Maintaining Independence and Sobriety through Systems Integration, Outreach, and Networking

NCT02942979

Document Date: 8/10/2021

Study Protocol and Statistical Analysis Plan

Study Design

This study involved a multi-site, randomized, hybrid type III modified stepped-wedge implementation-effectiveness trial in seven homeless programs at two VA Medical Centers (VAMCs) serving homeless Veterans with co-occurring mental health and substance use problems (Curran et al., 2012). Instead of starting all intervention and control sites together, the design staggered introduction of the Facilitation strategy. We selected a stepped-wedge design to compare Maintaining Independence and Sobriety through Systems Integration Outreach and Networking-Veterans Edition (MISSION-Vet) uptake under two staff level intervention conditions: Implementation as Usual versus Facilitation and to help identify and control for secular trends better than parallel-groups' randomized controlled trials (Curran et al., 2015). In our study, both sites received six months of Implementation as Usual and crossed over to Facilitation for another six months. In addition, to further the existing literature supporting MISSION-Vet outcomes, this trial also enabled us to extract existing data from the VA Electronic Medical Record to examine treatment engagement among those receiving MISSION-Vet. The hypothesis of this project was that Facilitation would yield better adoption and fidelity to MISSION-Vet among sites compared to Implementation as Usual. The project was deemed quality improvement and received an exempt status by the Institutional Review Board at the Bedford, Massachusetts VAMC according to the VA Program Guide 1200.21 (Department of Veterans Affairs, 2019).

MISSION-Vet Intervention

MISSION-Vet is a multicomponent care coordination and linkage intervention to address the needs of homeless Veterans with co-occurring mental health and substance use problems and can be flexibly used within many of the VA homeless programs. In brief, MISSION-Vet is delivered by a master's level social work case manager, and a peer specialist, the latter of which is someone with prior lived experience with homelessness, substance use and mental

health issues. The MISSION-Vet team delivers the following five treatment components: critical time intervention (CTI), dual recovery therapy (DRT), peer support, vocational and educational support, and trauma-informed care, all guided by Housing First and harm reduction philosophies that emphasize low barrier services for clients (Susser et al., 1997; Ziedonis & Stern, 2001; Chinman et al., 2010; Bond et al., 2008; Najavits, 2012; Tsemberis et al., 2004). One of the core components of MISSION-Vet is CTI (Susser et al., 1997). CTI is an empirically supported assertive community treatment approach intended to reduce the risk of homelessness by enhancing continuity of support for individuals with mental illness during the transition from institutions such as inpatient psychiatry units, residential treatment programs and homeless residences to community living (Herman & Mandiberg, 2010). The primary focus of CTI is on housing placement and support. The next component is DRT which consists of 13 psychoeducational sessions delivered by the case manager. DRT helps educate Veterans on the impacts of substance use, mental illness, and harmful behavior, offering exercises and tools to aid in recovery. The third component is Peer Support which includes 11 Peer-Led sessions that help Veterans engage in sobriety and mental health stability services with a “buddy” who offers role modeling and empowerment. In addition to the structured psychoeducational sessions designed to empower Veterans to engage in treatment, both the case manager and peer specialist also offer unstructured community outreach sessions to engage clients in care and link Veterans to other needed community support. The personal relationship and support provided by someone who “has been there” also bolsters the effectiveness of the other interventions. The fourth component is vocational and education support which helps Veterans find and maintain employment. MISSION-Vet includes educational supports to help Veterans understand and utilize benefits such as the Post-9/11 GI Bill, navigate enrollment and registration processes, and further and sustain their educational goals. Lastly, MISSION-Vet uses a trauma-informed care approach. MISSION-Vet Case Managers and P Specialists are trained to screen for trauma-related symptoms and refer to treatment providers when more

intense treatment is needed. They are also trained to provide ongoing support for Veterans who are receiving treatment from a specialized PTSD program or to serve Veterans who do not require specialized PTSD services. MISSION-Vet was offered for approximately 2-hours a week for 6-months, and service delivery was guided by a Treatment Manual (Smelson et al., 2011a). Veterans could also receive a MISSION-Vet Workbook that includes assignments reinforcing recovery (Smelson et al., 2011b).

Participation Sites

Site Composition

This project was conducted at two VA Medical Centers (VAMCs; hereafter Sites A and B) and offered to staff at seven homeless programs (four locations at Site A and three locations at Site B) with the unit of measurement being the two VAMCs. The two VAMCs were selected because of the size and scope of the healthcare systems, geographic dispersion, and the rate of homelessness in the regions (Department of Veterans Affairs, 2014). Site A was in a large VA urban setting, serving approximately 83,000 unique Veterans annually with the highest-level complexity, and two on-site residential buildings, and two off-site buildings. Site B was a smaller suburban medium complexity VA serving approximately 18,000 unique Veterans annually, with one on-site and off-site residential building. Both Sites A and B had community-based non-residential treatment which included housing placement, case management, linkages to mental health and substance use programing, but not MISSION-Vet.

Recruitment

There were two groups of participants in the study: staff and clients. The first group were the case managers and peer specialists delivering MISSION-Vet; staff participation was voluntary with no incentives provided. The second group were, Veterans (clients) being served by these staff in their respective VA homeless programs. Staff were encouraged to follow the recommended MISSION-Vet inclusion and exclusion criteria. This included: (1) enrolled in a VA homeless program at one of the implementation sites; (2) met Diagnostic and Statistical Manual of

Mental Disorders, 5th Edition (American Psychiatric Association, 2013) diagnostic criteria or International Classification of Diseases, 10th Revision (World Health Organization, 2004) for current substance use or dependence disorder (e.g., alcohol, marijuana, cocaine) and a co-occurring mental illness which includes anxiety, mood, or a psychotic spectrum disorder; and (3) was willing to participate in the service.

Implementation Strategy

Passive Implementation: Implementation as Usual

Implementation as Usual for MISSION-Vet is comprised of a 1.5 hour webinar training which provides an overview of the MISSION-Vet approach, staff roles, as well as key information on how to access and use the MISSION-Vet Treatment Manual and Consumer Workbook. The manual is posted on the web and available inside the VA on the National Center for Homelessness among Veterans website or at missionmodel.org. The webinar was offered at least twice to case manager and peer specialist staff within the two VAMCs and seven programs to accommodate scheduling. It also presented how to use the MISSION-Vet service delivery fidelity measure, embedded within the VA medical record. This fidelity measure was used to capture the total number and type of MISSION-Vet sessions delivered, which served as our measures of MISSION-Vet uptake.

As previously mentioned, MISSION-Vet includes the following resources developed and ready to use for this study:

<u>MISSION-Vet Treatment Manual:</u> The manual is a “how-to” guide that describes the core components of the approach, including the delivery of CTI, the role of the MISSION-Vet team (case manager and peer specialist), the co-occurring mental health and substance use psycho-educational sessions and suggestions for offering vocational, educational, and trauma-informed support delivered. The manual also includes a number of appendices with didactic materials to assist with service delivery.

MISSION-Vet Consumer Workbook: The workbook serves as a resource for MISSION-Vet participants to help them integrate DRT and peer support concepts while also offering homework assignments to develop needed skills to maintain housing and other supports. In addition, the Consumer Workbook contains materials designed to increase a MISSION-Vet client's internal motivation for and engagement in outpatient services.

MISSION-Vet Fidelity Measure: Our fidelity measure quantifies all of the components involved in delivering MISSION services. It is embedded in the VA medical record and used by VA staff to determine model adherence.

Implementation platform: Facilitation

Following the initial training, there was a 6-month waiting period prior to the 6-months of Facilitation being offered to each of the seven programs at the two VAMCs. Facilitation is a comprehensive approach in which implementation experts partner with local staff to support implementation planning and to tailor adoption strategies to local contexts (Ajzen, 1977; Rosenheck, 2001). This approach builds capacity for implementing evidence-based programs by strengthening the knowledge, attitudes, and skills practitioners need to carry out evidence-based program implementation. In this study Facilitation included external and internal facilitators working in tandem to support MISSION-Vet implementation. Specifically, external facilitators are external to the implementation site and have general expertise in implementation strategies and relevant clinical models and their evidence base. An internal facilitator is familiar with facility-level organizational structures, procedures, and culture as well as the clinical processes within the system at the regional or local facility level. The external and internal facilitators work together to present sites with important design considerations and steps practitioners can follow to obtain positive results, and then provide practitioners with guidance necessary to complete those steps (i.e., to perform each task as close to the ideal as possible). The goal was to work with leadership and staff to integrate MISSION-Vet into routine operations, closing the gap between research and practice. Over time, the external facilitator

transfers understanding of effective implementation activities to the internal facilitator and thus fosters introduction and retention of skills in the local organization.

The external facilitators held bi-weekly meetings with local program staff executing MISSION-Vet to address implementation barriers, troubleshoot, and provide implementation fidelity reports, which included feedback on number and type of MISSION-Vet services delivered. External facilitators also provided regular feedback on the staff's use of the fidelity measure within the VA medical record since this fidelity measure was used to construct our measure of implementation uptake.

Measures

Project measures captured information about implementation outcomes (both Facilitation and the implementation of MISSION-Vet), organizational readiness and VA health services utilization. Depending on the outcome, data were measured at the site, staff, and/or veteran level.

Implementation Outcomes

Consistent with recommendations for type III hybrid effectiveness-implementation designs, our primary outcome was MISSION-Vet uptake (as measured by number of MISSION-Vet sessions delivered) during the Implementation as Usual versus Facilitation time periods (Curran et al., 2012) and the secondary aim was to assess clinical outcomes (health service utilization). For this comparison of IU versus IF timeframes, we used a standardized facilitation tracking sheet completed by the external facilitators at the site level that included date, length of time, parties involved, activity type (Ritchie et al., 2019).

In addition, MISSION-Vet implementation was collected with a fidelity measure that was embedded in the Veterans' electronic medical record using a specially created service tracking note template to quantify the type and amount of MISSION-Vet delivered (Chinman et al., 2017). The MISSION-Vet Fidelity Measure tracks all the core elements of the MISSION-Vet treatment model, including Critical Time Intervention, DRT, Peer Support, vocational supports,

and trauma-informed care for each individual veteran. The fidelity index consists of 78 items assessing the presence or absence of certain activities within MISSION-Vet and will be captured in veterans' electronic medical records. Information captured in this note template included: which DRT sessions, peer support sessions, and Consumer Workbook exercises were completed; whether the MISSION-Vet Consumer workbook was provided; whether community activities were done with a Veteran (e.g., taken to appointment, NA/AA meetings, meetings with landlords); and referrals made to other services. Data on all veterans at all sites will be obtained from electronic medical records available in the VA's Corporate Data Warehouse.

Organizational Readiness

An abbreviated version of the Organizational Readiness to Change Assessment (ORCA) context subscale and Jacobs' Implementation Climate survey, was used to examine organizational readiness resulting in a 21-item 5-point Likert scale to get at site and staff level readiness (Helfrich et al., 2009; Jacobs et al., 2014). Higher scores indicate greater organizational readiness and implementation climate. Following MISSION-Vet training, staff were asked to complete the organizational readiness survey and demographic survey regarding their age, sex, role/position, and tenure in VA.

Veteran Treatment Engagement

Treatment engagement as an outcome was captured with Veterans' medical records obtained from the VA Corporate Data Warehouse, which included number of MISSION-Vet contacts and other outpatient visits (mental health, substance use, medicine, primary care, emergency department, other, total). Each service utilization outcome was aggregated over the 1-year period following the date of Veterans' initial MISSION-Vet session.

Semi-structured Interviews

Semi-structured interviews were conducted for a formative and summative evaluation. The formative evaluation interviews elicited key stakeholders' experiences with, and perspectives on MISSION-Vet training, barriers to and facilitators of implementing MISSION-Vet

as well as to identify particular areas to target for Facilitation. Summative evaluation interviews identified stakeholder's experiences with Facilitation and needed adaptations to MISSION-Vet as well as veteran experiences with MISSION-Vet.

All semi-structured interviews were conducted by phone. Interview questions focused on evaluating the implementation of Facilitation, Implementation as Usual, and MISSION-Vet with particular focus on barriers to Facilitation, perceptions of strengths and weaknesses of MISSION-Vet for this population and setting, and leadership support for implementation in VA. The goal of the qualitative portion of this project was to get an understanding of what staff thought about MISSION-Vet itself and for researchers to understand the organizational context and then to identify barriers and facilitators to implementation of MISSION-Vet so that these areas can be addressed through Facilitation once it is activated.

Statistical Analysis Plan

Our analytic strategy involved four components that align with the four study aims. Specifically, we examined: 1) pre-implementation organizational readiness; 2) IF process, including IF events; 3) MISSION-Vet implementation in the IU and IF time periods; and 4) association between MISSION-Vet and VA health services. Because the number of trained providers to deliver MISSION-Vet and the number of Veterans who received it at the seven homeless programs was too small for meaningful program comparison, our analysis focuses on a comparison between the two VAMCs (Sites A and B) rather than the seven individual programs when making comparisons for all measures of interest.

First, we examined organizational readiness using descriptive statistics and conducted comparisons of organizational readiness between the Sites A and B and by staff type (case manager vs. peer specialist), staff age, staff sex, and duration of employment with the VA using non-parametric Wilcoxon and Kruskal-Wallis tests. Second, we used descriptive statistics to examine IF events, including number, duration, and type of IF activities. Third, and similarly, we used descriptive statistics to examine implementation of MISSION-Vet. We summarize

information about the number and type of MISSION-Vet sessions provided overall, at the Veteran-level, and by VAMC. We also examined provision of MISSION-Vet separately by staff type (i.e., whether a case manager or peer specialist). Additionally, to assess the potential impact of IF on MISSION-Vet, we examined how the overall provision of MISSION-Vet changed over time both before and after the start of IF using descriptive measures of the number of MISSION-Vet sessions provided at each site by month. Our intent was to estimate the intervention effect using a statistical model in line with established practices for stepped wedge designs. However, because neither of the two sites provided any MISSION-Vet services in the IF period, there was no variation in the outcome of interest during this time thus rendering it impractical to estimate such a model. We therefore use descriptive statistics to examine the impact of IF on the provision of MISSION-Vet services.

Fourth, we examined the relationship between receipt of MISSION-Vet and Veteran-level measures of engagement in clinical service (i.e., VA inpatient and outpatient services). To do so, we estimated a series of bivariate linear regression models in which our service utilization measures (i.e., number of outpatient and inpatient visits, by type, in the year after a Veteran's initial MISSION-Vet session) served as the outcomes of interest and the number of MISSION-Vet sessions in the year following a Veteran's initial MISSION-Vet session served as the predictor of interest in all models.

Qualitative Analysis

Each interview will be recorded and transcribed verbatim. A codebook will be developed with a priori codes based on Consolidated Framework for Implementation Research (Damschroder et al., 2009) along with emergent thematic coding (Boyatzis, 1998). For the formative evaluation, interviews will be coded and analyzed to synthesize data on organizational strengths and weaknesses and to identify key areas for the Facilitation strategy to target. The same process will be followed with the summative evaluation. The summative evaluation will

enable us to identify the differences and similarities experienced by participants both within LA sites and across the sites. These similarities and differences within and across sites will serve as a key “lessons learned” for subsequent efforts to facilitate use of MISSION-Vet across a larger number of sites in the VA.

Ajzen, I.F.M. (1977). Attitude-behavior relations: A theoretical analysis and review of empirical research. *Psychol Bull, 84*(5), 31

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (DSM-5). Arlington, VA: American Psychiatric Publishing.

Bond, G.R., McHugo, G.J., Becker, D.R., Rapp, C.A., & Whitley, R. (2008). Fidelity of supported employment: Lessons learned from the National Evidence-Based Practice Project. *Psychiatr Rehabil J, 31*(4), 300.

Boyatzis, R.E. (1998). Transforming qualitative information: Thematic analysis and code development. Thousand Oaks: Sage Publishing.

Chinman, M., Shoai, R., & Cohen, A. (2010). Using organizational change strategies to guide peer support technician implementation in the Veterans Administration. *Psychiatr Rehabil 33*(4), 269.

Chinman, M., McCarthy, S., Hannah, G., Byrne, T.H., & Smelson, D.A. (2017). Using Getting To Outcomes to facilitate the use of an evidence-based practice in VA homeless programs: A cluster-randomized trial of an implementation support strategy. *Implement Sci 2*(1), 34.

Curran, G.M., Bauer, M., Mittman, B., Pyne, J.M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care, 50*(3), 217.

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A., & Lowery, J.C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implement Sci, 4*, 50.

Department of Veterans Affairs. (2014, March). VA 25 Cities Initiative 2014, March. Available from: https://www.va.gov/HOMELESS/25cities.asp.

Department of Veterans Affairs. (2019). Office of Research and Development Program Guide: 1200.21. VHA Operations Activities That May Constitute Research. Washington, DC.

Herman, D.B., & Mandiberg, J. M. (2010). *Critical Time Intervention: Model Description and Implications for the Significance of Timing in Social Work Interventions. Research on Social Work Practice*, *20*(5), 7.

Najavits, L.M. (2012). Expanding the boundaries of PTSD treatment. *JAMA, 308*(7), 714-716.

Ritchie, M.J., Kirchner, J.E., Townsend, J.C., Pitcock, J.A., Dollar, K.M., & Liu, C.F. (2019). Time and organizational cost for facilitating implementation of primary care mental health integration. *J Gen Intern Med, 35*(4),1001-1010.

Rosenheck, R.A. (2001). Organizational process: A missing link between research and practice. *Psychiatr Serv, 52*(12), 6.

Smelson, D.A., Sawh, L., Kane, V., Kuhn, J., & Ziedonis, D.M. (2011a). *MISSION-VET Treatment Manual*. Worcester: University of Massachusetts Medical School.

Smelson, D.A., Sawh, L., Rodrigues, S., Munoz, E.C., Marzilli, A., Tripp, J., et al. (2011b). *The MISSION-VET Consumer Workbook.* Worcester: University of Massachusetts Medical School.

Susser, E., Valencia, E., Conover, S., Felix, A., Tsai, W.Y., & Wyatt, R.J. (1997). Preventing recurrent homelessness among mentally ill men: A "critical time" intervention after discharge from a shelter. *Am J Public Health, 87*(2), 256-262.

Tsemberis, S., Gulcur, L., & Nakae, M. (2004). Housing first, consumer choice, and harm reduction for homeless individuals with a dual diagnosis. *Am J Public Health*, *94*(4), 651-656.

World Health Organization. (2004). *International statistical classification of diseases and health related problems (The) ICD-10*: World Health Organization.

Ziedonis, D.M., & Stern, R. (2001). Dual recovery therapy for schizophrenia and substance abuse. *Psychiatr Ann, 31*(4), 255.