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14. ABSTRACT

Reducing suicide risk among active duty soldiers and Veterans is a national priority. Because substance use disorders (SUDs) are key risk factors for both fatal and non-fatal suicidal behaviors, SUD treatment program staff are in frequent contact with high-risk individuals. However, no data exist on the efficacy of suicide-specific interventions conducted in SUD
Treatment. The proposed research study addresses this gap by testing the efficacy of a targeted intervention designed to reduce suicide risk in Veterans treated for SUDs.
The primary objective of this study is to evaluate the impact of a Cognitive Behavioral Therapy (CBT) intervention compared to a Supportive Psycho-education Control (SPC) condition on subsequent suicidal thoughts and behaviors in Veterans with SUDs. Participant follow-ups

15. SUBJECT TERMS

Suicide, Veterans, Substance Use Disorders

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1. INTRODUCTION

The evaluation of strategies to reduce suicide among former members of the US armed forces is of high public health significance. Previous research has found that substance use disorders (SUDs) are key risk factors for both fatal and non-fatal suicidal behaviors. Because of this, SUD treatment program staff are in frequent contact with high-risk individuals. However, no data exist on the efficacy of suicide-specific interventions conducted in SUD treatment. Testing an intervention for use with suicidal Veterans seen in intensive outpatient SUD treatment programs within various Veteran Affairs Medical Centers (VAMCs) has the potential to significantly improve functioning and well-being, and decrease the substantial loss of life in Veterans with SUDs due to suicide. The overall purpose of this project is to adapt and evaluate the impact of a Cognitive Behavioral Therapy (CBT) intervention compared to a Supportive Psycho-education Control (SPC) intervention on subsequent suicidal thoughts and behaviors in Veterans with SUDs. The study has two primary components: (a) refining the intervention content for use in Veterans Health Administration (VHA) patients and (b) conducting a multisite randomized controlled trial (RCT) with 300 participants to examine the efficacy of this individual CBT intervention in reducing suicidal thoughts and behaviors in VHA patients receiving treatment for a SUD over a 2-year follow-up period.

2. KEYWORDS

Suicide, Suicidal Thoughts, Suicide Attempts, Substance Use Disorders, Alcohol Dependence, Drug Dependence, Addiction, Veterans, OEF/OIF

3. ACCOMPLISHMENTS

- *What are the major goals and objectives of the project?*

The project is a fully-powered randomized controlled trial (RCT) of a Cognitive Behavior Therapy for suicide prevention (CBT-SP) intervention versus the Supportive Psychoeducational Control (SPC) intervention for 300 suicidal Veterans seen in SUD Intensive Outpatient treatment at various VHAs to examine changes in suicidal thoughts, non-fatal attempts, substance use and depression for two years post-intervention. The specific aims are to: (1) compare CBT-SP and SPC in reducing the frequency and intensity of suicidal thoughts at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) compare CBT-SP and SPC in decreasing the likelihood of suicide attempts at 1-, 3-, 6-, 12-, 18-, and 24-months. The secondary aims are to (1) compare the CBT-SP condition to the SPC condition in the frequency of illicit drug use, alcohol use, nonmedical opioid medication misuse, self-efficacy to avoid suicide and depressive symptoms at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) examine whether OEF/OIF status moderates the effect of treatment assignment (CBT-SP vs. SPC) on post-treatment suicidal thoughts, behaviors and substance use.

For this study, patients were approached for participation and provided written consent to participate in the study. Participants were screened for current suicidal ideation and other conditions by completing a self-report survey questionnaire. Eligible participants (N = 300 across all sites) provided an additional written consent and completed a baseline assessment which included a self-report survey questionnaire, a research staff administered interview, and a voluntary urine drug screen. Participants were randomized to either the CBT-SP or SPC intervention condition. Both conditions involved receipt of 8 one-on-one sessions lasting approximately one hour over a period of approximately 4-6 weeks in addition to their standard SUD outpatient treatment they may be receiving at the VAMC. Participants were re-assessed immediately after receiving the study intervention (at 1-month post-enrollment) and then again at 3-, 6- 12-, 18-, and 24-months post- enrollment. These follow-ups occurred in person, were approximately one hour in length, and consisted of a series of self-report surveys, researcher administered interviews, and a voluntary urine drug screen. To ensure adequate monitoring of suicidal ideation, additional follow-up assessments occurred 2-, 4-, and 5-months post-enrollment over the phone and were shorter in length (approximately 10 minutes. Data is collected by means of interviews and self-report questionnaires specifically for research purposes.

The study timeline below (Table 1) outlines and establishes the specific performance expectations that will be met at each stage of the study. These steps are essential to ensure the successful completion of the proposed randomized controlled trial of a Cognitive Behavioral Therapy (CBT) intervention versus a Supportive Psychoeducational Control (SPC) to reduce suicidal thoughts and behaviors in Veterans with Substance Use Disorders (SUDs). In December of 2018, we received a project modification to include a 12-month No Cost Time Extension to continue data collection in order to adequately accomplish our project aims, therefore Year 6 has been added to the timeline. In December 2019, we received a second project modification to include an additional 12-month No Cost Time Extension to complete data collection and analyses. These additions have been added to the timeline to represent the work to be completed.

Table 1. Study Timeline and Scope of Work

	Years						
	1 2014	**2 2015**	**3 2016**	**4 2017**	**5 2018**	**6 2019**	**7 2020**
Domain 1: Project start-up							
Task 1: Hire project staff							
Task 2: Refine intervention manuals for military Veterans							
Task 3: Create study binders (ex. regulatory, training, etc.)							
Task 4: Refine risk management procedures							
Task 5: Modify study measures for all assessments							
Task 6: Obtain Human Subjects and Research and Development approval							
Task 7: Obtain Certificate of Confidentiality							
Task 8: Train CBT and SPC therapists at all sites							
Task 9: Train all staff in research protocols and risk management							
Task 10: Assemble Data Safety and Monitoring Board							
Domain 2: Conducting the randomized controlled trial							
Task 1: Recruit, consent and screen potentially eligible participants							
Task 2: Randomize 300 participants to either CBT or SPC conditions							
Task 3: Collect baseline assessment data							
Task 4: Provide clinical supervision for study therapists							
Task 5: Conduct 1-month follow-up assessments							
Task 6: Conduct brief 2-month follow-up assessments							
Task 7: Conduct 3-month follow-up assessments							
Task 8: Conduct brief 4- and 5-month follow-up assessments							
Task 9: Conduct 6-month follow-up assessments							
Task 10: Conduct 12-month follow-up assessments							
Task 11: Conduct 18-month follow-up assessments							
Task 12: Conduct 24-month follow-up assessments							
Task 13: Conduct chart abstractions							
Task 14: Modify and maintain regulatory binders							
Task 15: Conduct regular Data Safety and Monitoring Board meetings							
Domain 3: Data cleaning, management and analysis							
Task 1: Develop and maintain computerized assessment tool							
Task 2: Create and maintain participant tracking databases							
Task 3: Conduct regular data quality checks							
Task 4: Conduct cleaning and recoding of data							
Task 5: Code tapes of CBT and SPC conditions for assessments of fidelity							
Task 6: Conduct analyses of study data							

	Years						
	1 2014	2 2015	3 2016	4 2017	5 2018	6 2019	7 2020
Domain 4: Project reports and dissemination of findings							
Task 1: Submit regular progress reports							
Task 2: Conduct professional presentations and submit manuscripts							
Task 3: Translate and reformat manual for broader distribution							
Task 4: Submit final report							

- *What was accomplished under these goals?*

General project overview

During this sixth year, our main objectives, activities, and accomplishments have focused on continuing primary data collection through the completion of follow-up assessments, preparing data for analyses, and disseminating information about the project at national and international conferences. We continue to meet regularly as a team to ensure that all study activities and objectives are being achieved. We have focused our attention during this sixth year on completing follow-ups with study participants and entering and coding data to prepare for analyses. All study sites have diligently tracked follow-up progress for each time point throughout this sixth year and continue to strive to achieve a high follow-up rate at each time point. Throughout this year, all study staff continued to receive thorough trainings on how to identify, monitor, and manage emergencies involving risk to participant safety. We continue to monitor participant safety throughout all parts of the study and continue to notify our Research Monitor when issues arise. We have collaborated closely across study sites to ensure successful completion of a wide array of study-related tasks. We continued weekly project meetings between the Michigan site (e.g., Ann Arbor) and the sites in Colorado (e.g., Colorado Springs and Denver), via phone and/or e-mail and have added regular supervision meetings across sites. During this reporting period, we have also met in person several times in order to discuss issues related to data management and analysis in order to develop a collaborative process to ensure data is consistently entered and coded across sites. These meetings have also included discussions of strategies related to study management, including data related issues (e.g. the management and transferring of data, including where and how the data may be stored, creating a shared drive for communication between sites, creating and finalizing study measures, and the creation of the study databases), necessary budgetary adjustments for the revised study timeline and risk management.

In January 2019, the Principle Investigator, project coordinator and data manager traveled to Colorado for a site visit. The purpose of the visit was to review data questions, standardize data decisions, and review study files. As part of the data review and cleaning process, during this reporting period we have focused on compiling and reviewing screening, baseline, and therapy session data. We have begun to analyze aspects of these datasets to submit as abstracts for presentation at various national and international conferences. A focus has also been on examining participant feedback from the therapy sessions and revising the treatment manuals based on participant feedback, therapist feedback, and input from project consultants. A cursory analysis of participant feedback data indicates that participants found the sessions helpful and were able to provide feedback on aspects of the treatment they found the most helpful, and those pieces they found not helpful. Also, in January 2019 the Data and Safety Monitoring Board (DSMB) reviewed the bi-annual project report and reviewed project enrollment and retention, safety monitoring (including participant hospitalizations), adverse events tracking, protocol deviations, and unanticipated events since initiation of recruitment. The Board did not identify any patient safety concerns based on their review of the provided materials and recommended unconditional approval of the study.

In April 2019, the Principle Investigator and project coordinator traveled to Colorado for a site visit. The purpose of the visit was to review data questions, standardize data decisions, review study files, and strategize about budgeting for the remaining study period. Staff across sites continue to work together to

standardize and streamline data entry processes. Updates on data entry progress are provided by the data manager to the project manager on a daily basis, and any issues that arise are communicated with the study team as needed. Additionally, in April 2019 project staff presented at the 52nd Annual American Association of Suicidology Conference in Denver, CO. Staff presented information and data regarding our Supportive Psychoeducational Control Condition that was utilized as the attention-matched active control for our study. This presentation included information obtained from participant feedback following the study sessions and provided insights as to the main components of the session the participants found helpful. The presentation was well-attended and well-received by conference attendees. Since this presentation, we have shared information on our control condition with fellow suicide research colleagues interested in implementing a similar condition in their trials.

In May 2019, the project PI presented at the Military Operational Medicine Research Program In-Progress Review for Suicide Research and gave an update on the status of the project. Information presented included final recruitment numbers and information regarding baseline demographics and clinical characteristics of our study sample. Therapy session attendance rates as well as overall study retention rates for follow-up time points were also shared as part of the presentation. We received positive feedback from the panel who stated they were impressed with the design of the study and our high recruitment and retention rates.

In June 2019, we held a Data and Safety Monitoring Board meeting at the University of Michigan. Three of four Board members were present for the meeting. During the meeting, Dr. Ilgen (PI) provided an overview of the study design and protocol. The project coordinator provided an overview of the DSMB report which included study timeline, enrollment and retention tables, recruitment and retention flow chart, SAE/AE/UAP tables, and preliminary data. The DSMB report included information through June 1, 2019 and included enrollment and retention and safety monitoring. During this period, there were 0 serious adverse events, 0 protocol deviations, and 0 unanticipated events that required reporting to local IRBs or HRPO. The board members reported that they had no major concerns based on the report. The board discussed the results of the internal randomization audit that was conducted by study staff, and they reported no concerns regarding the outcome of that audit. The board members discussed the number of deaths and hospitalizations across sites and the potential reasons for differences in the number of events reported at each site. A recommendation was made by the board to extract hospitalization data from participant medical records to supplement patient self-report on these phenomena, which the study team will work towards during the next reporting periods.

Throughout this reporting period, project staff have participated in several national and international conferences to begin dissemination of study information. In August, 2019 project staff presented at the Military Health System Research Symposium in Kissimmee, FL. Staff presented both an oral presentation and a poster at this conference. The poster presentation focused on reporting results from the screening sample on the association between sleep disturbance, alcohol use, and suicidal ideation in Veterans receiving Substance Abuse Treatment at the VA. Our analysis found that 65% of our screening sample reported experiencing sleep problems within the past month, suggesting that disordered sleep is quite common among those presenting for SUD treatment. Participants who reported experiencing sleep problems were significantly more likely to report experiencing suicidal ideation in the two weeks prior to enrolling in SUD treatment. Those who reported experiencing sleep disturbances were also significantly more likely to report being current heavy drinkers, endorsing drinking 6 or more drinks per day for men, and 4 or more drinks per day for women when compared to participants who were not experiencing sleep problems. In addition to the poster presentation, study staff gave an oral presentation at the conference on the association between lifetime trauma exposure and suicide risk. This presentation, also on data collected from our screening sample, focused on the well-documented relationship between substance use disorders and trauma, and examined how PTSD symptoms, as well as substance use, can lead to an increased risk in suicidal ideation and behaviors. Our data suggested that the exposure to traumatic lifetime events within this sample was extremely high (with 91% of the sample reporting directly experiencing at least one traumatic event in their lifetime), with the most prevalent traumas endorsed among this sample include physical assault, transportation accident, assault with a weapon, combat or exposure to a war-zone, and life-

threatening illness or injury. Participants who reported experiencing traumatic events were significantly more likely to report adverse outcomes such as higher prevalence of current suicidal, and more severe current PTSD symptoms when compared to those who reported no direct trauma exposure. In addition, those who reported moderate or severe trauma exposure were more likely to endorse using marijuana, amphetamines, and misusing prescription sedatives than those who reported no trauma. Certain demographic characteristics were also associated with more trauma exposure: those who reported more trauma exposure were more likely to be younger in age, married or cohabitating, and were more likely to report being homeless at some point in their lifetime. Those participants who identified themselves as African American were less likely to report moderate or severe trauma exposure relative to those who self-identified as White. Both the poster and the presentation were well attended, and study staff received positive feedback regarding the presentation content.

Study staff attended and presented at the 2019 VA/DoD Suicide Prevention Conference in Nashville, TN in August 2019. One presentation focused on the process of measuring and coding data obtained through the Columbia Suicide Severity Rating Scale (C-SSRS). The goal of this presentation was to understand the pros and cons of using the Columbia Suicide Severity Rating Scale (C-SSRS) in clinical research and to learn about a standardization process used to categorize suicidal behaviors. This presentation outlined the Columbia case consultation meetings that have occurred throughout the project in which study staff, including investigators, review all study assessments in which the C-SSRS is administered. These meetings focus on clinical discussions regarding the data collected and making consistent coding decisions to ensure that all data are accurately represented according to our decision guidelines. We have found these meetings to be extremely helpful in providing continuity across sites in administration of this crucial study measure. Through these meetings, we have produced a threshold table, which delineates between categories of suicidal behaviors for over 20 different methods. We also created a list of decision rules that apply to coding procedures in an effort to maintain consistent decision making across events. The second presentation focused on highlighting participant feedback gained from the intervention sessions. The goals of the presentation were to describe the CBT-SP intervention, to examine patient feedback on CBT-SP during and following treatment completion, and to understand, from a patient's perspective, the components of CBT-SP that are helpful in reducing suicidal thoughts and behaviors. Both presentations were well-received, and the study team has received requests for additional information following each of the presentations from colleagues in the field.

In September, 2019, study staff also attended and presented at the 30th World Congress of the International Association for Suicide Prevention in Derry, Northern Ireland. This international conference included 2 oral presentations from study staff, including a presentation that described how we were able to achieve highly reliable coding of the C-SSRS through our Columbia meetings. At each session, the C-SSRS was administered to staff presenting a mock patient case. Cases were designed to encapsulate the typical level of complexity in the population. Raters scored C-SSRS items independently using the thresholds. Ratings were then compared, and agreement for each item was assessed. Interrater reliability was calculated using total percent agreement among all raters per session. Overall, reliability was high, with percent total agreement across sessions reaching 93.2% (range 85.1%-99.0%). The suicidal ideation section had the highest agreement (96.9%), while the lethality section had the lowest (87.4%). Categorizing suicidal behaviors also remained high at 91.3% agreement. The second presentation focused on examining the mechanisms of action that contributed to participant enjoyment of the CBT-SP intervention sessions. Data regarding session completion and participant satisfaction for the CBT-SP sessions were presented, highlighting the fact that 69.3% completed all 8 CBT-SP therapy sessions. Participants who attended fewer than 8 sessions were significantly more likely to be of younger age, have prior combat experience, and report more intense suicidal ideation over the past month. Overall, participants responded positively to the CBT-SP treatment, with 70.8% reporting an increase in their mood immediately following the session. Participants receiving CBT-SP reported participating actively in the sessions, feeling comfortable discussing issues around suicide with their therapist, and feeling better about themselves following treatment. Participants reported specific components of CBT-SP as helpful including the Hope Kit, Coping cards, homework/handouts, breathing exercises, and Safety Planning. While most feedback was positive, patients also identified difficulties with the treatment related to discussing emotionally distressing topics.

During this reporting period, we also began the process of conducting fidelity reviews of therapy sessions. Through this process, we have been reviewing recorded sessions to provide ratings regarding adherence to the session content provided in the manuals, as well as how well the therapists delivered the therapy. While this process of reviewing session recordings has been ongoing throughout the study by the clinical supervisor, those ratings were utilized for therapist training and feedback and will not be utilized as official fidelity ratings. Fidelity will be conducted by independent study raters to reduce any potential biases. During this reporting period, therapy raters have participated in weekly meetings with clinical supervisors and other study team members in order to learn the intricacies of the intervention condition. Training on the intervention has included a review of study manuals and listening to recordings of study therapy sessions. Fidelity ratings will continue into the next reporting period.

Establishing a high-quality dataset has continued to be a priority during this reporting period. We continue to work with our data manager and staff across sites to monitor data completion, entry, and cleaning processes. As part of the data review and cleaning process, during this reporting period we have focused on compiling and reviewing screening, baseline, and therapy session data. A focus has also been on examining participant feedback from the therapy sessions to include in presentations and revising the treatment manuals based on participant feedback, therapist feedback, and input from project consultants. We continue to focus on achieving high retention rates for all follow-up time points as the study progresses. During this reporting period we have focused on increasing our retention rates across all sites by implementing different strategies in reaching participants. We have had some success in reaching participants through increasing our contact efforts. As always, we continue to monitor participant safety throughout all parts of the study and continue to notify our Research Monitor when issues arise. We collaborate closely across study sites to ensure successful completion of a wide array of study-related tasks. We continued regular project meetings between the Michigan site (e.g., Ann Arbor) and the sites in Colorado (e.g., Colorado Springs and Denver), via phone and/or e-mail.

Please note: Since the project is still actively completing follow-up assessments, data collection, data entry, and data cleaning are ongoing at this time. Any data presented below should be considered preliminary in nature. Data on primary and secondary outcomes will be available following the completion of all data collection.

Study recruitment

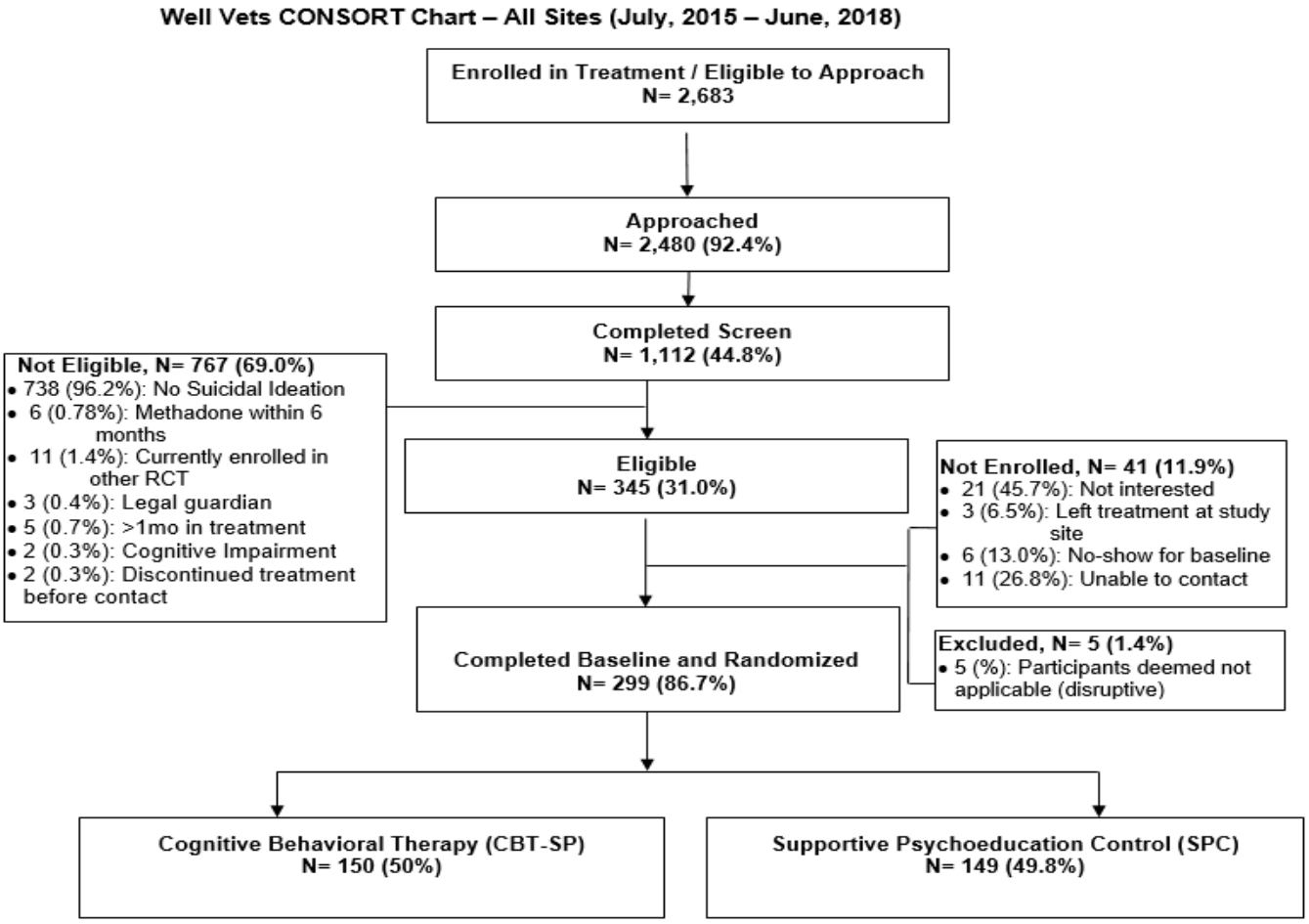
Figure 1 provides the CONSORT diagram for study recruitment and enrollment across all sites. In summary, study recruitment and enrollment began in July, 2015 and was completed in June, 2018. Although recruitment began later in the project than anticipated, and we encountered many challenges at the study sites with patient flow and availability, we were able to enroll our full projected sample of 300 Veterans into the study in just under 3 years, which was the recruitment timeframe originally outlined in our proposal and Statement of Work.

Participants were recruited from outpatient substance use treatment clinics (both intensive outpatient and standard outpatient) located within the VA Ann Arbor Healthcare System (which included recruitment clinics at the Ann Arbor VA Main Hospital and the Toledo Community-Based Outpatient Clinic in Toledo, OH), and the VA Eastern Colorado Healthcare System (which included recruitment clinics at the Denver VA Main Hospital [now the Rocky Mountain Regional VA Medical Center] and the Colorado Springs Community-Based Outpatient Clinic [now the PFC Floyd K. Lindstrom Department of Veterans Affairs Clinic]). This study had a two-step enrollment process. First, participants were approached by research staff for participation in the screening portion of the study (Part I), which involved completing a self-report questionnaire to collect data on relevant topics and to screen for study trial eligibility. Participants who provided written information consent prior to completing the screening survey were considered enrolled in Part I of the study. Enrollment numbers for Part I of the study are presented in the CONSORT Chart (Figure 1) and described below. Following the completion of the screening survey, participant responses were reviewed by a research staff member at the study site to determine eligibility for the RCT (Part II). Eligible participants were informed of their eligibility status and were provided with

information about Part II of the study. Participants who were eligible, interested, and signed a written informed consent document were considered enrolled into the RCT (N=300). During one baseline assessment, research staff at one of the study sites determined a consented participant was no longer eligible for participation due to an increased level of psychosis exhibited during the interview. Research staff concluded the assessment following the administration of the interview and the participant was withdrawn from the study at that time. Because of this, this participant was not randomized to receive a condition, and therefore the total number of participants randomized and included in subsequent data analyses will be 299.

In total, 2,683 patients presented for treatment at the recruitment clinics during the recruitment period. Of those patients, research staff approached 92.4% (n=2,480) for participation in Part I of the study (screening survey). For those patients who were not approached, reasons included staff missing the patient appointments, patients not being engaged in treatment (e.g. patients attending only the intake appointment at the treatment clinic, but did not return to receive follow-up care), patients being under the care of a legal guardian and therefore ineligible to be approached to provide informed consent, or other reasons including being hospitalized or intoxicated during the intake appointment and subsequently not returning for care at the treatment clinic. Forty-nine percent of the patients (n=1,217) approached by study staff agreed to participate in Part I of the study and signed the informed consent document. Of those participants, 105 (8.6%) did not complete the screening questionnaire for various reasons (e.g., not enough time, no longer interested in participating, failure to return the screening packet to study staff, etc.) which produced a total screening sample of 1,112 participants who provided data to determine eligibility for Part II of the study. Of this final screening sample, 91.9% were male (n=1,022) and the mean age was 48.5 (SD = 13.0) years old. Of those participants, 345 participants (31.0%) met eligibility criteria for Part II (the RCT). For those who were not eligible, reasons included no current suicidal ideation (n=738, 96.2%), receiving Methadone for the treatment of a substance use disorder within the previous 6 months (n=6, 0.8%), concurrent enrollment in another randomized controlled trial at the study site (n=11, 1.4%), participant report of a legal guardian (n=3, 0.4%), being in treatment at the study site for longer than 1 month, therefore not being considered within a new treatment episode (n=5, 0.7%), exhibiting cognitive impairments (n=2, 0.3%), and discontinuing treatment at the study site (n=2, 0.3%). Of the participants eligible for the RCT, 5 participants (1.4%) were excluded by the research team prior to approach for Part II of the study. These participants were excluded based on PI discretion for reasons surrounding either participant appropriateness for the RCT (e.g. evidence of psychosis) or for staff safety concerns (e.g. participant history of violent or disruptive behavior towards staff). Three hundred participants were enrolled into the trial and were administered a baseline assessment. The main reason a potential participant was not enrolled into the full trial was due to a lack of interest in participating (n=21, 45.7%). Other reasons included leaving treatment at the study site before research staff contact could be made (n=3, 6.5%), not attending a scheduled baseline assessment at least 3 times (n=6, 13.0%), and being unable to be reached to schedule an appointment by research staff given the contact information provided (n=11, 26.8%). As noted previously, one participant was excluded after enrollment and therefore 299 participants (86.7% of those eligible) were randomized to receive one of the two study conditions.

Figure 1. Well Vets CONSORT



In Figure 2, recruitment and enrollment totals for each site are depicted. In total, 150 participants were enrolled and randomized from Ann Arbor, which equates to 50% of the total sample. Denver enrolled a total of 91 participants into the RCT which equates to 30.3% of the total sample. Only 90 of the 91 were randomized at the Denver site. The Colorado Spring site enrolled and randomized 19.7% of the total sample, or 59 participants.

Figure 2. Study enrollment progress by study site.

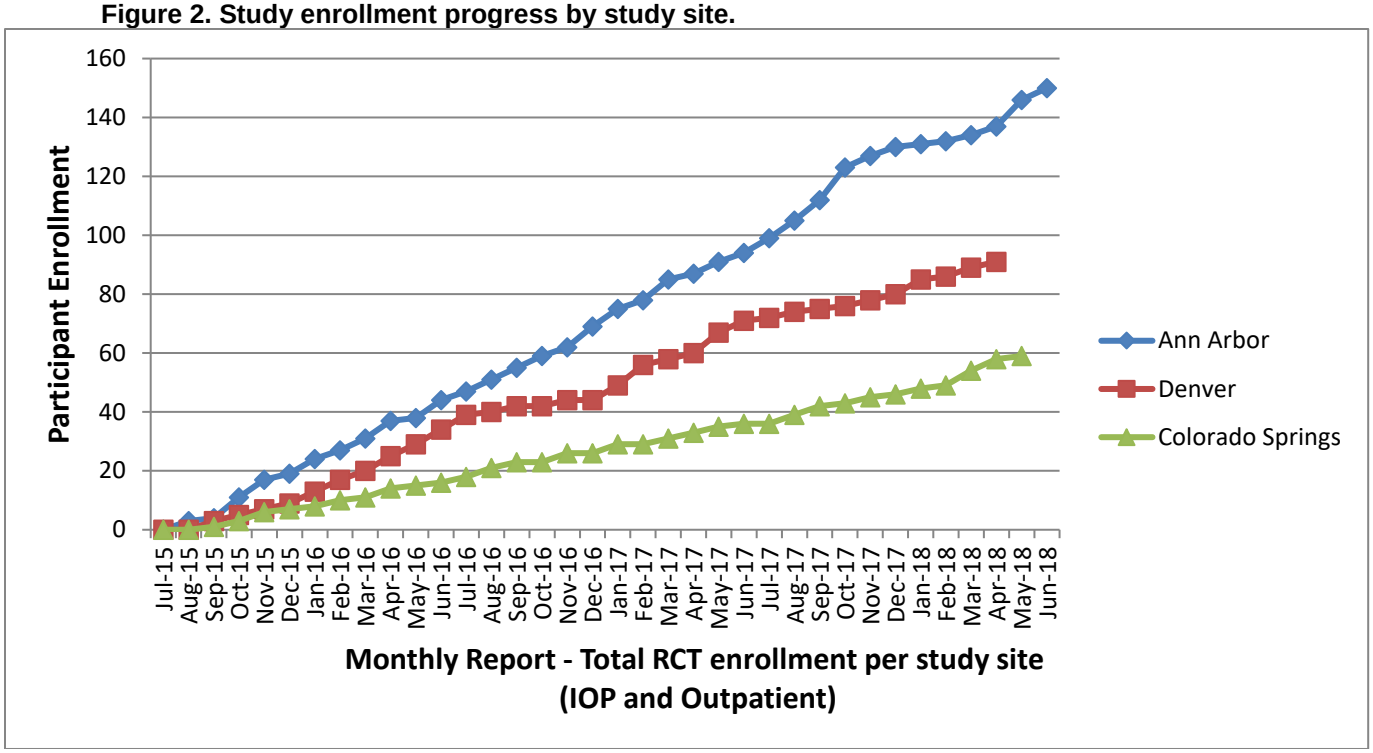


Table 2 below provides preliminary demographic information for the screening sample (n=1,112). Data is presented for each site individually and across all sites (total). Tables 3, 4, and 5 provide preliminary information for the RCT sample (n=299) including baseline demographic characteristics, military history, and clinical characteristics. Despite differences between sites occurring in the screening sample, as hoped, we did not detect any significant differences between conditions in terms of basic demographic characteristics, or important clinical characterizes that may have suggested improper randomization. Assignment to condition appears, according to this data, to have been equal based on demographic and clinical characteristics.

Table 2. Screening Characteristics – Demographics, Total and by site

	Total	Ann Arbor	Denver	Colorado Springs
N	1112 (100%)	669 (60%)	302 (27%)	141 (13%)
Demographics				
Age (yr.) (mean, SD) [A]	48.5 (13.0)	48.3 (13.5)	50.4 (12.1)	45.5 (12.2)
Male gender	1022 (92%)	619 (92%)	273 (90%)	130 (92%)
Hispanic ethnicity [A]	109 (10%)	31 (5%)	49 (16%)	29 (21%)
Race group [A]				
White	719 (65%)	468 (70%)	163 (54%)	88 (62%)
African-American	241 (22%)	148 (22%)	76 (25%)	17 (12%)
More than one race, or other race	152 (14%)	53 (8%)	63 (21%)	36 (25%)
Ever been homeless - yes [A]	567 (51%)	301 (45%)	181 (60%)	85 (60%)
Military service history				
Service Era [A]				
OEF/OIF/OND	403 (36%)	250 (37%)	84 (28%)	69 (49%)
All other eras	709 (64%)	419 (63%)	218 (72%)	72 (51%)

Table 3. RCT sample characteristics – Demographics, Total and by condition

		Condition	
	Total	SPC	CBT
N	299	149 (50%)	150 (50%)
Demographics			
Age (yr.) (mean, SD)	45.5 (12.1)	45.3 (12.1)	45.7 (12.1)
Male gender	270 (90%)	134 (90%)	136 (91%)
Domestic status: Married/cohabitating	76 (25%)	36 (24%)	40 (27%)
Hispanic ethnicity	44 (15%)	27 (18%)	17 (11%)
Race group			
White	197 (66%)	94 (63%)	103 (69%)
African-American	54 (18%)	33 (22%)	21 (14%)
More than one race, or other race	48 (16%)	22 (15%)	26 (27%)
Education			
H.S./GED, or less, or unspecified	66 (22%)	35 (23%)	31 (21%)
At least some college, w/ or w/o degree(s)	233 (78%)	114 (76%)	119 (79%)
Employment			
Full time/part time/self-employed	56 (19%)	30 (20%)	26 (17%)
Disabled	95 (32%)	53 (36%)	42 (28%)
All others	148 (49%)	66 (44%)	82 (55%)
Ever been homeless - yes	187 (52%)	88 (59%)	99 (66%)

Table 4. RCT sample characteristics – Military History, Total and by condition

Military service history	Total	SPC	CBT
Rank			
E1-E4 (Junior Enlisted)	202 (68%)	102 (68%)	100 (67%)
E5-E9 (Non-commissioned officer)	94 (31%)	44 (29%)	50 (33%)
O1-O9 (Officer)	3 (1%)	3 (2%)	0 (0%)
Service Era			
OEF/OIF/OND	134 (45%)	65 (44%)	69 (46%)
All other eras	165 (55%)	84 (56%)	81 (54%)
# Deployments, of any sort, in career			
None	85 (28%)	40 (27%)	45 (30%)
One	87 (29%)	45 (30%)	42 (28%)
Two or more	127 (42%)	64 (43%)	63 (42%)
Any combat experience - yes			
One combat tour	87 (62%)	40 (61%)	47 (63%)
Two or more combat tours	53 (38%)	26 (39%)	27 (36%)
Branch served			
Army	170 (57%)	86 (58%)	84 (56%)
Marine Corps, Navy, or Air Force	112 (37%)	54 (36%)	58 (39%)
More than one branch	17 (6%)	9 (6%)	8 (5%)

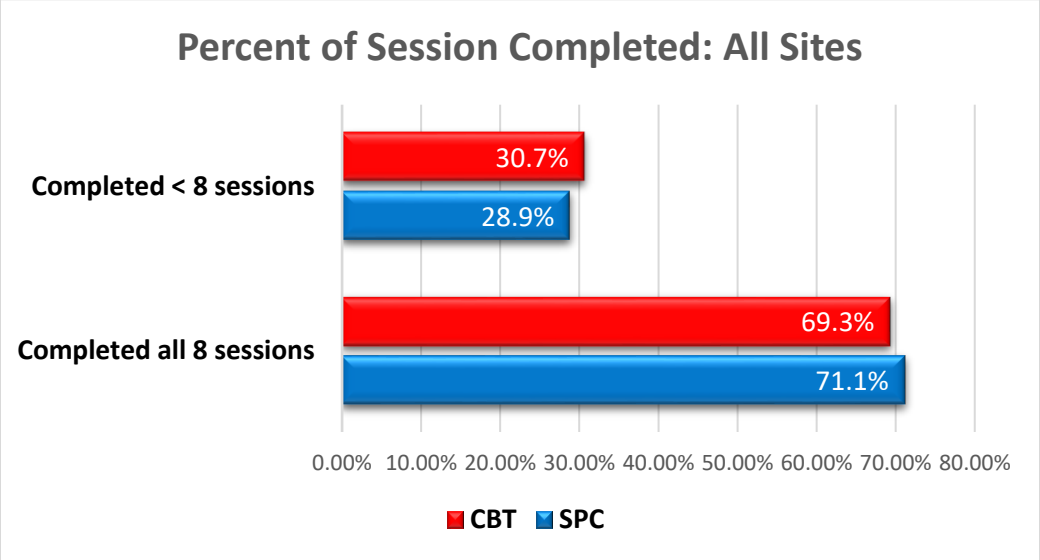
Table 5. RCT sample characteristics – Clinical characteristics, Total and by condition

Clinical Characteristics	Overall (N=299)	CBT (N=150)	SPC (N=149)
Level of Suicidal Ideation (M, SD) (Beck Suicidal Severity, Self-Report [BSS-SR]; maximum score= 38)	14.1 (6.1)	14.3 (6.4)	13.7 (5.9)
Level of Depressive symptoms (M, SD) (Patient Health Questionnaire [PHQ-8]; maximum score = 24)	13.8 (5.6)	13.7 (5.9)	13.9 (5.2)
Self-efficacy to avoid suicide (M, SD) (Self-efficacy to Avoid Suicide [SEASA]; maximum score = 54)	33.0 (11.7)	32.2 (11.6)	33.9 (11.8)
Substance Use			
Yes Alcohol use in prior 6 months (n, %) (Substance Abuse Outcomes Module [SAOM])	248 (84%)	121 (83%)	127 (85%)
Yes Drug use in prior 6 months (n, %) (Substance Abuse Outcomes Module [SAOM])	241 (81%)	117 (79%)	124 (83%)

Intervention Delivery

As previously noted, out of the 300 participants recruited across all study sites, 299 were randomized to a treatment condition; Out of a total of 299 randomized patients, **149 (49.8%) were randomized to receive the Supportive Psychoeducational Control condition (SPC)** across all study sites. Of those participants**, 71.1% (n=106) completed all 8 sessions** and 82.6% (n=123) completed at least 4 sessions. **For the Cognitive Behavioral Therapy (CBT) intervention condition, 150 participants (50.0%) were assigned** to receive the condition, and of those **104 participants (69.3%) completed all 8 Condition B therapy sessions**. Likewise, for the CBT intervention a high number of participants (n=124; 82.7%) completed at least 4 sessions. These rates can be seen in Figure 3 below. For both treatment conditions, those who completed fewer than 8 sessions were significantly more likely to be younger ($p < 0.005$) and have prior combat exposure ($p < 0.01$). In addition, participants in both treatment conditions reported the condition they received as being helpful and participating actively. Minor differences between conditions were detected, with participants in the SPC condition reporting feeling more comfortable discussing issues regarding suicide with their study therapist, and participants in the CBT condition reporting their therapist explained the structure and purpose of the sessions with them better than those in the SPC condition.

Figure 3. Intervention Session Completion rates, all sites



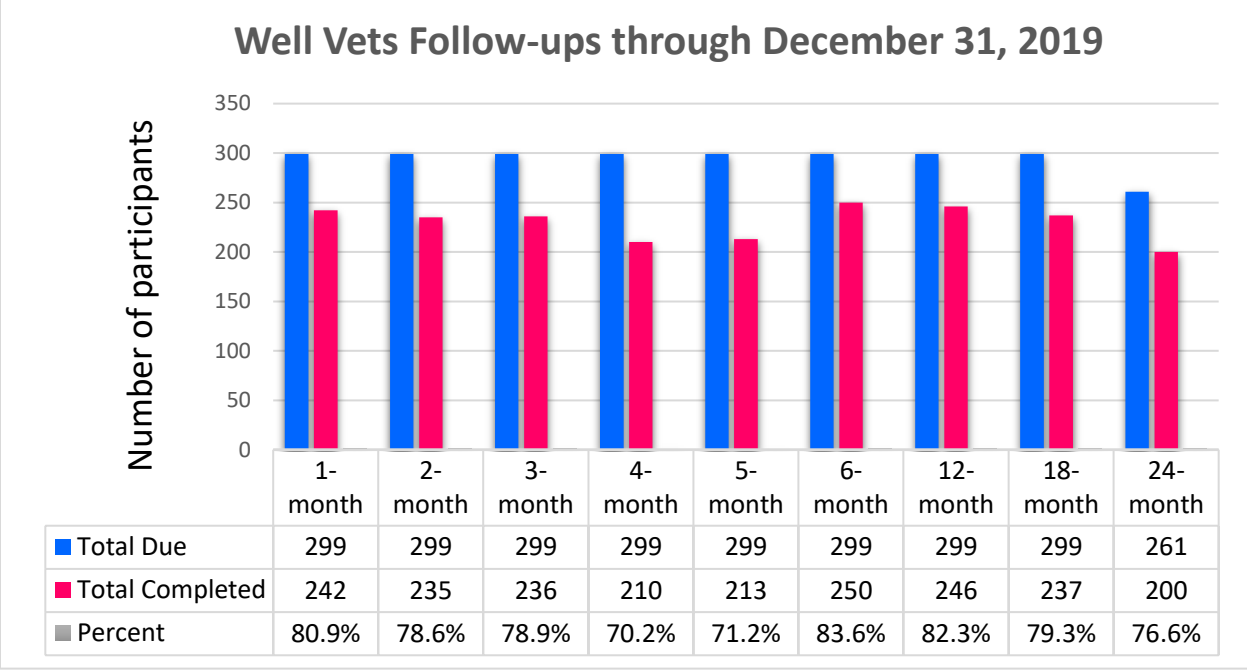
Participant Follow-up and Retention

During this reporting period, we have also continued conducting follow-up assessments and continue to maintain a high retention rate for all follow-up time periods across all sites. We have completed primary data collection for the following assessment time points: 1-month in-person (e.g. post treatment) follow-up, 2-month phone brief check in follow-up, 3-month in-person follow-up, 4- and 5-month phone brief check-in follow-ups, and the 6-month and 12-month in-person follow-ups. We remain in the process of actively completing the final time points of primary data collection (18- and 24-month follow-ups) across all study sites. **To date, there have been a potential 2,654 follow-up assessments due for all participants. We have completed 2,069 follow-up assessments to date over the course of the project.** Based on these numbers, across all study sites, the overall follow-up retention rate is **78.0%**. Out of those participants that have completed the study so far, 60.5% (n=121) have primary outcome data from all nine follow-up time points, with 73.5% completing at least 8 time points.

For the 1-month post enrollment follow-up assessment, the retention rate is 80.9% across all sites. The follow-up rate for the brief 2-month phone follow-up assessment is 78.6%. The follow-up rate for the 3-month post enrollment follow-up assessment is 78.9%. The 4-month and 5-month follow-ups are both brief phone assessments and the follow-up rates are 70.2% and 71.2% respectively. The follow-up rate for the 6-month assessment is 83.6%, and for the 12-month assessment, the rate is 82.3%. For the 18-month follow-up assessments, the completion rate is 79.3%. Finally, the 24-month follow-up assessment completion rate is 76.6%. These rates do not consider that some participants are not counted as completed but are still within the follow-up window and will successfully complete assessments for the 18- and 24-month follow-up time points. Incomplete follow-ups have been due to an inability to locate or contact participants using the contact information available, or an inability to complete the assessment due to the participant being in a controlled environment (e.g. incarcerated or at a treatment facility we are unable to visit).

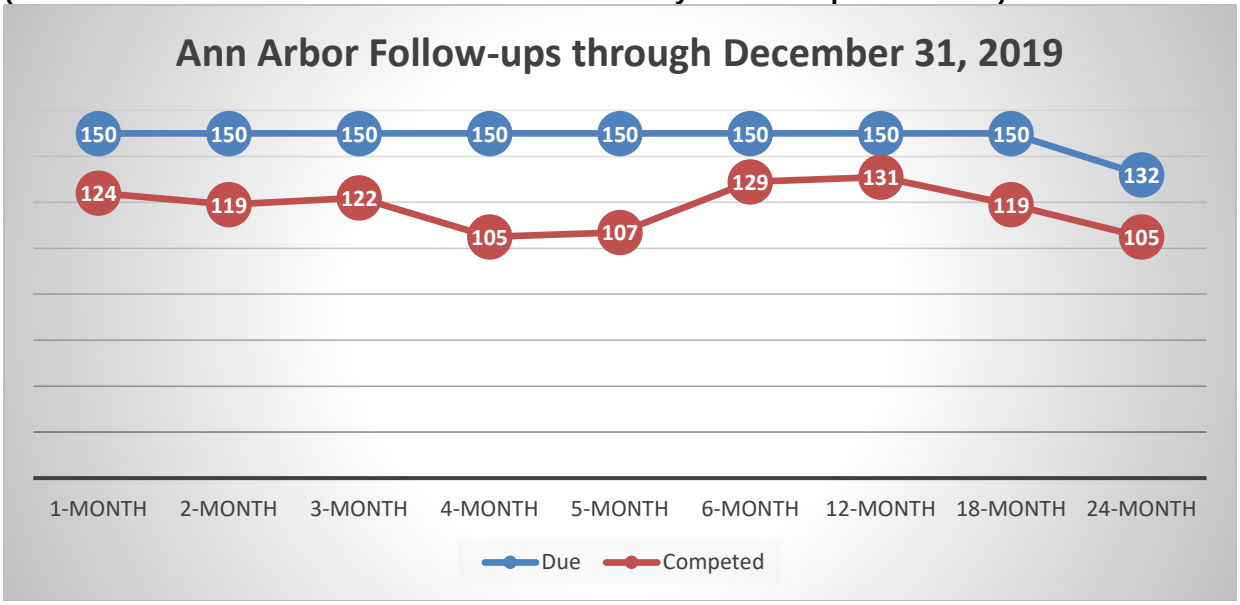
The Figures below (Figures 4, 5,6, and 7) provides more details regarding the follow-up assessment completion rates across all study sites and each individual site.

Figure 4. Follow-up retention statistics across all sites



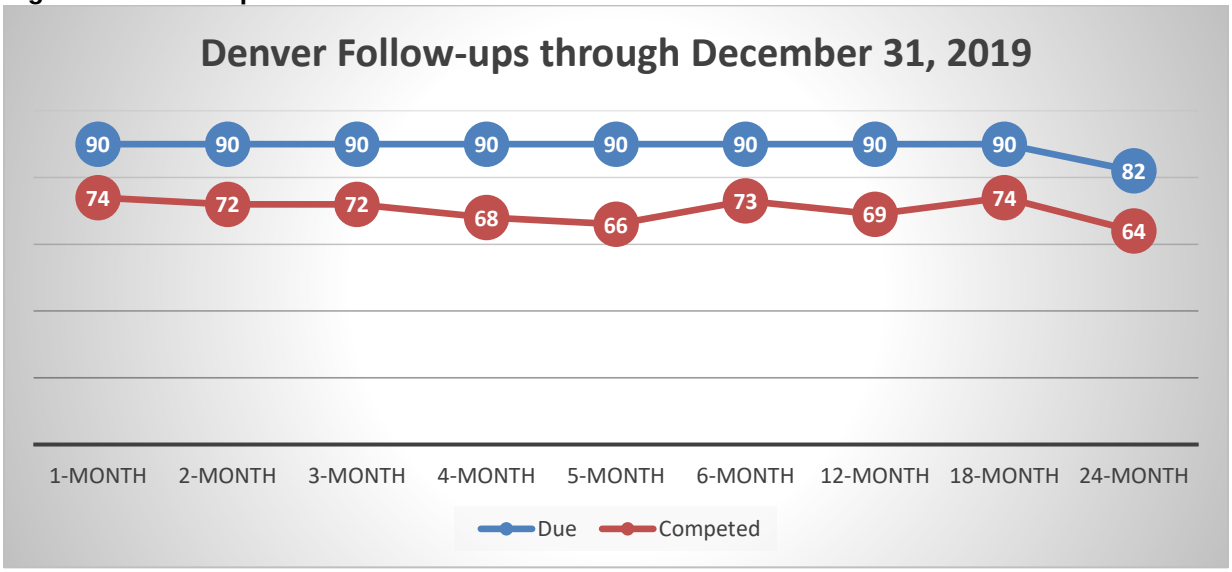
	1-month	2-month	3-month	4-month	5-month	6-month	12-month	18-month	24-month
Total Due	299	299	299	299	299	299	299	299	261
Total Completed	242	235	236	210	213	250	246	237	200
Percent	80.9%	78.6%	78.9%	70.2%	71.2%	83.6%	82.3%	79.3%	76.6%

Figure 5. Follow-up retention statistics – Ann Arbor sites
(Ann Arbor VA Medical Center and Toledo Community Based Outpatient Clinic)



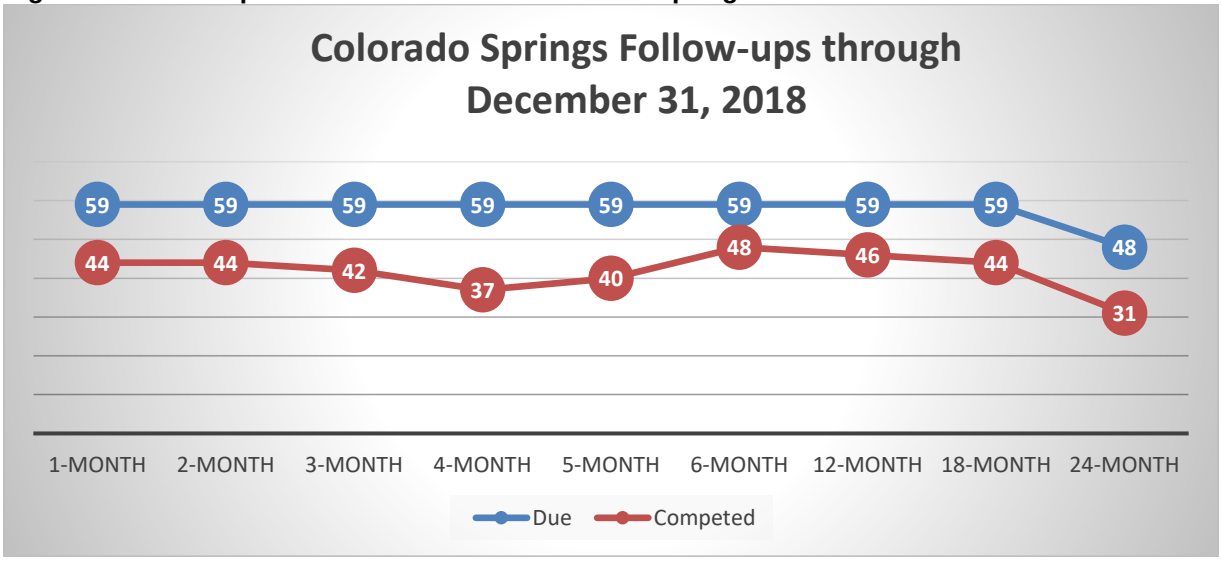
For the Ann Arbor site, the overall follow-up retention rate is 79.7%, with the following rates at each respective time point: 1-month is 82.7%, 2-month is 79.3%, 3-month is 81.3%, 4-month is 70.0%, 5-month is 71.3%, 6-month is 86.0%, 12-month is 87.3%, 18-month is 79.3%, and 24-month is 79.5%.

Figure 6. Follow- up retention statistics – Denver site



For the Denver site, the overall follow-up retention rate is 78.8%, with the following rates at each respective time point: 1-month is 82.2%, 2-month is 80.0%, 3-month is 80.0%, 4-month is 75.6%, 5-month is 73.3%, 6-month is 81.1%, 12-month is 76.7%, 18-month is 82.2%, and the 24-month is 78.0%.

Figure 7. Follow- up retention statistics – Colorado Springs site



For the Colorado Springs site, the overall follow-up retention rate is 72.3%, with the following rates at each respective time point: 1-month is 74.6%, 2-month is 74.6%, 3-month is 71.2%, 4-month is 62.7%, 5-month is 67.8%, 6-month is 81.4%, 12-month is 78.0%, 18-month is 74.6%, and the 24-month follow-up is 64.6%.

Patient Safety Monitoring

SAEs, AEs, UAPs, and participant study withdrawals.

There have been no SAEs or AEs reported during this reporting period at any study site.

There have been no Unanticipated Problems (UAPs) reported during this reporting period at any study site.

In total to date, we have had 15 participants request to withdraw from the study across all the sites (9 from Ann Arbor, 5 from Denver, and 1 from Colorado Springs). Reasons for study withdrawal have included an increased amount of stress and a lack of time to complete the study requirements. One participant requested to withdraw his participation citing his reason that he did not feel the study was beneficial to him. Additionally, to date we have had 10 total participant deaths across all study sites: 7 from the Ann Arbor site, 1 from the Denver site, and 2 from the Colorado Springs site. The cause of death for one participant from Colorado Springs was reported as a suicide. The causes of death from the remaining deaths are unknown at this time. Reports describing the details of these deaths were provided to the Research Monitor and it was determined by the Research Monitor that these events were unexpected and not study related. Because they were not study related, no additional reports to local IRBs or HRPO were deemed necessary based on reporting guidelines. The deaths were reported to the appropriate site IRBS at the continuing renewals.

Research Monitor Notifications

As of December 31, 2019, we have submitted 21 incidents to our Research Monitor for review. These were incidents that study staff acknowledged as concerns to participant safety and well-being in addition to reporting of participant deaths. Table 6 outlines all reports made to date and the outcomes.

Table 6: Research Monitor Notifications and outcomes – All Sites

Date of Event	Type of Event	Actions recommended by RM
10/22/2015	Hospitalization following study interaction	No changes proposed.
1/29/2016	Suicide attempt following study interaction	No changes proposed.
2/12/2016	Participant complaint- burden	No changes proposed.
7/10/2016	Participant death	No changes proposed.
11/29/2016	Hospitalization following study interaction	No changes proposed.
12/6/2016	Hospitalization following study interaction	No changes proposed.
2/2/2017	Hospitalization following study interaction	No changes proposed.
2/9/2017	Suicide attempt following study interaction	No changes proposed.
3/22/2017	Emergency medical attention during study interaction	No changes proposed.
4/11/2017	Participant death	No changes proposed.
10/24/2017	Hospitalization following study interaction	No changes proposed.
10/25/2017	Hospitalization following study interaction	No changes proposed.
11/15/2017	Hospitalization following study interaction	No changes proposed.
12/9/2017	Participant death	No changes proposed.
2/6/2018	Hospitalization following study interaction	No changes proposed.
Unknown (between 10/6/17 and 10/13/17)	Participant death	No changes proposed.
1/7/2018	Participant death	No changes proposed.
6/14/2018	Participant death	No changes proposed.
2/13/2019	Participant death	No changes proposed.

Date of Event	Type of Event	Actions recommended by RM
5/5/2019	Participant death	No changes proposed.
5/26/2019	Participant death	No changes proposed.

At this point, we do not have data to report regarding study aims since post-intervention follow-up assessments are ongoing.

- *What opportunities for training and professional development did the project provide?*

  Nothing to Report.

- *How were the results disseminated to communities of interest?*

As data collection remains ongoing, we have not conducted any data analyses related to any key variables of interest in order to preserve the integrity of the data collection process. We have, however, began to examine participant feedback regarding the feasibility and acceptability of the intervention condition content. We have presented this information at various national and international conferences during this reporting period. During the next reporting period we will focus on disseminating main study findings through both publications and presentations.

- *What do you plan to do during the next reporting period to accomplish the goals and the objectives?*

During the next reporting period, we plan to continue follow-ups with enrolled participants. Participant retention for follow-ups will be the key focus during the next reporting period, as we aim to increase our follow-up rate at each time point to above 80% completion. We will continue to coordinate with staff at the respective VA SUD IOP clinics and build relationships with additional outpatient clinics in order to identify strategies to accomplish project goals at their treatment clinics. Within the next reporting period we also will hold an additional Data Safety and Monitoring Board meeting. We will continue regular meetings (both remotely and in-person) to clean the data. Our goal is to have all available data cleaned and entered by the end of the funding period. That will allow us to rapidly conduct analyses of the study aims as the last follow-up assessments are conducted.

Throughout the next reporting period, we will continue to monitor all procedures at each site and ensure that all protocols and procedures are being followed consistently across all study sites. We will also continue with extensive training of all project protocols and procedures with study staff and monitor study staff closely. Since the population of this study is particularly high risk, all study staff will continue to receive extensive training in managing suicidal and homicidal crises. Project coordinators will work with all study staff in addition to the investigators to monitor risk assessments to ensure all protocols are being followed. We also continue to evaluate our internal study documents during the next reporting period, including project databases and information sheets that will be used to track participants throughout the study. We are optimistic that we will be able to achieve our goals as outlined in our SOW to complete all primary data collections within the next reporting period.

4. IMPACT

Nothing to Report.

5. CHANGES/PROBLEMS

Nothing to Report.

6. PRODUCTS

As data collection is still ongoing, there are no publications related to this project to report. Below is a list of presentations (both oral and poster) that have been presented based on data and information collected as part of the Well Vets project. The presentations that are bolded are the presentations from this current reporting period.

Oral Presentations

1. Ilgen MA, Olson-Madden JH, Friese A, Price AM. Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders. Oral presentation at the 49th Annual Conference of the American Association of Suicidology, Chicago, IL, April 2016.
2. Price AM, Olson-Madden J, Ilgen M. Alcohol and drug use prior to suicidal behaviors in Veterans receiving substance use disorder treatment. Oral presentation at the 51st Annual Conference of the American Association of Suicidology, Washington, D.C., April 2018.
3. **Price AM, Ilgen MA, Olson-Madden JH. The Use of an Active Control Condition in a Randomized Controlled Trial for Veterans in Substance Use Treatment at Risk for Suicide. Oral presentation at the 52nd Annual Conference of the American Association of Suicidology, Denver, CO, April 2019*. Acknowledgement of federal support (yes).***
4. **Thomas SM, Price AM, Stevenson KA, Shaughnessy NL, Ilgen MA, Olson-Madden JH. Lifetime trauma exposure and suicide risk among Veterans seeking Substance Use Disorder Treatment. Oral presentation at the Military Health Systems Research Symposium, Kissimmee, FL, August 2019. *Acknowledgement of federal support (yes).***
5. **Price AM, Ilgen MA, Olson-Madden JH. Patient Perceptions of CBT for Suicide Prevention. Oral presentation at the 2019 VA/DoD Suicide Prevention Conference, Nashville, TN, August 2019. *Acknowledgement of federal support (yes).***
6. **Ilgen MA, Olson-Madden JH, Gutierrez P. Measurement of Suicide Outcomes in Clinical Research. Oral presentation at the 2019 VA/DoD Suicide Prevention Conference, Nashville, TN, August 2019. *Acknowledgement of federal support (yes).***
7. **Ilgen MA, Price AM, Olson-Madden JH. Exploring the effectiveness of Cognitive Behavioral Therapy for Suicide Prevention in Veterans: Understanding patient perceptions of treatment. Oral presentation at the 30th World Congress of the International Association for Suicide Prevention, Londonderry, Northern Ireland, September 2019. *Acknowledgement of federal support (yes).***
8. **Ilgen MA, Olson-Madden JH, Steward HJ, Lindenauer S, Price AM. Measurement of suicide outcomes in clinical research: achieving reliability using the C-SSRS across multiple large scale research projects. Oral presentation at the 30th World Congress of the International Association for Suicide Prevention, Londonderry, Northern Ireland, September 2019. *Acknowledgement of federal support (yes).***
9. **Thomas SM, Olson-Madden JH, Price AM, Ilgen MA. Lifetime trauma exposure and suicide risk among OEF/OIF/OND Veterans seeking Substance Use Disorder treatment. Oral presentation at the 5th Annual San Antonio Combat PTSD Conference, San Antonio, TX, October 2019. *Acknowledgement of federal support (yes).***

Poster Presentations

1. Uju-Eke O, Hernandez K, Price AM, Jannausch M, Ilgen MA. The Effect of Homelessness and Perceived Social Support on Suicidal Ideation Among Veterans Receiving Substance Use Disorder Treatment. Poster presented at the 27th Annual Albert J. Silverman Research Conference, Ann Arbor, MI, April 2016.
2. Price AM, Sanborn M, Uju-Eke O, Goldman E, Jannausch M, Ilgen MA. Prevalence and Correlates of Suicidal Ideation and Behaviors in Veterans Receiving Substance Use Treatment. Poster presented at the 27th Annual Albert J. Silverman Research Conference, Ann Arbor, MI, April 2016.
3. Price AM, Ilgen MA. The Use of an Active Control Condition in a Randomized Controlled Trial for Veterans in Substance Use Treatment at Risk for Suicide. Poster presented at the International Summit on Suicide Research, Henderson, NV, November 2017.
4. Stewart HJ, Jordan JK, Thierbach AL, DeSantis AM, Lindenauer SL, Price AM, Yeagley EE, Pope BE, Ilgen MA. Improving Administration and Coding of the Columbia Suicide Severity Rating Scale for Individuals at High-Risk for Suicide. Poster presented at the 29th Annual Albert J. Silverman Research Conference, Ann Arbor, MI, May 2018.
5. Uju-Eke O, Wells J, Bak T, Price A, Yeagley E, Ilgen M. Assessing Perceived Health and Suicidal Ideation Among Veterans Receiving Substance Use Disorder Treatment. Poster presented at the 29th Annual Albert J. Silverman Research Conference, Ann Arbor, MI, May 2018.
6. Price A, Olson-Madden J, Stevenson K, Ilgen M. The Association Between Aggression & Suicidal Behaviors in Substance Use Disorder Treatment Seeking Veterans. Poster presented at the Military Health Systems Research Symposium, Kissimmee, FL, August 2018.
7. **Shaughnessy NL, Price AM, Thomas SM, Stevenson KA, Ilgen MA, Olson-Madden JH. The Relationship Between Alcohol Use, Suicidal Ideation, And Sleep Problems Among Veterans Actively Engaged in Substance Abuse Treatment Programming. Poster presented at the Military Health Systems Research Symposium, Kissimmee, FL, August 2019.**
8. **Stevenson KA, Price AM, Thomas SM, Olson-Madden JH, Ilgen MA. Examining the relationship between acts of aggression and suicidal behaviors in Veterans enrolled in substance abuse treatment programs. Poster presented at the International Summit on Suicide Research, Miami, FL, October 2019.**

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

• *What individuals have worked on the project?*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Mark A. Ilgen, PhD* *Principal Investigator* *3* *Dr. Ilgen has provided overall oversight of all project activities including monitoring study progress, reviewing regulatory and reporting documents, participating in clinical supervision, aiding in hiring and training of new staff, providing risk management for all phases of the project, attending project meetings, and presenting study materials at national and international conferences.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Jennifer Olson-Madden, PhD* *Site-PI (Denver & Colorado Springs)* *6* *Dr. Olson-Madden has facilitated the overall protocol and study coordination of the Denver sites, including the review of study measures, materials, and intervention manuals, overseeing any necessary study-related purchases, co-leading bi-weekly study organization phone meetings, provision of clinical training and supervision, and the preparation and review of regulatory documents.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Deirdre Conroy, Ph.D.* *Co-Investigator, Clinical Supervisor (all sites and conditions)* *2* *Dr. Conroy has reviewed study materials, provided training and clinical supervision to study therapists in both conditions, conducted fidelity assessments on therapy sessions, and attended project meetings.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Linda Mobley, MS* *IRB Coordinator* *2* *Mrs. Mobley assisted in revising the protocols and study materials, attended project meetings, and completed paperwork for local IRB submissions and project submissions to USAMRMC HRPO.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Amanda Price, MS* *Project Manager* *6* *Ms. Price has facilitated the overall protocol and study coordination of the study sites, including management and coordination of participant activities, attended and participated in project meetings, including coordinating monthly Investigator meetings, containing in the training and management of study staff members, has assisted in the creation of study databases and project binders, and has assisted in modifying study materials including study measures, intervention manuals, risk management protocol, and general project procedure protocols. Ms. Price continues to monitor data collection, entry, and analyses across study sites and aids in the preparation of presentations for conferences.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Neared person month worked:* *Contribution to the project:*	*Suzanne Thomas* *Project Coordinator (Denver & Colorado Springs)* *4* *Ms. Thomas has worked on preparation, review and submission of regulatory documents, participation in weekly study organization phone meetings, coordinated communication with project partners, recruitment, screening, enrollment and follow-up of participants, and budget management.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Mary Jannausch, MS* *Data analyst (all sites)* *4* *Mrs. Jannausch continues to develop systems for project databases and electronic data and storage and analysis and has provided preliminary data analyses for reports and presentations. She has worked with the PIs, project manager, and data manager to document and streamline data decision processes.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Neared person month worked:* *Contribution to the project:*	*Karson Stevenson* *Research Assistant (Denver & Colorado Springs)* *12* *Ms. Stevenson has participated in measures and risk assessment training, in addition to all regulatory training. She has conducted participant follow-up interviews and participated in data entry.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Katrina Hernandez, BA* *Research Assistant (Ann Arbor)* *7* *Mrs. Hernandez has participated in study-specific procedures training including consent and measures administration, completed VA required trainings and paperwork, and participated in participant recruitment, screening, enrollment and follow-up and participated in data entry.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Jazmine Wells, BS* *Research Assistant (Ann Arbor)* *9* *Ms. Wells has participated in study-specific procedures training including consent and measures administration, completed VA required trainings and paperwork, participated in intervention role play sessions as a mock client, and participated in participant recruitment, consenting, enrollment, and follow-up and participated in data entry.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Doctor Ashe, MPH* *Data Manager* *5* *Ms. Ashe has continued cleaning and finalizing data and attended meetings to discuss data needs.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Nathaniel Healy* *Research Assistant (Ann Arbor)* *2* *Mr. Healy has continued training on project activities including recruitment, assessments, and data entry. He has also attended project meetings.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Yang Ni* *Research Assistant (Ann Arbor)* *8* *Ms. Ni has continued to help with data management processes, including cleaning and finalizing data, and attending meetings to discuss data needs.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Nick Shaughnessy* *Research Assistant (Denver & Colorado Springs)* *9* *Mr. Shaughnessy has continued project activities including data entry. He has also attended project meetings.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Suzanne Hodge* *Research Assistant- temp (Ann Arbor)* *6* *Mrs. Hodge has participated in study-specific procedures training including, completed VA required trainings and paperwork, and participated in data entry.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Taryn Schiff, MSW* *Therapy Session Fidelity Rater* *3* *Ms. Schiff has reviewed study materials, participated in training on both therapy conditions, and attended project meetings. She has also begun conducting the fidelity monitoring for the study.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Brandon Terrell, MSW* *Therapy Session Fidelity Rater* *3* *Mr. Terrell has reviewed study materials, participated in training on both therapy conditions, and attended project meetings. He has also begun conducting the fidelity monitoring for the study.*

• *Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?*

YES, please see Other Support pages attached.

• *What other organizations were involved as partners?*

Organization Name: **Denver Research Institute (DRI)**

Location of Organization: Denver, CO

Partner's contribution to the project (identify one or more):

- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);

8. SPECIAL REPORTING REQUIREMENTS

Please find an updated version of the QUAD CHART in the appendices.

9. APPENDICES

a. Other Support
b. Quad Chart

Appendix A. Other Support

OTHER SUPPORT

ILGEN, MARK

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

Grants, Contracts, and Cooperative Agreements to U-M and Internal U-M Funds that are Separately Budgeted and Accounted For

W81XWH-14-1-0005 (Ilgen)	12/30/2013-12/29/2020	1.2 calendar
DoD-USAMRMC	$6,783,574	

Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

R33 AT010106 (Ilgen)	09/20/2018-09/19/2021	1.29 calendar
NIH-DHHS	$1,825,162	

Psychosocial pain management to improve opioid use disorder treatment outcomes

This trial would be the first to study an integrated CBT/acceptance-based approach for pain management in patients who are receiving medication assisted treatment for opioid use disorders, examine feasibility of phone-based delivery of the intervention and begin to estimate the potential impact on subsequent pain and opioid-related outcomes.

R34 DA047466 (Ilgen, Arnedt)	09/30/2018-07/31/2021	0.48 calendar
NIH-NIDA	$702,000	

Reducing cannabis use for sleep among adults using medical cannabis

As medical cannabis use becomes more common in the United States, it is essential to understand the ways in which adults who use medical cannabis perceive the benefits of cannabis use and to identify effective strategies to help them cope with these problems. Emerging data indicate that sleep problems and/or use of cannabis for sleep are very common in medical cannabis patients. The present study will evaluate the impact of a Cognitive Behavioral Therapy intervention on cannabis- and sleep-related outcomes in adults who use medical cannabis.

R01 AA027513 (Ilgen) 07/01/2019-06/30/2024 1.38 calendar
NIH-DHHS $698,963
Facilitating use of the National Suicide Prevention Lifeline in Alcohol Patients

The present study is a randomized controlled trial to test the efficacy of an intervention called Crisis Line Facilitation, designed to increase utilization of the crisis lines among high risk patients, compared to enhanced usual care based on utilization of the National Suicide Prevention Lifeline and suicide attempts among individual in residential treatment for Alcohol Use Disorders.

R01 AT010797 (Ilgen, Lin) 09/28/2019-08/31/2023 1.2 calendar
NIH-DHHS $3,237,471
Enhancing the impact of behavioral pain management on MAT outcomes

Aim 1: Increase the relevance to Veterans with comorbid pain and OUD by adding additional recruitment sites at the VA Ann Arbor Healthcare System (100 additional patients or 200 for the combined total N). Aim 2: Extend the measurement of longer-term outcomes by adding follow-up assessments at 6-, 9- and 12-months for the entire sample (N=200). Aim 3: Facilitate the rapid implementation of results by gathering qualitative data from key stakeholders including MAT treatment providers (N=15) and patients who received the PPMI intervention (N=20 participants recruited at the end of the trial).

R44 AA026119 (Fan) 08/10/2017-07/31/2020 0.24 calendar
Arborsense, Inc./NIH $402,177
NIH SBIR Phase II: Wearable Nanobiosensor to monitor transdermal alcohol vapors

Excessive alcohol consumption is the fourth leading preventable cause of death in the US. It led to around 88,000 deaths per year in the US from 2006-2010 and in 2006 alone cost the economy around $224 billion. Arborsense’s wearable alcohol monitoring device will lead to a better awareness about alcohol consumption amongst general population and will enhance health, lengthen life and reduce illness and disability. The wearable biosensors market is stated to reach $19 billion by 2018, pointing towards the potential commercial opportunity for self-monitoring wearables for personalized health-care. The successful commercialization of our sensors will help the company enter other parallel markets in future like drug abuse, ketone and food spoilage detection.

(Blow, Ilgen) 09/01/2017-12/31/2020 0 calendar
Internal-PUHS Joint Institute for Translational and Clinical Research $200,000
Building Collaborations to Address Drug Problems in the United States and China

This project supports efforts to develop and enhance collaborations between investigators at the University of Michigan and Peking University in the areas of addiction, chronic pain and mental health.

Other Grants, Contracts, Cooperative Agreements & Funds Not to U-M

RCS 19-333 / IK6 HX002841 (Ilgen) 08/01/2019-07/31/2024 5 calendar
VA Health Administration-HSR&D $569,959
HSR&D Research Career Scientist Award

This award provides a career track and salary support for scientists who have shown their commitment to VA research through committee participation, direction of core facilities, teaching, mentoring, supervising shared resources, acknowledgement of VA support, and other important research-related activities.

Appointments / Affiliations
Department of Veterans Affairs – VA Ann Arbor Healthcare System Person Months: 5
Research Career Scientist

In-kind Lab or Office Space, Equipment, Supplies
None

Materials that are Not Freely Available to Others
None

Foreign Collaborations / Foreign Components
Dr. Lin Lu at Peking University, China
Dr. Yan-ping Bao at Peking University, China

Visiting Faculty/Scholars/Scientists/Post-docs/Students Supported by Funds not Managed by U-M
None

Scientific, Financial and Effort Commitment Overlap Statement:
There is no overlap.

PENDING

Grants, Contracts, and Cooperative Agreements to U-M and Internal U-M Funds that are Separately Budgeted and Accounted For

R01 (Bohnert, K.) 09/01/2019-08/31/2023 0.6 calendar
NIH-DHHS $2,029,332
Understanding the Role of Alcohol in Unintentional Overdose and Suicide

GOAL: The proposed study will analyze Veterans Health Administration (VHA) electronic health records data, which include annual Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) screening information for all patients, all pharmacy records, all outpatient and inpatient treatment records including diagnostic data, and linked cause-specific National Death Index (NDI) mortality data for the population. The aims are: 1) To characterize, for the first time, the relationship between alcohol use and unintentional

overdose and suicide death using a competing risks framework; 2) To further examine the impact of alcohol use in combination with prescription drugs (i.e., opioid and sedative medications) on risk of unintentional overdose and suicide death; and 3) Recognizing that risks associated with alcohol use (and prescription medications) may not be static, to estimate five year trajectories of alcohol use (and prescription medications) and their relation to unintentional overdose and suicide risk.

R01 AA (Bohnert, K.) 04/01/2020-03/31/2025 1.2 calendar
NIH-NIAAA $3,382,569
Testing a PTSD m-Health Intervention to Improve Alcohol Treatment Outcomes

The goals of this study are to 1) estimate the impact of the PTSD Coach app intervention condition versus the TAU control condition in reducing PTSD symptoms among AUD patients with co-occurring PTSD; 2) compare the PTSD Coach app condition with the TAU control condition on short- and long-term alcohol-related treatment outcomes; and 3) test whether sex moderates the impact of the PTSD Coach intervention on PTSD and alcohol outcomes.

R01 (Bohnert, K.) 07/01/2020-06/30/2024 0.6 calendar
NIH-DHHS $2,165,539
Leveraging national electronic health records to understand risks of alcohol use for unintentional overdose and suicide

The proposed study will estimate prospectively risks that are associated with alcohol use and problems and other key variables on unintentional overdose and suicide mortality for the entire population of Veterans served each year over five years, and findings will inform prevention and intervention strategies for those at highest risk for overdose and suicide death.

Other Grants, Contracts, Cooperative Agreements & Funds Not to U-M
None

Appointments / Affiliations
None

In-kind Lab or Office Space, Equipment, Supplies
None

Materials that are Not Freely Available to Others
None

Foreign Collaborations / Foreign Components
None

Visiting Faculty/Scholars/Scientists/Post-docs/Students Supported by Funds not Managed by U-M

Department of Veterans Affairs – VA Ann Arbor Healthcare System USA
1 post-doc

Scientific, Financial and Effort Commitment Overlap Statement:

There is no scientific or budgetary overlap. Commitment overlap will be addressed by reducing effort in consultation with program staff if funding of any proposal creates an excess of 12 calendar months' effort.

OTHER SUPPORT

BLOW, FREDRIC

University yearly evaluation of the effort distribution between the UM and the VA is represented by the calendar months reported on other support. MOU is on file.

ACTIVE

Grants, Contracts, and Cooperative Agreements to U-M and Internal U-M Funds that are Separately Budgeted and Accounted For

R01 AA023122 (Blow, F.) 09/20/2013-08/31/2020 0.6 calendar
NIH/NIAAA/DoD $3,451,636
Preventing Alcohol/Prescribed Drug Misuse in the National Guard: Web and Peer BI

National Guard members, especially those who have been combat-deployed, are at high risk for developing alcohol- and prescription-related drug problems. The use of novel Web-based interventions combined with either Web-based boosters or Peer support sessions, can have a major public health impact for the National Guard, as well as the overall military, and can provide state-of-the-art techniques to prevent and intervene on these problems in the general population.

W81XWH (Blow, F.) 09/01/2014-08/31/2020 2.32 calendar
Case Western Reserve $2,193,031
University/DoD/USAMRMC
Early Intervention to Reduce Alcohol Misuse and Abuse In the Ohio Army National Guard

The proposed project is a fully-powered randomized controlled trial of a Web- and text-based alcohol brief intervention (WT-BI) versus and Enhanced Usual Care (EUC) condition for Ohio National Guard members who meet criteria for unhealthy drinking in the previous three months.

R01 DA044245 (Voepel-Lewis) 09/01/2017-07/31/2020 0.3 calendar
NIH-DHHS $505,680
Scenario-tailored opioid messaging program: An interactive intervention to prevent analgesic-related adverse drugs events in children and adolescents

With this proposal, we aim to demonstrate that our Scenario-Tailored Opioid Messaging Program (STOMP™) will: 1) Improve parents' opioid risk understanding and their analgesic decision-making; 2) Enhance parents' analgesic self-efficacy, analgesic use, storage behaviors and their children's pain outcomes, and 3) To demonstrate that the STOMP™ plus provision of a method to get rid of left-over medications will effectively nudge parents to safely dispose of left-over opioid analgesics.

AZ150087 (Blow) 09/15/2016-03/14/2020 0.3 calendar

Dept. of the Army – USAMRAA $735,875
WeCareAdvisor: A Web-Based Tool to Improve Quality of Life for Military Veterans with Dementia and Their Caregivers

The overarching goal of the proposed study is to determine the effectiveness of the WeCareAdvisor tool for the assessment and management of behavioral and psychological symptoms of dementia (BPSD) in military Veterans and their family caregivers. Using a mixed-methods strategy, the primary specific aims of this study are to: 1. Identify in a diverse set of family caregivers of military Veterans (total n=24) areas of particular need to extend the use of the WeCareAdvisor in this population. 2. Complete iterative changes to the WeCareAdvisor tool as needed for this population. 3. Evaluate effects of the WeCareAdvisor tool on caregiver quality of life, upset and confidence in the treatment group who receives the WeCareAdvisor tool (n=30 dyads) compared to a waitlist control group (n=30 dyads) at 3 months.

R01 AA027513 (Ilgen) 07/01/2019-06/30/2024 0.72 calendar
NIH-DHHS $3,321,013
Facilitating use of the National Suicide Prevention Lifeline in Alcohol Patients

The present study is a randomized controlled trial to test the efficacy of an intervention called Crisis Line Facilitation, designed to increase utilization of the crisis lines among high risk patients, compared to enhanced usual care based on utilitzation of the National Suicide Prevention Lifeline and suicide attempts among individual in residential treatment for Alcohol Use Disorders.

R01 AA026687 (Birditt, K.) 09/20/2019-08/31/2022 0.9 calendar
NIH-NIAAA $1,223,437
Alcohol Consumption and Cardiovascular Health Among Older Couples: The Roles of Genetics and Marital Quality

The goals of this project are to understand longitudinal patterns of alcohol use among older couples and the effects of alcohol use on cardiovascular health. The project will also determine the genetic and marital factors that exacerbate the effects of alcohol use on cardiovascular health and test prognostic risk models for predicting cardiovascular health.

UG3 DA050173 (Walton, Bonar) 09/30/2019-08/31/2020 0.6 calendar
NIH-DHHS $699,050
Optimized Interventions to Prevent Opioid Use Disorder among Adolescents and Young Adults in the Emergency Department

This project will adapt promising remote health coach-delivered interventions, and pilot test feasibility/acceptability among adolescents and young adults. Then, we will evaluate the efficacy of interventions and their combinations to prevent/reduce opioid misuse among adolescents and young adults in the emergency department. Finally, we conduct an economic evaluation to identify the most efficacious intervention combination for preventing

opioid misuse, and implement it in the emergency department among adolescents and young adults.

(Blow, Ilgen) 09/01/2017-12/31/2020 0 calendar
Internal-PUHS Joint Institute for Translational and Clinical Research $200,000
Building Collaborations to Address Drug Problems in the United States and China

This project supports efforts to develop and enhance collaborations between investigators at the University of Michigan and Peking University in the areas of addiction, chronic pain and mental health.

Other Grants, Contracts, Cooperative Agreements & Funds Not to U-M

(Blow, F) 01/01/17-12/31/20 (30% effort) 2.25 calendar
VA Health Administration–HSR&D, IIR 16-235 $464,196
Improving Outcomes for Emergency Department Patients with Alcohol Problems

The aim of the study is to conduct a hybrid randomized controlled trial to determine the effectiveness of an alcohol intervention starting in the ED with peer-delivered brief alcohol advice, combined with a 2-month program of post-ED structured peer mentorship to facilitate linkage to and engagement with primary or specialty care. This proposed study will provide key data on the effectiveness of using peer support specialists in the VHA to help Veterans with hazardous drinking who may have difficulty engaging in needed care that potentially improve their mental and physical health outcomes.

(Maust, D) 02/01/18-01/31/2022 (10%) 0.75 calendar
VA Health Administration–HSR&D, IIR 16-210 $298,518
Addressing inappropriate benzodiazepine prescribing among older Veterans

The aim of this proposal is to understand those combinations of local facility strategies and context (i.e., facilitators and barriers) 12 that generate these successful outcomes. In addition, it is critical to understand the patient experience of these strategies, as Veterans may experience some “successful” strategies as extremely distressful. In partnership with PDSI, Academic Detailing, and Pharmacy Benefits Management, this explanatory sequential mixed-methods study will examine the impact of local facility strategies on BZD use and associated patient outcomes, allowing identification of context-sensitive strategies that can immediately inform VA safe-prescribing initiatives.

(Bohnert, K) 05/01/17-04/30/21 (5%) 0.375 calendar
VA Health Administration–HSR&D IIR 15-348-2 $169,033

Cannabis use and health among VHA primary care patients

The proposed project will characterize patterns of regular cannabis use and determine how patterns of use relate to health, functioning, and service utilization among Veteran primary care patients in the VHA. The study will examine the extent to which cannabis use is associated with psychoactive medication use (e.g., opiates and other psychotropics), substance use, substance use disorder symptoms, mental health symptoms (e.g., PTSD), pain, functioning, and treatment utilization among a cross-sectional sample of patients with regular cannabis and those with no past-year use.

(Blow & Pfeiffer – Co-PI) 04/01/17-03/31/22 (10%) 0.75 calendar
SDA, VA Office of Research & Development $76,607
Precision Medicine in Mental Health Care (PRIME Care)

This project is a multi-site study designed to evaluate the utility of pharmacogenomics testing for psychotropic medications in treating Major Depressive Disorder. Role: Principal Investigator with Paul Pfeiffer

Appointments / Affiliations
Department of Veterans Affairs – VA Ann Arbor Healthcare System Person Months: 5
Research Health Sciences Specialist

In-kind Lab or Office Space, Equipment, Supplies
None

Materials that are Not Freely Available to Others
None

Foreign Collaborations / Foreign Components
Dr. Lin Lu at Peking University, China
Dr. Yan-ping Bao at Peking University, China

Visiting Faculty/Scholars/Scientists/Post-docs/Students Supported by Funds not Managed by U-M
None

Scientific, Financial and Effort Commitment Overlap Statement:
There is no overlap.

PENDING

Grants, Contracts, and Cooperative Agreements to U-M and Internal U-M Funds that are Separately Budgeted and Accounted For

R01 (Bohnert, K.) 09/01/2019-08/31/2023 1.8 calendar
NIH-DHHS $291,664
Understanding the Role of Alcohol in Unintentional Overdose and Suicide

The proposed study will analyze Veterans Health Administration (VHA) electronic health records data, which include annual Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) screening information for all patients, all pharmacy records, all outpatient and inpatient treatment records including diagnostic data, and linked cause-specific National Death Index (NDI) mortality data for the population. The aims are: 1) To characterize, for the first time, the relationship between alcohol use and unintentional overdose and suicide death using a competing risks framework; 2) To further examine the impact of alcohol use in combination with prescription drugs (i.e., opioid and sedative medications) on risk of unintentional overdose and suicide death; and 3) Recognizing that risks associated with alcohol use (and prescription medications) may not be static, to estimate five year trajectories of alcohol use (and prescription medications) and their relation to unintentional overdose and suicide risk

R01 AA (Bohnert, K.) 04/01/2020-03/31/2025 0.6 calendar
NIH-NIAAA $3,382,569
Testing a PTSD m-Health intervention to improve alcohol treatment outcomes

The goals of this study are to 1) estimate the impact of the PTSD Coach app intervention condition versus the TAU control condition in reducing PTSD symptoms among AUD patients with co-occurring PTSD; 2) compare the PTSD Coach app condition with the TAU control condition on short- and long-term alcohol-related treatment outcomes; and 3) test whether sex moderates the impact of the PTSD Coach intervention on PTSD and alcohol outcomes.

R21 (Vydiswaran, Fernandez) 04/01/2020-03/31/2025 0.12 calendar
NIH-NIAAA $1,588,355
Leveraging electronic health records to identify risky alcohol use prior to surgery

This project will create and validate a computable phenotype to classify risky alcohol use using electronic health record data from elective surgery patients. The phenotype will identify patients at risk for alcohol-related surgical complications that could benefit from targeted and timely pre-operative interventions.

R01 (Bohnert, K.) 07/01/2020-06/30/2024 1.8 calendar
NIH-DHHS $2,165,539
Leveraging national electronic health records to understand risks of alcohol use for unintentional overdose and suicide

The proposed study will estimate prospectively risks that are associated with alcohol use and problems and other key variables on unintentional overdose and suicide mortality for the entire population of Veterans served each year over five years, and findings will inform prevention and intervention strategies for those at highest risk for overdose and suicide death.

T32 AA 007477 (Blow) 07/01/2020-06/30/2025 2.4 calendar
NIH-NIAAA $1,813,870
Multidisciplinary Alcoholism Research Training Program

Each year, problems related to alcohol consumption, abuse, and dependence cause 79,000 deaths and cost approximately $223.5 billion in the United States. Scientific research into the causes and prevention of alcohol-related problems across the lifespan, as well as treatment advances for individuals diagnosed with alcohol dependence is urgently needed to address these public health concerns. The purpose of this training grant application is to train and equip the next generation of scientific researchers who are committed to understanding and ameliorating the costs, causes, and consequences of alcohol-related problems.

Other Grants, Contracts, Cooperative Agreements & Funds Not to U-M
None

Appointments / Affiliations
None

In-kind Lab or Office Space, Equipment, Supplies
None

Materials that are Not Freely Available to Others
None

Foreign Collaborations / Foreign Components
None

Visiting Faculty/Scholars/Scientists/Post-docs/Students Supported by Funds not Managed by U-M
Department of Veterans Affairs – VA Ann Arbor Healthcare System USA
1 post-doc

Scientific, Financial and Effort Commitment Overlap Statement:
There is no scientific or budgetary overlap. Commitment overlap will be addressed by reducing effort in consultation with program staff if funding of any proposal creates an excess of 12 calendar months effort.

OTHER SUPPORT

OLSON-MADDEN, JENNIFER

ACTIVE

W81XWH-14-1-0005 (Ilgen)	12/30/2013-12/29/2019	6.0 calendar
DoD-USAMRMC	$686,621	

Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders

It is crucial to develop, refine, and evaluate empirically-based strategies for addressing suicide risk among active duty and former members of the U.S. armed forces. Military and active duty soldiers with SUDs are at clear elevated risk for suicide but, currently, no clear interventions exist to decrease risk of suicide in these individuals. This study will provide a first-of-its-kind evaluation of the impact of a CBT intervention to reduce risk of suicidal thoughts and behaviors for Veterans with SUDs who are at elevated risk for suicide.

VHA (Olson-Madden)	10/01/2019-09/30/2020	3.0 calendar
Office of Mental Health and Suicide Prevention	$115,604	

Cognitive Behavioral Therapy for Suicide Prevention via Telehealth

To determine the feasibility and acceptability of the provision of CBT-SP by way of telehealth technologies. Information gathered from this pilot program will be used to inform broader efforts to disseminate this treatment across the Veterans Health Administration.

PENDING

None

OVERLAP

There is no scientific or budgetary overlap. Commitment overlap will be addressed by reducing effort in consultation with program staff if funding of any proposal creates an excess of 12 calendar months' effort.

OTHER SUPPORT

Name: Brenner, L.A.

ACTIVE

W81XWH-14-1-005 (Ilgen) 12/01/2013-01/01/2020 0.6 calendar
U.S. Army Medical Research & Material Command MOMRP $2,214,534
Intervening to +Reduce Suicide Risk in Veterans with Substance Use Disorders
The goal of this project is to provide a strong test of the efficacy of a Cognitive Behavioral Therapy intervention for suicidal Veterans with substance use disorders.
Role on Project: Co-Investigator

(Katz) 07/01/2015-01/01/2020 0.12 calendar
VA Cooperative Studies Program, CSP 590 $520,727 (Denver site)
Lithium for Suicidal Behavior in Mood Disorders
The study is a multi-site randomized clinical trial. Participants will be patients with bipolar disorder or depression who have survived a recent episode of suicidal self-directed violence or were hospitalized specifically to prevent suicide. Randomly, half will receive lithium, and half will receive placebo.
Role on Project: Local Site Investigator

W81XWH-16-2-0004 (Nazem) 04/10/2017-04/09/2020 1.8 calendar
Military Suicide Research Consortium $1,155,292
Efficacy of a Computerized Cognitive Behavioral Treatment for Insomnia: Increasing Access to Insomnia Treatment to Decrease Suicide Risk
The goal of this project is to determine the efficacy of Sleep Healthy Using the Internet (SHUTi), a potential upstream suicide prevention intervention, for treatment of insomnia in OEF/OIF/OND Veterans.
Role on Project: Co-Investigator

1 I01 CX001310-01(Postolache) 07/01/2016-06/30/2020 0.6 calendar
CSR&D VA Merit $625,769
Toxoplasma gondii, the kynurenine pathway, and suicidal behavior in veterans
The main goal of this project is to compare *T. gondii* seropositivity, KYN and its metabolites QUIN+ and PIC, and inflammation markers in Veterans who receive mental health services vs. those without a history of suicidal self-directed violence.
Role on Project: Co-Investigator/Local Site Investigator

W81XWH-10-2-0178 (Gutierrez & Joiner) 03/01/2016-02/28/2021 0.36 calendar
DOD, Military Operational Medicine Research $9,939,843
Military Suicide Research Consortium 2.0
The major goal of this project is to synchronize and integrate suicide prevention efforts through three main strategies: 1) produce new scientific knowledge about suicidal behavior in the military; 2) use high-quality research methods/analysis to positively impact policy and practice, and; 3) disseminate consortium information and findings to those accountable for ensuring mental health of military personnel.
Role on Project: Senior Advisor

W81XWH-16-2-0004 (Brenner) 03/31/2019-03/30/2021 1.8 calendar
Military Suicide Research Consortium $1,499,884
Facilitating Assessment of At-Risk Sailors with Technology (FAAST)
The goal of this project is to evaluate the efficacy of the Cogito Companion as an upstream suicide prevention intervention The Cogito Companion app uses smartphone technology to provide real-time data regarding individuals' behaviors, mood, and symptoms that can be recorded, stored, displayed, and monitored by self and others.
Role on Project: Principal Investigator

(Brenner) 07/01/2019-06/30/2021 0.36 calendar
Colorado Traumatic Brain Injury Trust Fund $322,529
MINDSOURCE
Microbiome, inflammation, and gut permeability: the onset of psychiatric conditions among those with acute mild traumatic brain injury (mTBI).
The goal of the project is to quantify dynamic changes in the human microbiome, inflammation, gut permeability, and the onset/recurrence of post-injury psychiatric conditions through longitudinal characterization of recovery in the population of individuals who seek care at a Level 1Trauma Center for an acute mTBI.
Role on Project: Principal Investigator

(Oslin) 04/01/2017-03/31/2022 0.72 calendar
VA ORD, Health Services Research and Development $267,573 (Denver site)
PRIME Care (PRecision medicine In MEntal health Care)
The project is a multi-site randomized clinical trial, in which patient/provider dyads will be randomly assigned to receive results of a PGx battery right after randomization (i.e. intervention group) or after 6 months of treatment as usual.
Role on Project: Local Site Investigator

(Zuscik) 07/01/2019-06/30/2022 0.44 calendar
Congressionally Directed Medical Research Programs $2,200,000
Targeting the gut microbiome to treat posttraumatic osteoarthritis
The goal of this project is to define the role of the gut microbiome in posttraumatic osteoarthritis.
Role on Project: Co-Investigator

(Barnes, Borges) 10/01/2018 – 9/30/2022 0.1 calendar

VA ORD, Rehabilitation Research and Development $462,453

Thriving in the Midst of Moral Pain: The Acceptability and Feasibility of Acceptance and Commitment Therapy for Moral Injury (ACT-MI) Among Warzone Veterans

The proposed pilot study is designed to support ACT and moral injury content experts in their continued refinement and evaluation of ACT-MI for warzone Veterans. The pilot study would solidify the treatment approach and study design for a future efficacy trial. The specific aims focus on evaluating the acceptability of ACT-MI and determining the feasibility of the efficacy study design.
Role on Project: Consultant

(Bahraini) 10/01/2019-09/30/2022 0.6 calendar
VA Quality Enhancement Research Initiative $2,001,118
Global Merit Review Award
Examining the Effectiveness of an Adaptive Implementation Intervention to Improve Uptake of the VA Suicide Risk Identification Strategy.
The goal of the proposed project is to employ a Sequential Multiple Assignment Randomized Trial (SMART) design to improve the implementation of VA Risk ID's three-stage screening and evaluation process *to fidelity* (in correct sequence, by the appropriate provider, and within the designated time frame) for Veterans receiving annual screenings for depression and PTSD.
Role on Project: Co-Investigator

1R01MH120122-01 (Brenner/ Adams) 09/01/2019-06/30/2023 2.4 calendar

NIH $1,852,567

Integrating Signals of Suicide Risk from DoD & VHA Data to Improve Upon Suicide Risk Prevention Strategies for Combat Veterans

The proposed study will be the first to facilitate the merging of large data sets from the Department of Defense (DoD) and Veterans Health Administration (VHA) to identify factors associated with suicide risk. The ability to observe individuals' symptoms and behaviors over time, including during periods of transition (e.g., discharge from the military, transition into VHA care) is expected to inform improved risk assessment and intervention strategies. Knowledge gained will improve the wellbeing of military members and Veterans, and reduce future deaths by suicide.

(Interian) 10/01/2019-09/30/2023 0.3 calendar
VA ORD, BLR&D $97,865 (local)
Health Services Research and Development

CTBI: Traumatic brain injury-induced inflammation effects on cognitive evaluations and response inhibition: Mechanisms of increased risk for suicidality.

The goal of the proposed project is to conduct objective molecular correlates (biomarkers) of suicide risk in humans and animals. The studies included are designed to accelerate the discovery of clinical useful universal biomarkers at the interface of TBI and suicidality.

Role on Project: Co-Investigator

PENDING

None

OVERLAP

None

Appendix B: Quad Chart

Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders
Log Number: 11224006 and EDMF 5787
W81XWH 14-1-0005

PI: Mark Ilgen, PhD **Org:** University of Michigan **Award Amount:** $6,783,574

Study/Product Aim(s)

Primary Aims:

- Compare CBT and SPC in reducing the frequency and intensity of suicidal thoughts at during the multiple follow-up periods.
- Compare CBT and SPC in decreasing the likelihood of suicide attempts at multiple follow-up periods

Approach

The proposed project is a fully-powered multi-site randomized controlled trial of the CBT intervention versus the SPC condition for suicidal Veterans seen in Veterans Health Administration (VHA) outpatient SUD treatment programs. Participants will be followed up once a month for the first six months (i.e., 1-month, 2,-month) and then every six months (i.e., 12-months, 18 months, 24-months) thereafter.

Caption: Helping Veterans with Substance Use Disorders (image taken from "Google Images-Images for Reuse")

Accomplishments: Received regulatory approvals, completed project recruitment in both Michigan and Colorado sites, completed participant enrollment and randomization into the randomized controlled trial, continued intervention delivery and post-treatment follow-up assessments, continued project trainings for study therapists and research assistants.

Timeline and Cost

Activities	CY14	CY15	CY16	CY17	CY18
Project Start up					
Project Recruitment					
Follow-up Assessments					
Data Management & Analysis					
Project Reports & Dissemination					
Estimated Budget	**$1,232,338**	**$1,631,991**	**$1,602,345**	**$1,377,263**	**$939,637**

Updated: (Ann Arbor (MI), January 29, 2020)

Goals/Milestones

CY14-CY15 (January 2015): Project Start up

- ☑ Hire and train study staff
- ☑ Assemble data safety and monitoring board
- ☑ Obtain Certificate of Confidentiality
- ☑ Obtain Human Subjects and Research & Development Approval
- ☑ Modify study procedures and measures
- ☑ Refine risk management procedures and intervention

CY16–CY 18 (January 2018) Goals: Conducting the RCT

- ☑ Recruit, consent, and screen participants
- ☑ Conduct baseline interviews
- ☑ Conduct therapy sessions
- ⊙ Conduct follow-up interviews *(in progress)*
- ⊙ Conduct Data Safety and Monitoring Board meetings

CY 18 (July 2018) Goals: Project Management

- ☑ Create and maintain participant tracking databases
- ☐ Conduct analyses and quality checks *(in progress)*
- ☑ Submit regular progress reports

Budget Expenditure to Date
Projected Expenditure: $6,783,574
Actual Expenditure: $6,173722