’s

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withdrawal from the study may be reviewed and public records, such as those establishing survival status may be consulted.

6.0 Reporting

For monitoring safety of participants, study staff will monitor and log all adverse events (AEs), serious adverse events (SAE), and unanticipated problems involving risk to participants or others (UPIRSOs) during the study. The primary study staff member (PI, Site PI, project managers, vocational counselors) interacting with the participant will record any adverse events and communicate immediately with PI. The PI will review any expected AE, SAE, and UPIRSO to determine if reporting criteria are met. SAEs and UPIRSOs will be reported to the IRB and the VA Information Security and Privacy Officers (ISO/PO) in accordance to reporting requirements. For all events, in order to determine whether it should be reported to the IRB, the site PI will assess the event to evaluate whether it is anticipated, related to the study, or places the participant or others at an increased risk for harm. As with all AEs, SAEs, and UPIRSOs, we will review any injuries that may occur while a participant is employed to determine whether they are related to the study and report them in accordance with reporting requirements (i.e., on-the-job injuries will not be automatically categorized at study related).

This study does not involve a drug intervention, device intervention, or highly invasive data collection procedure. However, recognizing that unanticipated events can occur during any study, even a minimal risk study, the following reporting protocols apply:

- Unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related PHI, individually identifiable private information, or confidential information, as defined by the HIPAA, the Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C.§§5701, 5705, and 7332: Report immediately to the Associate Chief of Research Service and the ISO/PO.
- Unanticipated SAEs that the Site PI considers to be related, possibly related, or probably related to study participation: Report within 24 hours of awareness to the IRB and ISO/PO.
- An Accounting of Disclosure will be created and maintained for any disclosure of individually identifiable information outside the VA including personal information. The employment intervention includes developing a vocational portfolio to illustrate the Veteran job seeker's skills, backgrounds, interests and abilities. With the written permission of the Veteran, this portfolio may be shared with prospective employers, or employment related agencies. The electronic spreadsheet will include the participant's name, date of the disclosure, nature or description of what was disclosed, purpose of each disclosure and the name and address of person or agency to which the disclosure was made.

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- Participants expressing suicidal ideation either in person or on the phone will be managed according to local VAMC protocols. The PI and Local Site Investigator (Drs. Ottomanelli and McDonald) are licensed mental health practitioners and will serve as the emergency contact. Referral for additional assessment or treatment will be done in accordance with the local site policy and procedures. The information sheet provides direction if a Veteran needs emergency care and indicates that if a Veteran expresses suicidal ideation study staff will follow established VA protocol and connect the Veteran with their VA providers and the Veterans crisis hotline.
- All study personnel who work directly with research participants will be given the names and phone numbers of the participant's medical care team. After the Veteran has been left in the care of appropriate staff, the PI will be informed.

The study will not have a separate data safety monitoring board. Data and safety monitoring for this study will be provided by the investigators in collaboration with the clinical team with oversight through the site IRB and R&D Committees. The IRB and R&D Committees will review the protocol and procedures for the proposed study prior to implementation. The IRB and R&D Committees and the PI will continue to monitor the project. All changes to the study protocol and procedures will be submitted to the IRB and R&D Committees for approval prior to implementation. Data safety and monitoring will include review and discussion of any reported SAEs and UPIRSOs during regularly occurring study investigator meetings.

7.0 Privacy and Confidentiality

PHI. Collected PHI will include name, social security number, date of birth, gender, ethnicity, address, phone number, and email address. As part of the vocational profile, the subjects will disclose VA services received, benefits received, home environment, employment history, educational history, lifestyle, details of injury, physical health and mobility-related issues, and cognitive/mental health-related issues.

As part of the qualitative interview data collection, audio recordings of interviews may be used with verbal consent of the Veteran. We will explain the interview purpose and ask permission to audio-record and use the interview script to ensure that all topics are covered. An audio voice consent must be completed, and voice recorded at the time of the telephone interview process. The participants will be informed that they will be recorded and will need to state on the recorded telephone interview whether they agree to participate prior to the start of the telephone interview. An encrypted VA-approved device (Philips Pocket Memo Voice Recorder DPM8000) will be used for audio data capture. The devices will be password protected.

As part of the intervention, photographs, video, audio recordings may be obtained by vocational providers with the written VA audio-visual consent (Form 10-3203).

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Recordings or images of the Veteran will be used (1) as part of the intervention (e.g., a visual career portfolio) and (2) for use in publication, presentation, or education. A VA-approved device (typically a VA-issued cell phone) will be used for capturing recordings or images. Information from vocational assessments or the vocational portfolio may be shared with the Veterans written permission (VA Form 10-5045, Request for and Authorization to Release Medical Records or Health Information and VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research) to communicate essential information to community employers to match Veterans with customized jobs.

Veterans identified for the exclusive purpose of describing the medical complexities of this populations and in accordance with 38 USC 7332, this information will be kept confidential and will not be disclosed in presentations, publications, or any other dissemination of the study results, or to anyone outside of the IRB-approved study team

Once downloaded from the VA-approved device (recorder or cell phone), all recordings and images will be stored in digital format in a VA-encrypted secured folder, which can only be accessed by study staff. Once the data quality is verified, files on the recorders and cell phones will be erased.

Electronic data storage. All computer systems and programs will be password protected. Good computer security practice (shutting down of computers after work hours, restricting physical access to machines, prohibition of password sharing) will be required of all study personnel, and all necessary training to enforce those practices will be provided. Virus protection software will be installed on each study machine as required on all VA computers. Backups will allow for quick restoration of data in the unlikely event that a hardware failure or security breach should occur.

Electronic data will be stored on a secure folder behind the VA firewall and encrypted per VA guidelines. This secure folder will be in the Research Service drives, which require special IT permission to access (e-pass). The cross-reference file that links study IDs and PHI will be stored in a separate secured folder that is accessed only by PI, lead qualitative researcher, project manager, and data manager.

Custody and disposition of VA federal records are maintained in accordance with Record Control Schedule (RCS) 10-1 (Data destruction). All research documents are considered federal documents and will be stored and destroyed according to VHA RCS 10-1. Currently, all VA documentation (digital and paper) will be maintained for 6 years after the project has been closed with the IRB. Removal of access to research study data will be accomplished for all study personnel when they are no longer part of the research team.

Paper data storage. Paper records are kept within a locked cabinet in a locked office at JAHVHC (13000 Bruce B. Downs Blvd, Tampa, Florida, 33612). All research documents are considered federal documents and will be stored and destroyed according to VHA RCS 10-1. Currently, all VA documentation (digital and paper) will be maintained for 6 years after the project has been closed with the IRB. At that time, paper documents will be shredded via a secure VA shredding service, and digital documents deleted from the server.

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Data transmission. Coded data from Tampa and Richmond will be entered into the Qualtrics system. Qualtrics is an electronic survey platform that has demonstrated a capacity for remotely and securely collecting participant data in other studies conducted within the VA system. The security of data stored in Qualtrics is ensured through a variety of systems, including firewall systems, regular vulnerability scans, nightly complete backups, and annual complete penetration tests. Currently, the FedRAMP version of Qualtrics, a version of the software with additional robust protections for data security, is being finalized with an authority to operate throughout the VA. The PIs and study coordinators will receive coded data for analysis.

Electronic data will be transmitted between sites by VA email with encryption. Study data will be coded using a single letter designation for site location and a three-digit subject number. For example, the first JAHVHC participant would be designated T-001. The master list will be kept separately from the study data in a secured folder behind a VA firewall.

Digital recordings of the qualitative interviews will be uploaded to the secure server of the Research Service at the JAHVHC for coding and analysis.

Any incident, such as theft or loss of data or storage media or unauthorized access of sensitive data or storage devices will be reported to the ISO/PPO within 1 hour of being discovered.

Study team training and requirements. Access to information obtained for the purposes of this study will be restricted to authorized research personnel who have completed human-subjects training, although, just like other hospital records, they are subject to subpoena by court order. Due to HIPAA and IRB guidelines, any personal identifying information transmitted from the participant to research staff will remain private and confidential. Every member of the research team will be trained and monitored on how to handle and protect both medical and research records. No personnel involved in this study will identify, directly or indirectly, any individual participant or participant in any report of such research or otherwise disclose participant identities in any manner. Any information about participants obtained from this research will be kept strictly confidential. Access to identifiable research data will be restricted to research staff and IRB. People who ensure quality from the institutions where the research is being done and federal and other regulatory agencies will have access to all the research data. Removal of access to research study data will be accomplished for all study personnel when they are no longer part of the research team.

8.0 Communication Plan

The proposed project is a joint collaboration between JAHVHC and HHMVAMC with co-investigators at University of South Florida. A consultant at Virginia Commonwealth University who is a National content matter expert on customized employment is

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available as resource to the team by providing information on best practices for implementation, training, and dissemination of the customized employment intervention. Both recruitment sites (JAHVHC and HHMVAMC) will use the Central IRB as the board of record with local R&D Committee approvals. No research can begin without the approvals from Central IRB and local R&D Committee, which reports to the Directors of the respective facilities.

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Table 6. Summary of Management Plan for Recruitment Sites		
	Tampa, FL	**Richmond, VA**
Investigator	Lisa Ottomanelli, PhD (PI)	Scott McDonald, PhD (CI; Local Site PI)
Responsibilities	Protocol preparation, reports to funding agencies and data safety management board; quarterly progress reports; continuous risk assessment and protection of human participants.	Quarterly progress reports; continuous risk assessment and protection of human participants.
	Tampa regulatory approvals and maintenance.	Richmond regulatory approvals and maintenance.
	Oversee recruitment, screening, enrollment, intervention, and assessments at Tampa.	Oversee recruitment, screening, enrollment, intervention, and assessments at Richmond.
	Coordinates Tampa personnel.	Coordinates Richmond personnel.
	Interpretation of the study findings and publication of results.	
Communication Plans	Regular contact through in person meetings with local site staff.	
	Weekly teleconferences between Tampa and Richmond study team.	
	Monthly investigator meetings via teleconferences.	
Budget Consideration	Tampa funding is directed by Dr. Ottomanelli.	Richmond funding is directed by Dr. McDonald.
Conflict Resolution	Tampa personnel report to Dr. Ottomanelli.	Richmond personnel report to Dr. McDonald.
	Issues arising across sites will be addressed during the weekly study team and monthly investigator meetings.	
Data Management	Tampa will develop database in Qualtrics.	
	Staff will enter data collected from Tampa into a secure database (Qualtrics) behind the Tampa VA firewall. Quality assurance measures will be built into the database including forced response options, skip patterns and internal validation checks.	Staff will enter data collected from Richmond into a secure database (Qualtrics) behind the Tampa VA firewall. Quality assurance measures will be built into the database including forced response options, skip patterns and internal validation checks.
	Tampa will run reports to examine valid data values and missing data by variable and by person entering data.	
	Tampa will oversee statistical data analysis for dissemination.	
	Issues arising across sites will be addressed during the bi-monthly meetings.	

Collaboration. All investigators were actively involved in the study design and shared decision making. To ensure continued participation in the study, the team will hold

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monthly investigator teleconferences in order to problem solve any challenges. Richmond and Tampa will hold weekly teleconferences with study teams to review recruitment, flow charts, and all other study administrative tasks. Each meeting will have minutes, which will be disseminated via email to all sites and Co--Investigators. The team statisticians, which are in Tampa but will be a shared resource for both sites, will build and maintain the database, which will be housed behind the Tampa VA firewall.

Leadership plan. Dr. Ottomanelli will lead a weekly meeting with the Tampa and Richmond study staff to update them on the progress and state of the study. The purpose of the weekly meetings is to: (1) update the group on recruitment/enrollment, (2) address practical issues related to study design and implementation, (3) review regulatory and human subjects issues (AE, SAE, unanticipated problems, or interim results), (4) review advances in the scientific literature pertaining to the project, and (5) notify local sites when they are no longer required to engage in research activities. Conference calls with all Co-Investigators will take place at least monthly to discuss site status and challenges and ongoing decisions regarding the execution and conduct of the trial.

Accuracy and integrity of data. Statisticians, PI, and Site PI will meet regularly to ensure the information collected meets clinical and analytical expectations. Accuracy and integrity of data will also be discussed during the monthly calls with study teams from both recruitment sites. As data are entered, validation checks ensure data are within range. Logical checks (e.g., dates out of order) are programmed into forms whenever possible. On at least a quarterly basis, audits are performed in which randomly selected data from the database is compared with the original forms.

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