Improving Outcomes for Emergency Department Patients with Alcohol Problems

NCT03536546

November 18, 2021

SPECIFIC AIMS

Reducing alcohol problems among Veterans is both a national priority and a priority research area for the Veterans Health Administration (VHA).[1] Hazardous use of alcohol is a linchpin at the core of post-deployment health. It is directly related to high volume and high morbidity problems in Veterans, including PTSD, suicidality and homelessness. This is particularly evident among Veterans from the recent wars, a cohort that has historically higher levels of hazardous alcohol use and concomitant mental health problems. Over the last decade, the VHA has undertaken several initiatives that have the potential to either directly or indirectly impact Veterans at risk for alcohol problems, including: 1) the rollout of universal alcohol screening in primary care, and the expansion of primary care-based alcohol brief intervention (BI) training; (2) the expansion of Emergency Department (ED) services which provide 24/7 access to care, and are frequently used by Veterans who have alcohol and mental health concerns; and, (3) the hiring of over 1,100 peer support specialists into mental health services to facilitate engagement with care and provide social support to Veterans with substance- and mental health-related problems.

Research indicates that a high proportion of patients seen in EDs have hazardous or harmful (problem) alcohol use, making EDs an ideal setting to provide assessment and initiate interventions and referrals for alcohol problems.[2] Recent research indicates that problematic alcohol use is an even greater problem in VHA EDs, compared to community medical centers, increasing the utilization of ED services and affecting all age cohorts of Veterans.[3] Alcohol BIs typically consisting of a single session, have been shown to be effective in primary care settings[4] and have been implemented variably across the VHA.[5] Despite the potential positive impact of alcohol BIs in the ED, meta-analyses of one-session BIs in the ED have demonstrated smaller effects compared to primary care-based interventions on drinking behaviors for hazardous drinkers, and no effect on treatment-seeking for alcohol-related services for those with more serious alcohol problems[6,7] Further, due to limited provider time to screen for alcohol and deliver alcohol-related services in EDs,[8] few individuals currently receive the needed assistance to cut-back, stop drinking, and/or link to needed services during an ED visit. Together, these findings suggest that more intensive, but sustainable, interventions are needed to augment the efficacy of BIs in the ED as well as facilitate linkage from emergency care settings to the most appropriate VHA resource (e.g., substance abuse treatment, homeless program case management, embedded mental health in primary care).

In this regard, evidence-based approaches, such as strengths-based care management, could be added to BIs to enhance efficacy; however, to be feasible in the ED and VHA, service delivery needs to be modified to minimize demands on VHA providers. Peers are ideal candidates for providing alcohol BIs and post-ED strengths-based assistance in the form of peer mentoring because of their shared experiences with patients. Peers can serve as role models and provide emotional support resulting in greater self-efficacy, healthy behavior change, and linkage to needed services.[9,10] *Therefore, the objective of this proposed study is to conduct a hybrid randomized controlled trial (RCT) to determine the efficacy of an peer-delivered alcohol intervention starting in the ED with peer-delivered brief alcohol advice, combined with a continuing 6-session program of post-ED strengths-based peer mentorship, compared to standardized brief advice in the ED only, to facilitate reduction in risky drinking and linkage and engagement in primary and/or specialty alcohol treatment services care, if needed – an* ***Alcohol Peer-Mentor Intervention*** *(****APM****; n=225), compared to* ***Brief Advice*** *in the ED only (****BA****; n=225) condition. The* ***primary specific aims*** *are to:*

Aim 1: *Determine the efficacy of the ED APM intervention compared to BA on subsequent TLFB drinking frequency reports, including number of drinking days per month, number of drinks per drinking day, and number of binge drinking days at 3-, 6-, and 12-months post-baseline.* ***Hypothesis:*** *Veterans with hazardous drinking who are randomly assigned to APM will have significantly greater reductions in alcohol use as measured by TLFB reports, compared to those assigned to BA at 3-, 6-, and 12-month follow-ups.*

Aim 2: Determine the impact of the APM intervention on linkage to primary and specialty alcohol treatment services care, mental health symptoms and functioning at 3-, 6-, and 12-months post-baseline. **Hypothesis:** Veterans with hazardous drinking who are randomly assigned to APM will be significantly more likely to link and engage in primary, specialty care, and other VHA supportive services and to have improvements in mental health symptoms and functioning.

It is important to explore the mechanisms of action that explain how the APM intervention influences change. The **secondary specific aim is to determine the mediators** (e.g., motivation to change, self-efficacy, coping, perceived helpfulness of social support) of the effect of the intervention and linkage on subsequent alcohol use and alcohol-related consequences. An **exploratory aim is to conduct structured qualitative interviews** in order to understand barriers and facilitators of implementation of the APM

intervention in the ED with Veteran participants, clinicians, and peer mentors.

RESEARCH PLAN

Background

Extent of Hazardous and Harmful Drinking in Veterans. The recent Institute of Medicine (IOM) report highlights alcohol as a key problem needing intervention and/or treatment among military personnel, in general, and Veterans, in particular. Hazardous drinking occurs along a spectrum of severity from occasional over-consumption at levels that could be damaging to one's health, to engaging in risky behaviors (e.g., driving). Harmful drinking includes the development of an alcohol use disorder (AUD), which is characterized by a series of alcohol-related problems. Harmful and hazardous drinking, including binge drinking,[11] and alcohol-related problems are particularly common among Veterans.[5,12-15] The VHA serves a high proportion of Veterans with alcohol and comorbid mental health problems.[12,13,16] The percentage of Veterans enrolling in VHA with mental health problems, including substance abuse, has dramatically increased with the influx of Veterans from Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF). Official VHA data for the first half-million of these Veterans seeking care in VHA documented that 56% presented with a mental health problem, including substance abuse. This is a dramatic increase from Veterans in earlier wars. Hazardous and harmful drinking (AUDs) are common comorbidities in Veterans across age groups suffering with PTSD and other mental health concerns[16] Rates of more serious alcohol problems including AUD are particularly high among OEF/OED/Operation New Dawn (OND) Veterans.[16] Veterans with hazardous drinking have an elevated risk for poor outcomes, including injuries, reduced job performance, mental health problems, and suicide.[11,17] More broadly, hazardous alcohol use is a key risk factor for negative mental health outcomes, such as homelessness and depression,[18] which effect the spectrum of VHA patients across ages and service eras. As the proportion of VHA patients shifts to include more and more OEF/OIF Veterans and as evidence mounts of the strong associations between alcohol use and mental health problems and homelessness, it is essential to develop services that address these issues in all VHA patients in settings where those with poor functioning come into contact with the health care system.

Drinking Definitions

- ***Harmful drinking****: Use of alcohol that causes complications (includes abuse and dependence, problem drinking)*
- ***Hazardous drinking****: Use of alcohol that increases risk for complications (includes risky or at-risk drinking)*
- ***Non-hazardous drinking****: Use of alcohol without clear risk of complications (includes beneficial use)*

Source: World Health Organization

ED as a Setting for Addressing Hazardous and Harmful Drinking. Data from adult studies in non-VA EDs show elevated rates of hazardous drinking in ED patients compared to national surveys, making the ED an important setting for alcohol screening and interventions. Alcohol misuse has particular relevance to VHA EDs. In a recent VHA study, patients with high risk profiles, where hazardous alcohol use was a major risk factor, were three times more likely to use the VHA ED, compared to patients with lower risk profiles.[19] A study of OIF/OEF Veterans utilizing VHA, found that they underutilized specialty mental health care and over utilized ED care, and that ED utilization was significantly related to alcohol misuse.[3] Despite the high rates of hazardous drinkers in EDs,[8,20] few ED patients are screened and receive interventions to cut-back or stop drinking, and/or link to needed services because of substantial barriers such as staff time.[8]

The VHA ED is an important contact point for medical care for Veterans at high risk for hazardous alcohol use.[3,21] Universal alcohol screening and interventions for Veterans seeking VHA ED care is not a routine practice. Nonetheless, one of the major drawbacks to providing evidence-based BIs in the ED is that it is a fast-paced environment in which staff have multiple demands on their time around emergent care and little training in alcohol interventions. The combination of staff time demands and the fact that most Veterans who have hazardous drinking do not present with acute intoxication (making identification difficult) suggests the need for alcohol screening and intervention approach in the VHA ED which can be done with minimal demands on busy provider time and include post-ED structured help to access primary and/or specialty services.

Alcohol BIs. There are well over 100 RCTs testing the efficacy of alcohol BIs, which typically take between 5 and 30 minutes[6,22] and include varying levels of training in motivational interviewing.[23,24] BIs reduce costs associated with injury and other health consequences, with savings of $3.81-$4.30 for every $1 spent.[25,26] Although study results indicate that participants reduced alcohol consumption and/or consequences, effect sizes are generally modest and dissipate over time,[27,28] suggesting that such single session approaches may not be sufficient to sustain behavior change, particularly for those with higher drinking levels and/or comorbid mental health problems. To date, alcohol screening and BIs have been widely implemented in VHA primary care but have not been integrated into the ED. *From a public health perspective, alcohol BIs need to be applicable to the full spectrum of heavy drinking and the interventions need to be tailored to the level of problem severity. General guidelines recommend limited-intensity support for reducing hazardous drinking for the less-severe end of the spectrum and referral to specialty alcohol treatment (either in primary care or*

specialty care settings) for those with harmful drinking, including moderate or greater alcohol-related problems. The choice to provide Screening, Brief Intervention and Referral to Treatment (SBIRT) interventions across the spectrum of drinking patterns is based on the following: 1) the patient population seen in VA EDs often have mental health problems in addition to hazardous drinking/alcohol problems which can augment the negative effects of drinking; 2) because there are a range of drinking problems seen in VA EDs nationally and locally, it is important to test methods that can be rolled out to the national VA ED system; 3) brief interventions have been tested across the range of drinkers, mostly in primary care settings but some in EDs, with positive results; and 4) the core of the SBIRT model includes referral to treatment for those who have alcohol use disorders. Further, a key aim for hybrid pragmatic trials is to reflect a diverse study population (range of drinkers encountered in real clinical practice in VA EDs). Hence, the inclusion criteria are broad and the exclusion criteria are kept to a minimum.

A recent meta-analysis of RCTs in the ED found evidence that one-session alcohol BIs reduce alcohol use among hazardous drinkers,[6] but the effects were smaller than those in primary care.[4] One-session BIs have not had a large effect on individuals with more serious alcohol problems. Further, following an alcohol BI in the ED, few patients who needed more intensive specialty alcohol treatment services received it.[7] Recent data indicates that telephone monitoring and brief care management are potentially effective higher intensity options to overcome barriers to substance use treatment, demonstrating the promise of these approaches.[29] Given the constraints of existing ED provider resources, peer support specialists could serve a vital role in delivering BIs plus additional supportive contacts for Veterans with hazardous or harmful alcohol use detected in the ED. *This study will use structured 6-session post-ED visit peer mentoring compared to a 1-session ED-based clinician brief advice intervention. If the peer mentoring SBIRT (including additional post-ED contacts and support) is found to be more efficacious compared to clinician brief advice conducted in the ED, it will answer the pressing question regarding whether peers should be allocated to provide SBIRT assistance in the VA ED setting, with the benefit of ongoing structured contact that a caring, engaged peer can provide to extend the potential impact of brief interventions and increase motivation to change. If successful, this can both expand the use of peers who have lived experience that is directly related to the issues facing many Veterans seeking ED care, and will free up clinicians to address other critical emergent clinical Veteran concerns.*

Use of Peer Support to Address Behavioral Health and Substance Use Issues. In 2008, the VA's Uniform Mental Health Services Handbook mandates counseling from peer support specialists who are available to patients with serious mental illness across all VA facilities.[30] Over 1,100 peer support specialists have subsequently been hired in VA and deployed to a wide range of mental health programs. The use of peers has a long, successful history in VHA alcohol treatment, and the new VHA peer counseling program has built on that tradition by assigning peers to VHA substance abuse programs. More recently, peer support has also often been used to assist patients with serious mental illnesses or to help individuals with alcohol/drug use disorders maintain recovery.[31] Meta-analyses of peer support interventions support their efficacy in the treatment of depression[32], and a recent systematic review of nine studies of peer-delivered recovery support services for individuals with alcohol and substance use disorders demonstrated positive effects on substance use and other health outcomes.[33] For example, an RCT of a one-time peer-delivered motivational intervention demonstrated that the intervention was associated with reduced drug use at 6 months post-treatment, and an RCT of peer-led support groups resulted in lower levels of alcohol use.[34]

Peer mentoring interventions also show promise in improving outcomes for individuals with alcohol and substance use disorders, showing that providing peers as recovery coaches increased use of primary care visits and decreased use of costly services (e.g., ED, detoxification).[35] Other studies show peer support interventions improve treatment retention[36] and reduce re-hospitalization.[37] A small RCT (N=74) of patients with 3 or more psychiatric admissions also found peer mentorship resulted in fewer subsequent re-hospitalizations compared to usual care.[38] Using peers to deliver brief alcohol interventions in the ED, with follow-up peer mentoring to support reductions in hazardous or harmful drinking, and enhance linkage to services, is an untapped potential alternative to single session clinician-delivered BIs. Peers are less costly than ED providers, including social workers, which could facilitate implementation in VHA. There are currently no consistent strategies to take advantage of the ED as a screening and intervention setting for Veterans with hazardous or harmful drinking concerns. The combination of expanded ED access and the expanded use of peers throughout the VHA system provides an ideal opportunity to develop new strategies to capitalize on these system-level changes to positively impact alcohol outcomes.

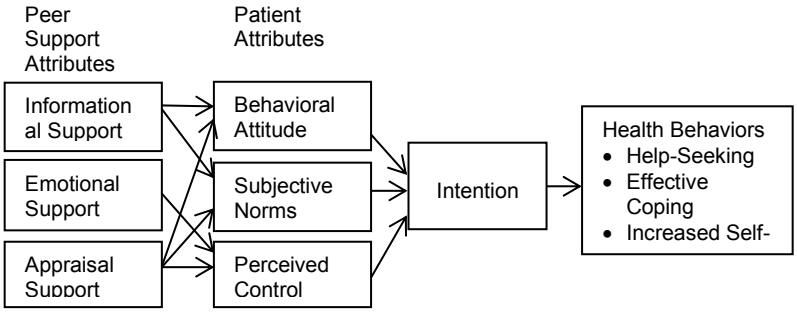
Strengths-Based Peer Mentoring. The proposed peer mentoring approach is grounded in the Strengths-Based theoretical perspective. It has been evaluated for patients with serious mental illnesses[39] and adapted for use with alcohol disorders. The principles of a Strengths-Based model include: 1) focus on strengths rather

than on pathology; 2) interventions are based on patient self-determination; and 3) individuals with mental health or substance disorders can continue to learn, grow, and change. Dr. Blow and colleagues[39] found that both Assertive Community Treatment and Strengths-Based care management reduced inpatient days while increasing outpatient care. Although all patients improved clinically, the Strengths model of care management demonstrated a significantly greater advantage with symptomatology reduced by half.

The Strengths-Based approach is particularly useful in working with persons who have hazardous drinking or AUD because of the focus on accessing primary and specialty services[40] when necessary. For patients currently receiving VHA services in various programs, it can also facilitate them recognizing how hazardous/harmful alcohol use can impact their other mental and physical health problems, and assist them in opening a dialogue with providers. In our prior work, comparing a 5-session strengths-based care management approach with 2 sessions of motivational interviewing, the Strengths-based approach was most effective in linking individuals with substance use disorders to assessment services (see Preliminary Studies).[41,42]

Guiding Conceptual Framework for Proposed Interventions. The proposed intervention will have two phases. First, following screening, those who screen positive for past 3-month hazardous/harmful drinking and agree to participate will be randomized to either the APM or the CBA condition. *In this brief advice intervention, both groups (APM and CBA) will receive the "gold standard" of care in the ED, a one-session brief advice intervention, the content of which is based on the previous alcohol BI work of the investigators. The brief advice in both the APM and CBA conditions will be guided by a computerized program that ensures fidelity.* Each participant is given a pamphlet to take with them that includes information on alcohol use and problems and resources in the VHA and community. Second, all patients in the APM arm of the study will receive 6-sessions over 2-months of peer mentorship, personalized to each individual's concerns. Those with more severe alcohol and/or mental health problems will also be mentored to seek appropriate primary and or specialty care (see Table 1: 6-session guide in Methods). This intervention was designed with an eye towards implementation, i.e., it is feasible to deliver and makes use of an existing and potentially underutilized resource, peer specialists.

Figure 1: Conceptual Model of Peer Facilitated Health



This intervention approach is based on a conceptual model adapted from the Theory of Planned Behavior (TPB)[43]; and a concept analysis of peer support within a health care context.[44] In this conceptual model of Peer-Facilitated Health Behaviors (see Figure 1), the effects of peer specialists on health-promoting behaviors are mediated through changes in patient beliefs and perceived self-efficacy. Peer support attributes (Column 1) consist of (1) Informational Support, (2) Emotional Support, and (3) Appraisal Support. Informational support provides knowledge relevant to problem-solving and includes availability of relevant resources, assessments of problem etiology, alternative courses of action, and guidance about effectiveness. Emotional support includes encouragement, attentive listening, reflection, and reassurance. Appraisal support, or affirmational support, aids self-evaluation and self-efficacy by affirming the appropriateness of emotions, cognitions, and behaviors. This type of support includes encouragement to persist in problem resolution, reassurances that efforts will result in positive outcomes, assistance to endure frustration, and communication of optimism.[44] Peer support attributes positively influence patient attributes relevant to behavior change (Column 2). These attributes include (1) Behavioral Attitudes (which are based on behavioral beliefs); (2) Subjective Norms (which are based on sense of social pressure/norms); and (3) Perceived Behavioral Control (based on the sense of self-efficacy to engage in the behavior). For behavioral attitudes, if behavioral beliefs suggest that engaging in the behavior will lead to a positive outcome, an individual will be more likely to engage in the behavior. For subjective norms, if an individual believes that engaging in the behavior is socially acceptable, the more likely s/he is to engage in the behavior. Perceived behavioral control produces a sense of self-efficacy in relation to a behavior, or sense that the individual can successfully complete the behavior. The likelihood of engaging in health behaviors (in this case, linking to primary and/or specialty care or other appropriate services, and cutting down or stopping the use of alcohol) is guided by these three core constructs.

Summary. Despite VHA advances in annual screening for hazardous drinking using the AUDIT-C in primary care, VHA EDs do not routinely screen or provide alcohol BIs, nor is there adequate linkage to primary care, mental health, or specialty alcohol treatment services for those needing more intensive interventions.

Challenges to ensuring sufficient staff effort to train, maintain fidelity, and sustain programming are barriers to implementation. The proposed brief advice plus peer mentorship intervention will build upon existing peer specialist training programs and prior successful work by the investigators to provide training in the delivery of a standardized alcohol brief advice protocol in the ED, combined with a structured post-ED peer mentorship program to support changes in drinking and linkage to services, such as primary care, specialty services, homeless outreach and case management, or vocational assistance (e.g. through Vet Center contacts).

Significance and Responsiveness to VHA Priority Areas

The proposed project is responsive to Health Services Research and Development Service (HSR&D) priority areas. The public health significance is clear given the high priority placed on problems related to alcohol use in Veterans as well as the general US population. VHA EDs often serve Veterans experiencing acute problems related to hazardous/harmful alcohol use, including those enrolled in other areas of VHA care. The availability of VHA ED care has expanded rapidly over the past decade as VHA has mandated that all medical centers provide 24-hour emergency care. Many Veterans seen in VHA EDs report problematic drinking that is either tied directly to their presenting problem or complicates the care of medical and/or psychiatric symptoms. There is good evidence that patients with hazardous/harmful alcohol use present in the ED but do not receive interventions to reduce their drinking or link to services. The VHA has a large network of peer specialists across the country. Testing the potential for peer support personnel to provide standardized brief alcohol advice during an ED visit and assist in supporting reduced hazardous drinking and/or linking those who are drinking at harmful levels to needed services. By supporting decision-making related to reducing hazardous drinking and facilitating linkage to treatment for those with more serious alcohol problems, the proposed project has the potential to harness a visit to a VHA ED as a "window of opportunity" for identification and intervention for those with hazardous drinking, and ensure that those with more severe harmful alcohol problems are linked to VHA services for ongoing care. Linkage to care is a particularly important step for the large population of Veterans with alcohol problems and has been under-developed in prior interventions.

The scientific significance of this project is based on the innovative test of the efficacy of a peer-delivered VHA ED alcohol brief personalized advice protocol for hazardous/harmful drinkers, followed by 6 sessions of structured peer mentoring to link and engage as needed with VHA services that is tailored to their level of alcohol consumption and concomitant medical and mental health needs. There are currently no data to support this new role for VHA peer specialists despite the use of peers in a wide range of settings with chronic diseases. Determining the efficacy of this approach to improve outcomes for this large group of Veterans has the potential to significantly advance the science supporting the potential utility of peer specialists and has broad-ranging importance for alcohol researchers and policymakers both inside and outside VHA.

The proposal is directly responsive to HSR&D Priority Area E - Mental and Behavioral Health, which encourages research to study best practices in treating substance-related problems. The hazardous use of alcohol is heavily related to PTSD, and is often the gateway into treatment for PTSD, especially among post-deployment Veterans who are struggling, but in denial about their PTSD.[45] Alcohol is implicated in most military-related suicides, often being used to deal with post-deployment stress and depression. The disinhibiting effects of alcohol facilitate impulsive acts, including suicidal behavior. *The proposal is also responsive to HSR&D Priority Area B- Health Disparities. Homelessness is a major problem among Veterans. Homeless Veterans are cut off from healthcare access, and have significant difficulty communicating their health needs or accessing care. A recent study of ED utilization by homeless Veterans found that 53% used the ED in the past year; significantly more often even than non-Veteran homeless. The study also found heavy alcohol use among these Veterans.[18] A recent survey of over 23,000 homeless Veterans found that 76% of Veterans homeless for over 2 years had substance abuse problems, and that among all OIF/OEF Veterans, regardless of length of homelessness, the rate was 57%.*

The proposed RCT, with its aims focused on alcohol use and consequences, functioning, and linkage to care, and an intervention that is designed to be straight-forward and readily transportable to other settings and patient populations in and out of VHA, is consistent with the overall mission and goal of HSR&D to develop and test interventions with broad-reaching importance and the potential for broader implementation. The last year of the proposed study will involve the collection of in-depth qualitative data to aid in the ultimate implementation of this intervention approach, should it be found to be effective.

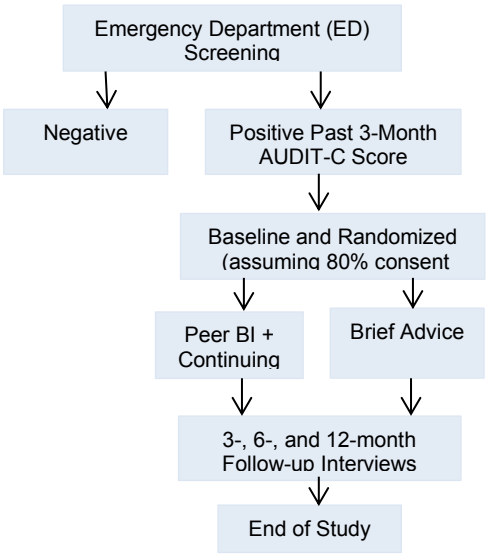
Research Design

Overview. *The aim of the study is to conduct a hybrid RCT [46] to determine the effectiveness of an alcohol intervention starting in the ED with peer-delivered brief alcohol advice, combined with a 6-session program of post-ED structured peer mentorship to facilitate linkage to and engagement with primary or specialty alcohol treatment services: APM (n=225) condition, compared to a Brief Advice in the ED only condition: BA (n=225)*

condition. As a secondary objective, the study will determine mediators of change (see Figure 2). In order to serve as a transition to implementation research, this RCT will use an Effectiveness-Implementation Hybrid design. *As a Hybrid Trial Type 1, this RCT will test the effects of the clinical intervention on patient outcomes while also observing and gathering information useful for implementation. As such, it will include mixed method process evaluations of delivery/implementation such as feasibility and acceptability, sustainability potential, and barriers and facilitators to implementation.*[47]

Preliminary Studies. The proposed study builds on the project team's substantial prior experience in studying BI techniques and peer support in a variety of settings. The team also has extensive experience in working with and studying military Service Members and Veterans. Drs. **Blow, Bohnert, Sripada and Walton** are all investigators at the HSR&D COIN Center for Clinical Management Research (CCMR) at VA Ann Arbor Healthcare System. This interdisciplinary group of investigators has the range and depth of experience to ensure successful refinement of the **APM** and longitudinal tracking and data analyses for the proposed study. Within this section, we highlight some of our prior experience: (1) testing the efficacy of BIs; and (2) developing and testing peer-delivered interventions for substance misuse.

Figure 2: Study Design



Brief Interventions. Drs. **Blow and Walton** were funded by NIDA and NIAAA to conduct two RCTs among individual ages 19 and older with substance use disorders to compare two interventions with a control condition to promote linkage to assessment/ treatment. Patients presenting to an inner-city ED participated in screening, and eligible participants were randomized into one of three study conditions. Among the 22,924 potentially eligible patients who presented during the recruitment period, 80% (n = 18,286) were approached by study staff and 80% of the approached patients (n = 14,557) completed the screening survey; 1,938 (13.3%) met criteria for a substance use disorder (6.8% alcohol only; 6.5% any drug); 1,441 of these individuals participated in the RCT.[2] Importantly, our team had developed fidelity procedures that enhance delivery of content to guide intervention delivery.[48] Rates of follow-up were high and, consistent with our prior work in substance users seen in a variety of settings, exceeded 80% at 3-, 6- and 12-months post-intervention. Results from our group indicate that BIs are associated with post-intervention reductions in both substance use and other negative outcomes.[49,50] Dr. **Blow** and others conducted an alcohol BI pilot study to determine the feasibility of a larger study with Psychiatric Emergency Services (PES) patients and to determine if there were differences between patients who had serious mental illnesses (schizophrenia; bipolar disorder) and those with depression/anxiety in their response to the alcohol intervention. Of the 390 patients screened, 87 (22.3%) screened positive for hazardous drinking and received the brief alcohol intervention in the PES. Six-month follow-up was conducted and both groups of patients reduced their drinking by 7 drinks/week. Across groups, participants found the intervention helpful and acceptable.[51,52]

Finally, because many hazardous/harmful drinkers require linkage to services, in prior work in the ED among adults with substance use disorders, warm referral to a multi-session, in-person case management intervention increased treatment assessment (OR=1.79, p<.001) and engagement (OR = 1.48 p<.05)[42] however, only 50% attendance with the therapist-delivered case management underscores barriers to referrals that could be more directly addressed by peers who have credibility as well as training in service options, leading us toward the peer approach proposed in this application**. Thus, our team has prior experience screening for alcohol in the ED, and delivery of interventions, with exceptional retention with longitudinal follow-up.**

Peer Support Interventions. Peer outreach programs have had wide acceptance in the VHA and numerous "grass roots" peer programs have been implemented within the VHA, and more generally in the military and National Guard (NG).[53] One of the leading peer outreach and linkage to mental health or other community resources in the NG is the Buddy-to-Buddy (B2B) Volunteer Veteran program implemented in the Michigan NG. Co-I Dr. **Pfeiffer** and others conducted a qualitative study of the role of peer support and linkage to treatment among Michigan NG soldiers which informed the development of the B2B program. In this program, Volunteer Veterans from the community who are outside the NG chain of command are trained in communication skills, attend drill weekends, are available by telephone to offer support and linkage to a variety of community, VA, and NG/military resources. Papers describing the partnership and development of B2B have

been published.[54] Peer support efforts, such as B2B, provide key potential resources to increase the impact of Screening, Brief Intervention and Referral to Treatment (SBIRT) but have not been used for alcohol misuse.

Drs. **Blow (PD/PI), Walton, and Bohnert** are currently testing the efficacy of the B2B peer support program among NG soldiers who screen positive for hazardous alcohol consumption. Over 120 Veterans have been trained as B2Bs for the Michigan program and 82 are currently active in 36 armories. B2Bs have attended drill weekends, reintegration events, and weekly guidance telephone conference calls, and have documented over 400 referrals/year (over 1,100 total) to a variety of resources (i.e., financial, employment, mental health). Thus far, in this ongoing study we have screened 1458 NG soldiers, with 27% screening positive for hazardous alcohol consumption and 347 enrolling in the RCT; follow-ups have started. In addition, Dr. **Pfeiffer** was a co-I on a mutual peer support intervention for VHA patients with depression (PI: Marcia Valenstein) and PI for a pilot study of peer mentorship following psychiatric hospitalization for depression; he currently is the PI for a RCT of peer-supported computerized cognitive behavioral therapy for depression within VHA primary care and PI for an NIMH-funded trial of peer mentorship to reduce suicide risk after psychiatric hospitalization. Finally, as part of recent IIR's, Drs. **Bohnert and Pfeiffer** have expertise and have conducted qualitative interviews with primary care and other VA clinicians. This experience that will be valuable for conducting the qualitative work to be done in the final year to inform implementation of results from the project.

Summary. These studies demonstrate the ability of our team to develop and train peers to deliver interventions for hazardous/harmful drinking. The proposed study is innovative by translating this prior experience with intervention development to the unique needs of Veterans seen in the ED, whose spectrum of alcohol consumption requires alternative approaches to address their drinking and connect them with services.

Methods

The overall purpose of this project is to test the efficacy of a BI designed to reduce alcohol consumption and problems among VHA ED patients using a peer-mentor intervention. The study will generally take the form of a pragmatic trial, following the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) model, e.g., using few exclusion criteria. All study procedures will be approved by the Institutional Review Board at the Ann Arbor VHA, and a Certificate of Confidentiality will be obtained from NIH.

Description of Study Site. The proposed study will recruit from the ED in the VA Ann Arbor Healthcare System (VAAAHS). The following numbers are based on data from 2015. This ED treated a total of 10,653 patients drawn from a relatively wide geographic area that included western Wayne County (Detroit area), as well as several mid-sized cities and rural communities. Patients seen had the following characteristics: 9% female; 75% White, 10% African American, and 3% of another race (mainly multiple races); about 2% Hispanic. The VAAAHS ED is very supportive of this research project. Only one site will be included in this study to enhance our ability to ensure fidelity of peer-delivered intervention content through closer supervision and monitoring. If shown to be efficacious, we will scale up in order to add many sites later through an implementation study.

Inclusion Criteria for Screening. (1) adults age 18 years of age or older presenting for care in the Ann Arbor VHA ED; and (2) medically stable and able to provide informed consent per Mini-Cog assessment score of 3 or more.

Inclusion Criteria for the RCT. *Individuals will be eligible to participate in the RCT if they: (1) have an AUDIT-C score of 4 or more for men and 3 or more for women in the prior 3 months, indicating that they meet criteria for hazardous use[55];* and 2) have a telephone and/or the ability to provide information about individuals who can help contact the participant. Homeless Veterans may not have a telephone but will be asked for individuals who can help to contact them (e.g. shelter, family, friends, etc.). Importantly, the study will include not only those with less severe hazardous drinking but also those with more harmful use and severe problems to address the problems and needs of Veterans who can most benefit from linkage to primary and secondary care. *Furthermore, a recent study validates the full AUDIT among Veterans, with scores of 14 and 10 (male, female, respectively) indicating an AUD.[56] However, to be inclusive and sure that all Veterans who may need specialty care have the information to get to that care, we will set scores for specifically recommending specialty care to the Veteran participant more conservatively at 10 for men and 8 for women.* Both study conditions will receive information on accessing VHA primary/specialty services.

Exclusion Criteria for Screening. (1) patients who do not understand English; (2) prisoners; (3) patients currently in or having received substance abuse treatment in the past 3-months per medical record; (4) patients currently in or having received peer services in the past 3-months per medical record; (5) pregnant women; (6) patients deemed unable to provide informed consent as stated above; and (7) profound psychotic symptoms and/or cognitive deficits that would prevent patients from understanding the content of the intervention and/or assessments.

Exclusion Criteria for RCT. (1) individuals currently active in or having received alcohol or other substance abuse treatment in the past 3-months per self-report in screening; (2) patients currently in or having received peer services in the past 3-months per self-report screening.

Participants may be excluded at the discretion of the Principal Investigator based on participant or study staff best interest (e.g., if participant should become physically or verbally aggressive towards study staff, or if the study staff know a patient or their family personally, in order to fully ensure participant privacy).

Participant Remuneration. Participants will be remunerated $5 for completion of the screening instrument and $25 for completion of the baseline assessment. Participants will be provided $10 remuneration for completing the baseline assessment in-person the same day of enrollment in the ED. Remuneration will also include: $25 for each of the 3-month and 6-month surveys, $10 for each of the 3-month, 6-month, 12-month TLFB interviews, $40 for the 12-month survey for a total of $160.

Recruitment / Informed Consent. Veterans will be recruited at the VAAAHS ED. The study will involve a 2-stage consent process utilized in our prior ED research, providing separate verbal consent with waived documentation for the screening, and written consent for the randomized trial. All who screen positive on the AUDIT-C, agree to participate, and sign consent forms will be enrolled. They will receive a baseline assessment as described in the measures. Participants may have the option to complete paper-form alone, or within up to 2-weeks after enrollment if necessary. *Research staff will recruit, obtain consent, and participants will self-administer the screening and assessment questions. The peers will shift in the ED to deliver the brief advice with supervision from the research supervisor, likely a social worker who is a Licensed Independent Practitioner.*

ED Staffing / Subject Accrual. Because it is not possible to staff the project continuously (168 hours/week), this study will use the following sampling frame that has been used successfully in our previous ED research to ensure obtaining a representative sample of Veterans presenting to the AAVA ED. Project staff in the ED will recruit patients for the study 5 days per week between the hours of 10AM to 6PM. The majority of the recruitment time will be spent in the ED between 10AM and 6PM because 65-70% of patients enter the ED during those hours. In addition, another three days/week will include a weighted sampling of recruiting between either 7AM-3PM or 3PM-11PM time period. Thus, a total of 8 shifts (8 hours each) will be staffed each week to recruit, consent, screen patients, conduct baseline assessments, and deliver brief advice. Based on our previous ED studies where we have used similar staffing schedules we expect to accrue the following numbers: 30 months of screening x ~130 patients/month approached = 3,900; it is expected that 80% (n=3,120) will agree to participate and will be screened. We conservatively expect that 15% of the screened patients will have a positive screen and will be randomized (450 randomized; 225 per group). Randomization Procedures. Stratified random assignment to conditions will be by sex and presence of an AUD (yes/no) defined as a score of 14 for men and 10 for women on the AUDIT. Randomization by sex will be used because men and women generally differ in their rates and nature of alcohol use, problems, and outcomes. Random assignment will also be stratified based on meeting criteria for past year AUD (yes/no) because of potential differences in problem severity and potential intervention response. Randomization will proceed in blocks of 10 within study cells, in order to equalize randomization over time. Follow-up staff will be blind to condition. Participants in both conditions will receive written information regarding alcohol and VHA resources and be re-contacted to complete 3-, 6-, and 12-months follow-ups.

Alcohol Brief Advice Content. Participants who are randomized to either condition (APM or BA) will receive a modified BI (brief personalized advice guided by a script, a short pamphlet on alcohol, other health issues, and VHA contact information, and an infographic sheet about VA drinking guidelines as an additional layer of advice). In the APM condition, the brief advice session will be followed by 6 sessions of peer mentoring over 2 months. The BA condition includes the initial brief personalized advice and pamphlet. Materials for the APM and BA sessions will be provided in the ED. Participants may have the option to complete the session in-person or on the phone up to two-weeks after enrollment. The proposed brief advice for both the APM and BA groups will be short and personalized, based on factors such as gender, and severity of hazardous/harmful drinking.[50] The alcohol brief advice pamphlet to be given to the participants will provide information on alcohol and resources available at the VHA and in the community, with places for the peer to add tailored content (e.g. alcohol issue; reasons for use, strengths to help with change; plans for change, etc.) to: 1) enhance the Veteran's cognitive preconditions for message processing or acceptance (receptivity); and 2) enhance message impact (salience) by selectively modifying behavioral determinants of desired outcomes. Tailoring allows broad topics to be narrowed to participant experience for relevance in a short time period. The APM intervention includes the peer establishing an ongoing relationship with the patient to share their story, and schedule a time for the first Post-ED 'booster'.

6-session Peer Mentorship. Peer mentors will provide structured booster support to Veterans who have been assigned to the intervention condition. The peer mentor will work with each participant in the APM condition over a 2-month period to discuss strategies for reducing hazardous drinking, support behavior change and encourage linkage to care. Peer mentors will address participants' goals and will provide emotional, informational, and appraisal support designed to help Veteran engage in primary and specialty care, as needed. Cases will be reviewed on a weekly basis by the project supervisor and one of the clinical investigators (Pfeiffer and Sripada). Training will be manualized, peers will receive weekly supervision, and post-ED sessions will be audiotaped.

Table 1: Overview of Peer Mentor Post-ED Visits

Week	Session Focus
1: Triggers and Motives	• Solicit Veteran's issues and questions prompted by initial meeting in the ED • Begin the process of identifying Veteran's strengths, abilities, skills • Address Veteran's personal needs and barriers to health care • Identify triggers and motives for alcohol use (e.g., feelings, people, places, activities) • Identify initial coping strategies • Encourage linkage to primary and/or specialty care as needed • Summarize the major points in session • Set up next weekly meeting with flexibility to meet more often for specific help
2: Coping and Quality of Life	• Solicit Veteran's issues & questions since last contact • Continue to emphasize Veteran's strengths • Encourage cutting down alcohol use and/or assessment and treatment linkage • Review triggers and motives for alcohol use (e.g., feelings, people, places, activities) • Further explore coping strategies to increase quality of life and reaching goals • Encourage contact with primary and/or specialty care • Summarize the major points of the session • Set up next weekly meeting with flexibility to meet more often for specific help
3: Problem Solving & Overcoming Barriers	• Solicit Veteran's issues and questions since last contact • Identify and address Veteran's personal needs and relationship to drinking • Review service options and barriers to seeking health care • Problem solve solutions to barriers and encourage service use • Summarize the major points of the session • Set up next weekly meeting with flexibility to meet more often for specific help
4: Social Support	• Solicit Veteran's issues and questions since last contact • Encourage decreased alcohol use with strategies and linkage to care • Identify existing sources of social support • Explore options for obtaining additional support • Encourage contact with primary and/or specialty care • Set up next weekly meeting with flexibility to meet more often for specific help
5: Leisure Activities and Work	• Solicit Veteran's issues and questions since last contact • Encourage decreased alcohol use with strategies and linkage to care • Identity enjoyable, alternative activities to drinking alcohol • Examine work concerns and work/life balance • Encourage contact with primary and/or specialty care • Set up next weekly meeting with flexibility to meet more often for specific help
6: Planning for the Future	• Solicit Veteran's issues and questions since last contact • Encourage decreased alcohol use with strategies • Review coping, social support and leisure options • Review solutions to barriers and service options • Encourage contact with primary and/or specialty care • Summarize progress and plans

Peer Mentor Content. Peer mentors will deliver the brief advice in the ED and will initiate conversations with the patient for up to 6-sessions over 2 months post-ED visit. Strengths-based discussions will include a combination of scripted and open-ended content to best facilitate reductions in drinking and engagement across severity (see Table 1). All sessions will be audiotaped and will emphasize strengths and goals, focusing on reducing/stopping alcohol use and linkage to care and barriers (e.g., transportation, going with the Veteran to the first appointment, housing, job or family issues, etc.).

Brief Advice Condition. Participants assigned to BA will receive brief alcohol advice from a research assistant. Content is comparable in intensity and scope to the current computer protocol that is required to be used in VHA primary care, and a health pamphlet with VHA and community resources and information about alcohol use and other issues. Those randomized to the BA condition will receive no post-ED sessions, consistent with current usual practices of ED-based brief interventions and current staffing models. One-session brief clinician advice by a social worker in the ED has had mixed and modest positive effects, but it remains the cornerstone of most alcohol brief interventions in large health systems. Thus, the comparator will be real-world relevant, potentially helpful yet also conservative in terms of the extent to which it can influence longer-term drinking outcomes.

Peer Mentor Hiring, Training, and Supervision. Peer mentors will be hired according to current policy guidelines provided by the VHA Office of Peer Support Services. As is standard practice in VHA programs, we will not require the peer specialist to be matched with study patients on specific demographic characteristics (e.g. military service era, gender) because these requirements introduce practical and ethical hiring challenges and are unlikely to be upheld if the program is implemented across VA facilities with existing peer specialists. However, preference will be given to peer specialist applicants with experience with hazardous drinking/ substance use disorders.[57] Peer specialists will complete standardized VA peer support training and certification through a training program approved by the Office of Peer Support Services. An example training

program offered by the National Alliance on Mental Illness (NAMI) consists of 10 two-hour sessions including topics such as stigma, self-disclosure, disorder-specific information, suicide prevention, and recovery.[58] Online training is also available through the New England MIRECC Peer Education Center. Peer mentors will be trained by experienced investigator trainers (Blow, Walton, Pfeiffer) in alcohol issues, intervention content, linkage in primary and specialty care. The investigators will refine the peer intervention delivery manual.

Initial training will be conducted over 5-days and include: a) review of hazardous alcohol use and AUDs in the military and in the VHA, signs and symptoms, risks, and common comorbid conditions; b) delivery of the BI; c) content of the structured linkage sessions; d.) an overview of the array of VHA programs and services that (including shadowing peer counselors in these programs), e) motivation for change, methods to support gains, and ways to foster linkage to care, and, f) presentations from key staff in programs, including the homeless, embedded MH, Veteran Centers, and substance abuse programs. Following recommended guidelines[57], training will also include site-specific information such as (1) documentation requirements and progress notes in the electronic medical record, (2) crisis recognition and procedures, (3) a review of Ann Arbor VA policies and procedures, and (4) facility emergency trainings. Ongoing training with the peer mentor supervisor, a licensed social worker, will include any additional resources needed throughout the project. Following VHA Psychosocial Rehabilitation and Recovery Peer Support Handbook, the peer supervisor will be a Licensed Independent Professional with clinical privileges at the AA VHA. After the initial 3-day training that includes didactic and experiential content (e.g. role playing), the peers will meet on a weekly basis with the peer mentor research supervisor for supervision to discuss cases, content, and troubleshoot each of the interventions and follow-up contacts. Supervision will also include discussions of peer identity and how to prevent peer drift, an undesirable shift from a recovery-oriented role toward a more medical treatment role.[59] Some of the supervision will be provided in group format to foster a fellowship and mutual support among peer mentors. The supervisor will be encouraged to engage in the VHA Peer Support Supervisors National monthly conference call and to join the VHA Peer Supervisors' email listserv where helpful information is shared between listserv participants.[57] Supervision will follow best practice guidelines as laid out by the Pillars of Peer Support Services Summit on Peer Specialist Supervision.[60] The Project Supervisor will provide day-to-day supervision and will report progress to the investigators in monthly meetings.

Using the VA criteria for hiring and training peers, we expect that there will be a range of mental health conditions that peer mentors have dealt with in their lives. We will not exclude peers because of any conditions for which they are in stable recovery. Our priority will be to hire Veterans who are in long-term recovery. Because the peer mentors will work as part of the research team and will be supervised by the PI and the research coordinator, with support from other clinician investigators, we will have close monitoring of peer staff, as well as other staff, and are prepared to address any mental health and substance use issues that arise. If a peer is experiencing relapse, they will be assisted in seeking needed care and will not work with participants until they are stable. Also, if a peer relapses, participants will be reassigned to an alternative peer (supervised via weekly group supervision and bi-monthly individual supervision).

Follow-up Methods and Assessments. At the 3-, 6- and 12-month post-randomization follow-ups, participants will be called to complete a telephone follow-up survey. Participants may have the option to meet in person if necessary. The TLFB interview during follow-ups will be audio recorded. At enrollment, study staff will obtain consent, telephone numbers, and addresses, as well as information for contacts, at least one of whom does not live with the participant, who should know their whereabouts in the next 12 months. In addition, the following procedures will be implemented: 1) reminder calls/ letters will be started one month prior to each follow-up assessment until completed; 2) incentives will be given to participants who complete follow-ups ; and 3) participants will be encouraged to call the study office with any questions, and to notify us of address/telephone changes. *A review article contains more detailed information regarding the follow-up protocol that will be used.[61] Using these strategies, we typically achieve 12-month follow-up rates exceeding 80% at each assessment point.[49,62,63]*

Measures (see Table 2 for measures and timing). The screen (~10 minutes) will be completed on paper by participants and will include demographics and the 10-item Alcohol Use Disorders Identification Test (AUDIT). Veterans screening positive on the AUDIT-C (4+ men/3+ women) will be consented to participate in the study. The baseline (~45 minutes) will be completed as an in-person interview in the ED and recorded on paper forms by RA. Participants may have the option to complete the baseline alone on paper-form or on the phone within up to two-weeks after enrollment, if necessary. Follow-up assessments will be completed over the phone (or in person if necessary) and responses will be entered into VA REDCap in real-time.

Screening Measure

The Mini-Cog assessment will be administered to all potential participants to detect cognitive impairment and inability to consent. A score of 3 or more will indicate no sign of cognitive impairment, therefore patient will be eligible for recruitment and screening.

Primary Outcome

Alcohol Consumption. We will administer a 30-day Timeline Follow-back (TLFB) for finer grained data (e.g., average consumption, percent days drinking, binge drinking days) (Hoeppner et al., 2010)[96]

Secondary Outcomes

Alcohol Consumption: We will administer the AUDIT which includes the 3 questions of the AUDIT-C[64,65,97] assessing alcohol consumption and binge drinking over the past 3-months, and 7 consequence questions, with established reliability and validity.[65,66] In addition to standard item responses (e.g., categorical), we will enhance responses to obtain exact numbers for data analyses purposes to produce continuous response scales. Inclusion criteria are scores of 3+ for women and 4+ for men. *A recent study validates the full AUDIT among Veterans, with scores of 14 and 10 (male, female, respectively) indicating an AUD.[56] However, to be inclusive, we will set the score for recommending specialty care conservatively at 10 for men and 8 for women.*

Alcohol Consequences. The Short Index of Problems (SIP) will be used to assess drinking consequences with adequate reliability and validity.

Self-Report Healthcare Service Use. We will use the Treatment Services Review (TSR) to measure health services use. which has adequate reliability and validity.[70] We will also access VHA electronic health data, focusing on primary care; substance abuse treatment, and psychiatric treatment services *(including mutual aid groups such as AA, receiving detox services, and other substance abuse care settings).*

Health Care Utilization using Medical Records. In the last year of the study, a review of participants' medical records will be conducted to determine diagnoses, service use (i.e., ED visits, hospitalizations, primary and specialty care) for one year pre- and post-entry into the study. We will use these data to assess agreement with self-report service use, particularly VHA services, and seek to understand sources of discrepancy. Data will be accessed through CPRS, Corporate Data Warehouse (CDW), and the Joint Legacy Viewer (JLV).

Health Functioning. One item from the SF-12[71] will assess perceived health functioning, which are accepted outcomes for intervention studies.[24,74]

Table 2: Study Measures	Instrument	When*	#Min
Primary Outcomes			
Alcohol Consumption	TLFB	B, 3,6,12	20
Secondary Outcomes			
Alcohol Consumption	AUDIT	S, 3, 6, 12	5
Alcohol Consequenses	SIP	B, 3, 6, 12	5
Health Service Use	TSR/CPRS	B, 3,6, 12	10-15
Health Functioning	SF-12	S, 3,6,12	
Depressive Symptoms	PHQ-9	B, 3,6,12	
PTSD Symptoms	PC-PTSD-5	B, 3,6,12	
Substance Use	ASSIST	B, 3, 6, 12	
Opioid Misuse	COMM	B, 3, 6, 12	
Problem Severity	BAM	B, 3,6,12	
Individual Factors			
Demographics	SAOM	S/B	5-10
Motivation to Change/Readiness	Rulers	B, 3, 6, 12	
Self-Efficacy	Ruler	B, 3, 6, 12	
Social Factors			
Social Support	mMOS	B, 3, 6, 12	10
Peers Services	WAI-SR	3	
Intervention Interaction	Metric, Sentiment		0
*S=Screen; B=Baseline, 3-month, 6-month, 12-month follow-ups			

Depressive Symptoms. The PHQ-9[75] will assess symptoms of depression (94% specificity, 99% sensitivity for current major depressive disorder), including suicidal ideation.

The Primary Care PTSD screening (PC-PTSD-5) is a 6-item self report measure that assesses Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) symptoms of PTSD. The PC-PTSD-5 is currently used in VHA primary care clinics and has excellent internal consistency and is correlated with other PTSD measures.

Modified Brief Addiction Monitor (BAM). The Protective and Risk subscales of the BAM will be used and assesses severity of problems and can be used to measure change over time. The BAM has acceptable reliability and validity among Veterans.[29]

Substance Use

Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) is a structured interview for alcohol, tobacco, cannabis, stimulants, sedatives and opioid use disorders in general medical settings. We will use a brief screening for tobacco use (ASSIST-LITE) and the full ASSIST version 3 to measure use of all other substances.

Opioid Misuse: a modified version of the Current Opioid Misuse Measure (COMM) will assess extent of opioid medication misuse.

Individual Factors

Demographics: Background characteristics assessed include: age, sex, marital status, education, employment, income, legal history, deployment history, etc.[77]

Motivation to Change / Readiness: Based on theory[23], we will assess readiness, intention, importance, and help seeking with visual analog rulers, which correlate with longer measures and predict outcomes.[79-82]

Self-efficacy. We will assess self-efficacy with a visual analog ruler.

Social Factors

Social Support. Social support will be assessed by the Modified Medical Outcomes Study (mMOS) Social Support Survey, a 8-item measure that assesses perceived social support, including emotional/informational, tangible, affectionate, and positive support. These subscales capture the domains of our theoretical model.

Peer Services. At the 3-month follow-up assessment we will use a the Working Alliance Inventory – short revised (WAI-SR) to assess satisfaction with services provided by peer support specialists.

Qualitative Interviews

In the last year of the project, qualitative interviews with key stakeholders and clinical leaders will assess potential barriers and facilitators to the implementation of this approach in the VHA. In year 4, qualitative data will be obtained from structured individual interviews with samples of peer personnel (peer mentors and other peers employed in the Ann Arbor VHA), clinicians in the ED and primary/specialty care, and a sample of participants. No incentives will be provided, however per recommendation from the Associate Chief of Staff (ACOS) of Mental Health, clinicians will be excused from clinical duties to participate (see Dr. Martis' letter of support). This addresses the exploratory aim of the study, to conduct structured qualitative interviews in order to understand barriers and facilitators of implementation of the APM or CBA intervention in the ED. The qualitative analysis of semi-structured interviews will yield additional understanding of patient-, peer-, and clinician-level factors contributing to good and poor treatment response, as well as factors that could influence future implementation of this intervention. Based on our Conceptual Model of Peer-Facilitated Health Behaviors (Figure 1), the constructs that will be explored in qualitative interviews are: acceptability of SBIRT intervention; usefulness of the intervention approach; any alternative approaches that could be helpful to Veterans; and perceived facilitators and barriers to changing hazardous or harmful drinking. These constructs will be adapted for the interviews with Veterans, peers, and clinicians; also, clinicians and peers will be asked how this intervention could be rolled out to the VA nationally. Veteran interview themes will be triangulated with other study data to better understand changes in drinking and treatment-seeking in the VHA from the Veteran's perspective. The text data from interviews with Veterans, peers, and clinicians will be reviewed by two independent reviewers. NVivo9 will be used to perform content analysis and thematic coding for all the qualitative text. Each investigator will read through a sub-sample of interviews and begin identifying common themes. Once initial themes have been formulated, each team member will take the lead on coding responses. To ensure codes are systematically applied, the team will continue to meet to discuss their interviews and coding schemata and resolve disagreements.

Data analyses

Data Management. The project's data manager will conduct all data management and analysis activities under the supervision of Drs. Pfeiffer and Bohnert. Research staff will use double entry procedures and reconcile discrepancies. Data cleaning will be conducted throughout data collection to ensure a quality final dataset for analysis. Statistical Analysis System (SAS) will be used to examine and prepare data for the analysis.

General analytic approach. Hypotheses will be planned a priori, and will be limited to the examination of a limited number of outcomes. We will utilize an "intent-to-treat" approach. All analyses will use two-sided tests because it is possible that the APM participants might have worse outcomes compared to CBA participants. Analyses will begin with descriptive data analyses to determine distributions of key variables, to collapse categories, if necessary, and to review data for outliers and clear anomalies. Tests for linearity, independence, missingness, and distributional assumptions will also be performed. Normalizing transformations of the dependent variables will be utilized, if necessary. We will validate the randomization scheme by comparing the initial groups on key variables that could be associated with the outcomes. Where we identify significant differences between groups, we will adjust for these variables, *as well as other addictions treatment received if it was not initiated by referral from the APM or CBA clinician (and thus a potential mediator of effect)*. Prior to fitting any analytic models, a graphical exploration of the outcome variables will be conducted to select the appropriate models based on variable distributions.

Missing data. Every effort will be made to minimize missing data. Where we have missing covariates that are necessary for analysis, we will perform multiple imputation of missing data and combine the results from 5 imputations based on Rubin's method to produce an estimate and the corresponding confidence interval accounting for missing data uncertainty.[88] For follow-up attrition, the proposed mixed-effects regression model will allow the use of data from all participants (not just those with complete follow-up) and provide unbiased

parameter estimates that account for missing data under the missing-at-random assumption.[89] We will look for non-random attrition, and if we find, for example, attrition rates to depend on a baseline covariate, we will include this covariate in the model. If we find attrition to depend on treatment use or ideation at prior assessments, we will utilize an appropriate pattern mixture model or multiply impute data based on an appropriate pattern mixture model assumptions based on the observed missing data pattern.[88]

Aim 1: *Determine the efficacy of the ED APM intervention compared to BA on TLFB drinking frequency reports at 3-, 6-, and 12-months post-baseline.* ***Hypothesis:*** *Veterans with hazardous drinking who are randomly assigned to APM will have significantly greater reductions in total TLFB drinking frequency reports, compared to those assigned to CBA.*

Data Analysis for Aim 1: The primary purpose of Aim 1 is to examine the impact of the intervention on frequency of drinking per TLFB interview. This outcome will likely follow the assumptions required for linear regression model, but we will adjust the model type as needed. Assuming this is the case; we will use a linear mixed-effects model and estimate the treatment effect as the difference in the time-averaged TLFB frequencies over the year of follow-up. Because reduction in problem alcohol use is of primary interest, the analysis will model change-scores from baseline in the response variable as dependent variable, and the independent variables will include the baseline values of the response variable, time in months since randomization, and the treatment group indicator. The parameter estimate of the treatment group indicator will estimate the time-averaged treatment effect. *In a second model, we will include an interaction of time by treatment group indicator to formally test the possibility that the effect varies over time. Models will include a random effect for which specific peer/clinician a participant was assigned*.

Aim 2: Determine the impact of the APM intervention on linkage to primary and specialty alcohol treatment services care, mental health symptoms and functioning at 3-, 6-, and 12-months post-baseline, compared to BA. Hypothesis: Veterans with hazardous drinking who are randomly assigned to APM will be significantly more likely to engage in primary, specialty care, and other VHA supportive services and to have improvements in mental health symptoms and functioning.

Data Analysis for Aim 2: The focus of Aim 2 is to study intervention effects on secondary outcome of frequency of primary care and mental health specialty care visits (as two separate outcomes) from the TSR, calculated as an average number of visits per month during each follow-up period, Similar to Aim 1, analyses will generally use a mixed effect model framework. As described above, initial analyses will examine the distribution of outcome measures over follow-up in order to select an appropriate model (e.g. Poisson regression or a related method for counts of visits). Our analysis strategy will parallel Aim 1 in terms of the independent variables, *random effect for peer/brief advice*, focus on time-average treatment effects, *and additional modeling of interactions of group and time.*

Secondary Aim will determine the mediators (e.g., motivation to change, self-efficacy, coping, social support) of the effect of the intervention and linkage on subsequent alcohol use and alcohol-related consequences. **Hypothesis:** The effect of randomization to APM compared to BA on the primary outcomes (i.e., alcohol consumption and consequences) will be mediated by differences between groups in motivation to change, self-efficacy, and perceived helpfulness of peer support.

Data Analysis for Secondary Aim: *In order to establish temporal ordering, we will examine whether level of the hypothesized mediators at 3 and 6 months post-baseline mediates the effect of random assignment on 6- and 12-month measures of the three primary outcomes of alcohol use behaviors.[90,91] We will first determine the whether study condition is associated with the hypothesized mediators over the first six months of follow-up and check for a direct effect of the mediators at 3 and 6 months on alcohol use as measured at 6- and 12-months follow-up. We will estimate the indirect effect of the intervention on alcohol use through the mediators and conduct significance testing of this effect using macros created by Preacher and Hayes.[92]*

*We will also conduct secondary analyses to examine potential moderators of treatment effects. We will specifically examine the baseline factors of injury-related/non-injury-related reason for visit, current intoxication, level of baseline severity of alcohol use/problems, and/or mental health comorbid conditions as potential moderators. In the framework described for Aims 1 and 2 above, we will test an interaction between each factor and group assignment in order to test for moderation. A three-way interaction will be used if strong time*treatment group interactions were observed in prior modeling steps. Because of the number of analyses involved, this will be clearly identified as a secondary analysis in all reporting of the study outcomes.*
We will measure and analyze dose to inform future implementation in the VHA. First, we will examine baseline factors (e.g., self-efficacy, social support, and readiness to change; psychological distress/psychiatric comorbidity, and alcohol consumption and consequences) that distinguish participants who attend no vs. any peer boosters, and among those who attend at least one session. Other variables (e.g., gender, race, age,

employment, education) will also be included in the models. Second, as an exploratory analysis, we will examine number of sessions attended as a predictor of alcohol use outcomes at later follow-up times within the sub-set of the sample randomized to the peer condition (APM). If this analysis suggests an effect of dosage, we will conduct estimate a complier average causal effect model. In this method, individuals randomized to the BA condition are compared to individuals with similar characteristics in the APM (i.e., who are expected to have attended a similar number of APM sessions had they been randomized to that condition) in order to more accurately test the effect of compliance on outcomes.

Exploratory Aim will result in the collection of structured qualitative interviews to understand barriers and facilitators of implementation of the APM intervention in the ED with a subset of participants, key stakeholders and clinical leaders.

Data Analysis for Exploratory Aim*: Interviews will be audiotaped and transcribed verbatim for content. We will conduct analyses. We will use a rapid data analysis process, a technique used when there is a need for targeted, actionable information.[93] The research team will read early transcripts independently, and, in an iterative process, meet to develop and refine the coding scheme and code definitions, including developing new codes from the data based on ongoing data analysis. We will document code definitions, data interpretation, and analytic decisions in memos. Once the research team has agreed on codes and code definitions, Drs.* Pfeiffer *and Sripada, and the research supervisor, will independently review and code transcripts, meeting regularly to compare coding results, and resolving discrepancies through a consensus process. If coding definitions are refined during this process, the coders will recode transcripts already coded. Once data are coded, we will use QSR NVivo 10 software to organize the data. The study team will meet regularly to discuss code summaries and memos, developing findings with a focus on barriers and facilitators to implementation and potential testable implementation strategies. Members of the study team have used similar methods in a study of the acceptability of peer support interventions in Michigan NG soldiers.[94,95]*

Power and Sample Size Calculations

Of *450* participants randomized, we expect that at least 80% of participants will be retained (n=*360*). *We conservatively have estimated power without accounting for methods that will allow inclusion of participants with partial follow-up data because this benefit will be off-set to an unknown degree by the additional parameters estimated in a mixed effects model.* All power analyses used G*Power 3.1.9 software and a two-sided $\alpha = .05$. We calculated power based on several potential outcome measure distributions. If a linear model is appropriate, *which we expect to be the case for the primary outcome of total AUDIT scores, we achieve 80% power to detect an effect size (Cohen's d) of 0.30. This is a relatively modest and reasonable effect size for studies of SBIRT models of alcohol brief interventions.* For an outcome with a count distribution and assuming a mean level in controls of 1 *(e.g., an average of 1 alcohol-related treatment visit in a follow-up period), we achieve 80% power to detect an incidence rate ratio of 0.75 or 1.34 under a Poisson framework.*

Dissemination and Implementation Plan

Members of the research team are well-positioned to inform VHA policy on peer-delivered alcohol BIs, and follow-up linkage to care peer-delivered protocols to link VHA patients to primary and specialty care. We are acutely aware of VHAs priorities related to substance abuse and are well-positioned to rapidly disseminate key study findings. First, we will disseminate research findings through journal publication and presentations at conferences. We will submit at least three manuscripts to peer-reviewed journals geared toward health services researchers and/or clinicians working with Veterans who have alcohol and mental health problems and submit at least one presentation per year targeting researchers and clinicians. We will also seek out opportunities to utilize VHA cyber-seminars to reach VHA researchers and clinicians. Importantly, we will directly disseminate our findings to clinicians and policy leaders within the VHA (e.g., primary care and mental providers). Because the education of peer support specialists is important to the overall uptake of study results, investigators will keep leadership apprised of study findings and work to shape training efforts, with broader dissemination in mind. To increase the likelihood of broader use across the VHA, the proposed project will use an Effectiveness-Implementation Hybrid design[47] and employ qualitative methods to identify barriers and facilitators of implementation of the intervention and the linkage to care components nationally. If the peer-delivered intervention package is found to be effective, we plan to partner with VHA leadership to identify wider implementation strategies.

Project Management Plan

Table 3: Project Timeline	Year 1				Year 2				Year 3				Year 4			
	Months				Months				Months				Months			
	0-3	6	9	10-12	0-3	6	9	10-12	0-3	6	9	10-12	0-3	6	9	10-12
Hiring and Training																

Screening																
Follow-ups																
Informant interviews																
Data analysis																
Dissemination																

Timeline. The project will take place over four years (Table 3). The first six months will be used to hire and train staff and finalize protocols. In month 7, we will begin enrollment, with follow-ups ending in month 9, year 4. Key informant qualitative interviews will occur in the first 9 months of year 4. Dissemination of findings will begin with analyses of the screening data in month 10 of year one and continue through the end of the project.

Resources: Facilities and equipment and key personnel roles. The majority of project personnel will be located at Center for Clinical Management and Research (CCMR; Drs. Pfeiffer, Bohnert, Sripada) where office space and equipment for them will be provided. The ED at the VAAAHS will provide space for peer mentors and research supervisor, with a telephone, to conduct the research assessments and to conduct the brief personalized advice protocol. Key roles are described in the budget justification. Project staff in Ann Arbor will have weekly meetings to ensure that the study is progressing well. In addition, study staff will have a 2-hour meeting once a month to discuss logistical and larger scientific issues.

Data management and safety. Dr. Pfeiffer will be responsible for the safety and security of patient-level data, stored on firewall-protected servers at CCMR. A Master's-level data manager within CCMR will conduct the initial double data entry, cleaning, linkage and analysis. The project will create a shared study folder accessed by study personnel. Once the final file is completed in year four, in accordance with current regulations articulated by the 1996 Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, private health information will be stripped with the exception of ages and dates and kept physically separate on the VA secure network with password protection.

HUMAN SUBJECTS

Risks to Human Subjects

Human Subjects Involvement and Characteristics. Data will be collected from Veterans, men and women, ages 18 years and older, recruited from the VA Ann Arbor Healthcare System (VAAAHS) Emergency Department (ED). Screening will last through the end of month 12, year 3 (30 months). Follow-up assessments will begin at the start of month 10 in year 1 and continue until the end of month 12, year 4. Key informant qualitative interviews will occur in the first 9 months of year 4. Data entry, cleaning and/or analysis will begin at the start of month 7 in year 1 and continue through the end of year 4. Dissemination of findings and report writing will begin with analyses of the screening data around month 10 of year one and continue through the end of the project.

We expect that 15% of the screened patients will have a positive screen and will be randomized, yielding 225 per group (total=450). Based on data from the study site, we anticipate the gender composition of the sample to be approximately 7.5% female and 92.5% male; we expect the following racial composition of the sample: approximately 20% African American, 75% Caucasian, and 5% other (i.e., Asian, American Indian, Native Hawaiian or Other Pacific Islander). We also expect that 1-2% of adults will identify as Hispanic ethnicity.

Inclusion criteria for screening. 1) adult Veterans age 18 years of age or older presenting for care in the VAAAHS ED; 2) medically stable and able to provide informed consent.

Inclusion criteria for the RCT. Individuals will be eligible to participate in the RCT if they: (1) have an AUDIT-C score of 4 or more for men and 3 or more for women in the prior 3 months, indicating that they meet criteria for hazardous use (NIAAA 2005; World Health Organization); 2) a telephone and/or the ability to provide information about individuals who can help contact the participant. Importantly, the study will include those with more severe problems to address the problems and needs of Veterans who can most benefit from linkage to primary and secondary care. The more severe users will receive content that actively encourages treatment initiation.

Exclusion criteria for screening. (1) patients who do not understand English; (2) prisoners; (3) current or recent substance use treatment in past 3 months; (4) patients currently in or having received peer services in the past 3-months per medical record; (5) pregnant women; (6) patients deemed unable to provide informed consent as stated above; and (7) profound psychotic symptoms and/or cognitive deficits that would prevent patients from understanding the content of the intervention and/or assessments.

It has been our experience that some patients are unable to provide informed consent on entry to the ED (e.g. psychotic symptoms; acute intoxication) but that their status will improves sufficiently prior to ED discharge to make them eligible to be approached by research staff. Participants may be excluded at the discretion of the Principal Investigator based on participant or study staff best interest (e.g., if participant should become physically or verbally aggressive towards study staff, or if the study staff know a patient or their family

personally, in order to fully ensure participant privacy).

Exclusion Criteria for RCT. (1) individuals currently active in or having recently completed alcohol or other substance abuse treatment in the past 3 months; (2) patients currently in or having received peer services in the past 3-months per self-report screening.

After providing written informed consent to participate in the RCT component of the study, completing the baseline assessment, eligible participants will be randomized into Alcohol Peer-Mentored (APM) Intervention condition or the Brief Advice (BA) condition. Participants in both conditions will receive brief personalized feedback advice from an ED clinician or the peer mentor. For those in the APM condition, following the brief advice session, the peer will set up the first post-ED contact with the participant. All participants in both conditions will receive a community and VA resource guide covering health care and community assistance options.

All participants who choose to participate in the study will complete a baseline assessment and three additional follow-up assessments (i.e., 3-, 6-, 12-months post baseline).

Sources of Research Material. Data will be obtained by means of interviews and self-report inventories specifically for research purposes. Primary sources of data for this study will be gathered from an initial eligibility screening assessment, baseline assessment, and follow-up assessments (i.e., 3, 6, and 12 months post baseline). To supplement self-report measures, we will abstract VA records for health services information such primary care visits, substance abuse treatment, outpatient mental health service utilization.

Potential Risks. There is a minor potential risk for breaches of confidentiality with assessment data. The risk of a violation of confidentiality exists because human participants will be disclosing personal information, both in assessments and intervention sessions. This risk is related to the damage that could be caused by an inadvertent release of sensitive information (e.g., psychiatric symptoms, substance use, etc.). Our research team has considerable experience in maintaining the confidentiality of study datasets and will have procedures in place to ensure data confidentiality. (See details of protections below) All investigators have completed training in the requirements for handling protected health information as outlined by the Health Insurance Portability and Accountability Act (HIPAA). Participants will be informed of the procedures taken to protect their confidentiality. The focus of this study is not on child abuse or intention to harm others. However, because of the nature of the study (hazardous drinking and/or dependence) these issues may arise. The consent form will contain a statement explaining mandatory reporting requirements for information regarding child abuse and intention to harm self or others prior to participating in the study.

There is also a slight risk of psychological discomfort to study participants as a result of being asked personal questions, particularly during the assessments. Participants may also become anxious or upset during discussions about hazardous drinking that occur during the ED-based RA or peer delivered brief advice session and during the continuing peer mentoring intervention. Study staff will be trained to respond to this emotional distress and to refer participants to appropriate resources as necessary. All participants will be free to terminate the assessments at any time or refuse to respond to any questionnaire item.

There is a small risk that the intervention might upset participants. The project will utilize a standardized intervention content, with includes motivational, supportive, nonjudgmental language targeting behavior changes. The peer interactions are designed to be collaborative and avoid the use of any statements that could be perceived as coercive by participants. It has been the experience of the project's investigators that these approaches dramatically diminish risks to participants from the study's intervention. Still, unexpected events are always possible in intervention research. The investigators of this project will establish protocols for study staff to guide them in responding to crisis or potentially harmful situations.

Adequacy of Protection against Risks

Recruitment and Informed Consent. All eligible patients will be approached (after verifying record that the patient is sufficiently stable) by the research staff and recruited for the screening portion of the study. Those interested in participating in the study will complete a Mini-Cog standardized assessment to screen for cognitive impairment. If appropriate to move forward, they will be informed of the general nature of the survey and study, what their involvement entails, the risk/benefits, and limitations to confidentiality. As part of the informed consent process, patients will be able to describe to the research staff the essential elements of the study for which they are providing consent. Patients who are notably sedated or confused at the time of screening will be re-approached later in their ED stay if they are still interested. The study team has found that this protocol has worked well for recruitment in other ED-based alcohol studies. All participants will be told that participation is voluntary, that they can withdraw at any time, and that this will not impact their VHA care. The limits of the NIH Certificate of Confidentiality will be explained in the written consent form, but study staff will

also verbally explain the limits of confidentiality. When providing written informed consent, participants will be given a copy of the consent form and the original will be filed in a confidential research file.

Protections Against Risk. Several steps will be taken to minimize the risk of breaches of confidentiality. First, every effort will be made to ensure that study data are always confidential, in terms of staff training and data storage, so that data forms cannot be linked to a particular person except through the study cross-walk file that is securely stored and password protected inside the VA network. Training of staff will include information about the importance of confidentiality and techniques to maintain confidentiality of all information reported by research participants.

Risks will be discussed with individuals choosing to participate as part of the informed consent process. Throughout the study, VA IRB and HIPAA guidelines will be followed to ensure privacy of patient data. Unique identification numbers will be assigned to all participants who complete the assessments. The participant code will appear on assessment forms. All data forms and assessments will be coded with this number, rather than with a name. Participants' names and other identifying information will be kept separately from study data on password-protected files on a secure server with restricted access and/or in a locked cabinet in a locked room; and only participants' unique ID number will be kept in the database on password protected file. All research data will be presented in aggregate form only. Additionally, we will apply for a Certificate of Confidentiality from the NIH to protect the confidentiality of our participants.

Because there is a small risk that participants may experience some distress or psychological discomfort when answering assessment questions, participants will be made aware of their right to refuse to answer any questions that make them uncomfortable or that they do not wish to answer, and they will be informed of their right to withdraw from the study at any time without penalty. Participants may also be informed that they can take breaks. Additionally, study staff will be trained extensively to respond to emotional distress and to discuss concerns and issues should they arise. More specifically, study staff will be trained to perform attentive and empathic listening. To minimize this risk, research staff will be available during and following participation in the intervention condition and during assessments to manage (i.e., discuss and refer as needed) any unexpected issues that may arise. It has been the experience of the project's investigators that these approaches dramatically diminish risks to participants from the study's intervention.

It is possible that some participants will report levels of suicidal thoughts and plans that will require further intervention. We will have a detailed suicide risk assessment protocol and, if research staff determines that a participant is at acute suicide risk, we may ultimately need to inform treatment staff at the VA. Research staff, in consultation with Drs. Pfeiffer or Sripada will evaluate if the participant is at acute risk of suicide based on the presence of a coherent plan and a desire to act. For individuals that trigger the need for a suicide assessment, the study coordinator will inquire about plan, severity, and risk factors. Drs. Pfeiffer or Sripada will be contacted for individuals that are at high risk (i.e. distinct and/or immediate plan to harm oneself). The study physician will make a decision about appropriate next steps, including the need for emergency or follow-up evaluation, requesting the participant to contact a family member or friend, contacting facility/hospital staff member (i.e., psychiatrist on call, participant's provider) before the study staff leaves the location, performing a warm handoff.

Potential Benefits of the Proposed Research to Human Subjects and Others

It is believed that research participants may be helped in a number of ways. All participants will be assessed for alcohol use, progress toward cutting down/stopping and seeking primary or specialty care, as needed. Participants randomized to the APM condition will receive a single-session intervention in the ED aimed at addressing perceived barriers and facilitators cutting down/stopping alcohol use and seeking primary or specialty care. They will also work with the peer to set up the first at least 6 contacts over the next 2-month period to facilitate care seeking and changes in alcohol use. All participants will receive written materials that include VA and community resources encouraging them to seek primary and specialty care, if needed. Others may also benefit from this research. If efficacious, implementing a brief and effective peer-delivered alcohol intervention with ongoing structured peer mentorship can be rolled out nationally in the VHA and can have a significant and substantial impact on alcohol use and consequences. This study has the potential to enhance service delivery to Veterans experiencing alcohol problems, and to assist with coping during a potential crisis in the future, while posing few physical risks beyond those associated with usual care. In sum, the potential benefits for the research far outweigh the risks to participants.

Importance of Knowledge to Be Gained

Reducing alcohol problems is an urgent imperative within the Department of Veterans Affairs. There is a clear need to link individuals with more serious alcohol problems to available VA resources that can improve their mental and physical health outcomes. Despite significant investment in alcohol screening and

brief interventions in the VHA, many high-risk Veterans are not utilizing needed services and/or changing alcohol use patterns. This study is one of the first attempts to directly test the effect of peer-delivered alcohol interventions with post-ED peer mentorship to link with and engage in VA primary and specialty care. More so, this RCT will evaluate the feasibility and effectiveness of a low-cost and easy-to-deliver intervention designed to encourage the use resources. Developing this peer mentorship intervention has the potential to have a significant and substantial impact on the Veterans with more serious alcohol problems treated in the VHA and could be modified and exported to other populations and settings.

Inclusion of Women and Minorities

The study is open to participants of any racial or ethnic background. We will recruit any eligible Veteran who provides informed consent, regardless of race, ethnicity, or gender. We expect the study population to reflect the racial, ethnic, and gender distribution of Veterans seeking care in the Ann Arbor VHA ED. Every effort will be made to recruit racial minority patients and women. Representation of those groups will be monitored throughout the project and if it appears they are underrepresented among participants, significant efforts will be made to boost their enrollment.

Inclusion of Children

Children under the age of 18 are not included in this study, as they are not approved to be in VA-approved research.

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