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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. During this research period, project staff have completed participant recruitment and enrollment as well as delivery of the intervention. Participant follow-ups and data analyses are ongoing.

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 proposed project is a fully-powered randomized controlled trial (RCT) of the CBT intervention versus the 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 and SPC in reducing the frequency and intensity of suicidal thoughts at 1-, 3-, 6-, 12-, 18-, and 24-months; and (2) compare CBT 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 condition to the SPC condition in the frequency of illicit drug use, alcohol use, nonmedical opioid medication misuse, self-efficacy 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 vs. SPC) on post-treatment suicidal thoughts, behaviors and substance use.

As outlined in the SOW, the major goals for the fifth year of this project are primarily related to conducting the randomized controlled trial and include 1) recruitment of potential participants for screening and enrollment, 2) conducting baseline assessments, 3) randomization of eligible participants to either intervention condition, 4) delivery of intervention sessions, 5) conducting in-person and brief telephone follow-up assessments, 6) providing clinical supervision for study therapists, 7) developing and maintaining study databases, and 8) maintaining regulatory binders.

- *What was accomplished under these goals?*

General project overview

During this fifth year, our main objectives, activities, and accomplishments have focused on completing participant recruitment and enrollment into the RCT, completing intervention delivery to all enrolled participants, continuing follow-up assessments, and preparing data for analysis. A key objective during this fifth year was the evaluation and monitoring of recruitment activities and strategies across all study sites to ensure that participant enrollment was completed during this reporting period. Through this monitoring, we identified potential recruitment challenges including lower than anticipated treatment enrollment rates at several of the recruitment sites as well as challenges surrounding scheduling research therapy sessions around patient's extensive treatment programming commitments at the sites. Throughout this fifth year, we continuously monitored recruitment efforts across all sites and devised strategies to modify our recruitment plan, as needed, to overcome recruitment challenges while still maintaining the scientific integrity of the project and operating within our Statement of Work. We were pleased that during this reporting period we completed study recruitment at all study sites, enrolling our projected sample of 300 participants into the RCT. 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.

In addition to monitoring recruitment efforts during this year, we have also closely monitored therapy session attendance and delivery, as well as follow-up retention statistics across all sites. Project therapists met regularly during the reporting period to discuss challenging cases and receive supervision regarding therapy session delivery. Supervisors reviewed session tapes in order to monitor adherence to the treatment manual as well as the overall quality of the therapy sessions. All study sites have diligently tracked follow-up progress for each time point throughout this fifth 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 sites (e.g., Ann Arbor, Detroit) 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) and risk management.

During the first quarter, in January, 2018 our project was selected in the FY 2017 audit sample for a Federal Uniform Guidance Single Audit. Project staff worked with grants

management staff to respond to all auditor's questions regarding Departmental monitoring procedures and project specific reporting procedures. In February, 2018 we submitted an amendment to the Ann Arbor VA IRB to remove Detroit as a recruitment site and reallocate Detroit enrollment numbers to the VA Ann Arbor. We also requested approval to allow future enrolled participants to provide permission for the study team to use audio-recordings of their therapy sessions as part of formal training to professional audiences. This allows for the use of actual treatment recordings to be used in the training of therapists to administer the manualized treatment, which will be essential in the dissemination of the treatment manual at the end of the project. For those participants who provide consent, sections of the recorded sessions may be used as a tool to help train non-research VA and non-VA professional clinical staff in the delivery of the behavioral therapies administered in this project. All procedures for protection of audio recordings remain the same; however, recordings chosen to be used for professional clinical training will receive extra extensive review to ensure that they do not contain any identifying information about the participant. Recordings will be edited to remove anything that could potentially identify participants, such as specific dates, names or places. This amendment was approved in March, 2018 by the Ann Arbor VA IRB. Also in March, 2018 we received a request from the Ann Arbor VA Research Compliance Office to submit to a Regulatory Binder Audit (RBA). A regulatory binder is required by VHA research policy and is used to maintain study documents related to the operation of the study. The regulatory binder includes copies of documents the are necessary for study conduct, including all IRB project approvals and continuing review approval documents, copies of all protocol and consent form amendments, information regarding safety and data monitoring and reporting plans, documentation of informed consent and inclusion/exclusion review of all study participants and documentation of human subjects protection training for all staff involved with the project. We submitted our binder for review in March, 2018. We received results from the audit committee in March, 2018 which recommended no corrective actions. The audit committee commented the project had an excellent VA Project Regulatory Binder. Additionally, in March, 2018 we received a request from the Ann Arbor VA Research Compliance Office for an annual consent form audit. This audit was completed in May, 2018 and included the review of 362 project consent forms. The audit found only four minor errors in the consent forms which were corrected by the study team. No corrective actions were required by the Research Compliance Office and they commented on our routine use of an Informed Consent checklist to assure and document that all Subject Consent Process Requirements are met.

During the second quarter in May, 2018, 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 provided an overview of the study design and protocol. Amanda Price provided an update on the status of the study and directed the review of the DMSB report. Enrollment for Well Vets from July 2015 through March, 2018 (the period of time reviewed by the DSMB) included 1,057 patients who presented for substance use disorder treatment at VA SUD clinics at the study sites that were consented and screened. Of those, 283 participants were enrolled into the Main Study (the randomized controlled trial). The DSMB reviewed 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. Also during the second quarter, participant recruitment was completed with the recruitment of our proposed sample of 300

Veterans ending in June, 2018. We continued to deliver the intervention and control condition sessions to our final enrolled participants throughout the second quarter and into the third quarter. In total, out of the 300 participants recruited across all study sites, 149 participants were randomized to receive the CBT condition, and 150 were randomized to receive the SPC condition. One consented participant completed the interview portion of the baseline assessment before being withdrawn from the study. Therefore, this participant was not randomized to receive a condition. Clinical supervision of the CBT and SPC therapists continued throughout the reporting period to ensure fidelity of the intervention protocols. Study therapists and supervisors have continued to monitor participant satisfaction and comprehension of the session content and participants have expressed high levels of satisfaction with the sessions in both conditions. During the third quarter following the completion of intervention deliver, the focus shifted towards compiling and reviewing 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. During the next reporting period, we will begin the process of conducting fidelity reviews of therapy sessions. Through this process, we will be reviewing recorded sessions to provide ratings regarding how well the project therapists adhered to the session content provided in the manuals, as well as how well the therapists delivered the therapy. While this process of tape review 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 rates to reduce any potential biases.

Since study enrollment is complete and participants continue to complete the follow-up portion of the study, during this fifth year we have increased our focus on data management to ensure that all data collected is entered consistently across sites and cleaned in a timely fashion to be available for analysis and reporting. The project coordinator has worked closely with the data manager to develop data management procedures that are consistent across project sites and preserve the integrity of the data collected. In September, 2018 the 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. The project coordinator, data manager, and PI also traveled to Colorado in October, 2018 and December, 2018 in order to continue to refine and discuss data management issues. Also during this fifth year, project staff across sites continue to meet for our Columbia case consultation meetings. These meetings involve the review of all study assessments in which our outcome measure, the Columbia Suicide Severity Rating Scale (C-SSRS), are 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. In December, 2018, we requested a No Cost Time Extension to continue work on the project for an additional year. Through the No Cost Extension, study staff at both the Michigan and Colorado study site will continue to conduct follow-up assessments (6-, 12-, 18-, and 24-month follow-ups), enter all collected data, and continue to collaborate with the study staff to ensure all protocols and procedures are followed consistently across sites. Finally, in December 2018 the Data and Safety

Monitoring Board was provided a report which provided participant recruitment, follow-up, and safety information through September, 2018. Board members were in the process of reviewing the report at the end of this reporting period.

Project staff have continued to present preliminary findings from the project at national conferences during this reporting period. In April, 2018, project staff presented at the 51st Annual American Association of Suicidology Conference in Washington, D.C. Staff presented data from our baseline enrollment sample on the association between substance use and suicidal behaviors. The presentation was well-attended and well-received by conference attendees. In May, 2018, 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. In August, 2018 project staff presented at the Military Health System Research Symposium in Kissimmee, FL. Staff presented data from our screening sample on the association between aggression and suicidal ideation and behaviors in Veterans receiving Substance Abuse Treatment at the VA. The poster was well-received and conference attendees provided great feedback.

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.

Study recruitment

During this reporting period, we were able to complete project recruitment, enrolling our goal of 300 participants into the full study RCT. Out of these 300 participants, 150 were enrolled between the two sites in Colorado (the Denver VA and the Colorado Springs Community Based Outpatient Clinic), and 150 were enrolled in Michigan (the Ann Arbor VA [which includes the Toledo Community Based Outpatient Clinic]). We have recruited 100% of our overall projected study sample (n=300) through approximately 37 months of recruitment. Given the challenges with patient enrollment at the study sites, we are pleased that, despite the setbacks, we were able to reach our goal of recruiting 300 participants into the full study. Since project recruitment began across all sites, we have consented 1,218 participants for the screening portion of the study, of which 1,125 (92.5%) participants completed the screening questionnaire. Of this screening sample, 91.8% were male (n=1,033) and the mean age was 48.5 years old. Across all study sites in both Michigan and Colorado, 346 participants (30.8%) who completed the screening questionnaire were eligible to participate in the full study. Of those who were ineligible for participation in the trial, the reasons included: no report of current suicidal ideation (as indicated by a score of five or greater on the Beck Suicidal Ideation Scale [BSS-SR]), having a legal guardian , receiving methadone treatment for substance use within the past 6 month, experiencing active psychoses, actively participating in substance abuse treatment at the site for at least 1 month prior to recruitment, and actively participating in other randomized trial at the study site. Three hundred participants (86.7%) were consented and enrolled prior to the end of the reporting period. Participants were not enrolled into the RCT for the following reasons: declination of interest in the RCT, being discharged from treatment to another facility before study enrollment could take place, and repeatedly no-showing for enrollment appointment at the study site. One participant was excluded by the study team for behavioral reasons.

The Figures below reflects recruitment and enrollment numbers since recruitment began in 2015, and recruitment efforts for the reporting year. Numbers reflect participant recruitment across all study sites for enrollment in the RCT. Projected numbers reflect an initially proposed total recruitment window of 24 months.

Figure 1. Projected vs. Enrolled participants across all sites

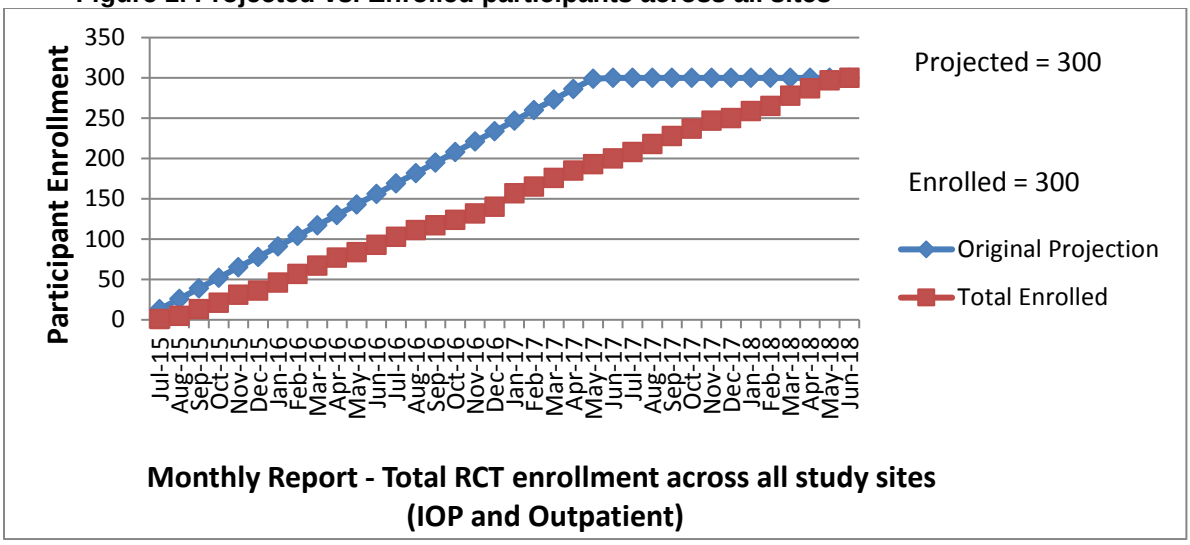
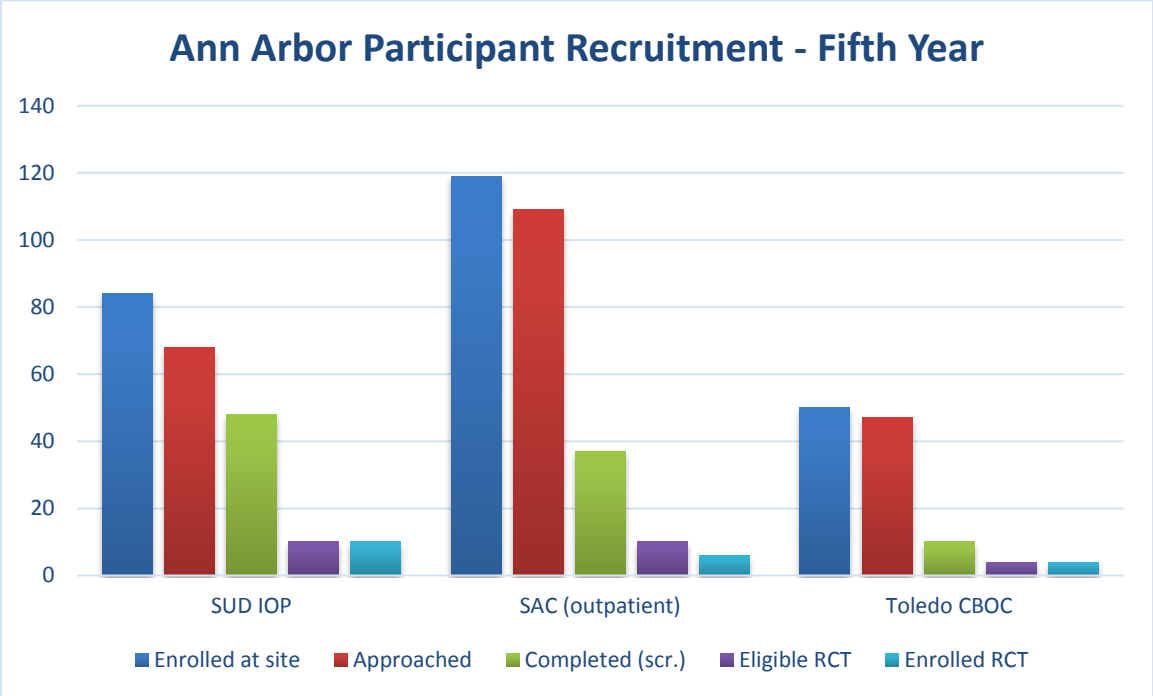


Figure 2. Recruitment for Ann Arbor VA site (IOP and Outpatient): December 31, 2017 through June 26, 2018

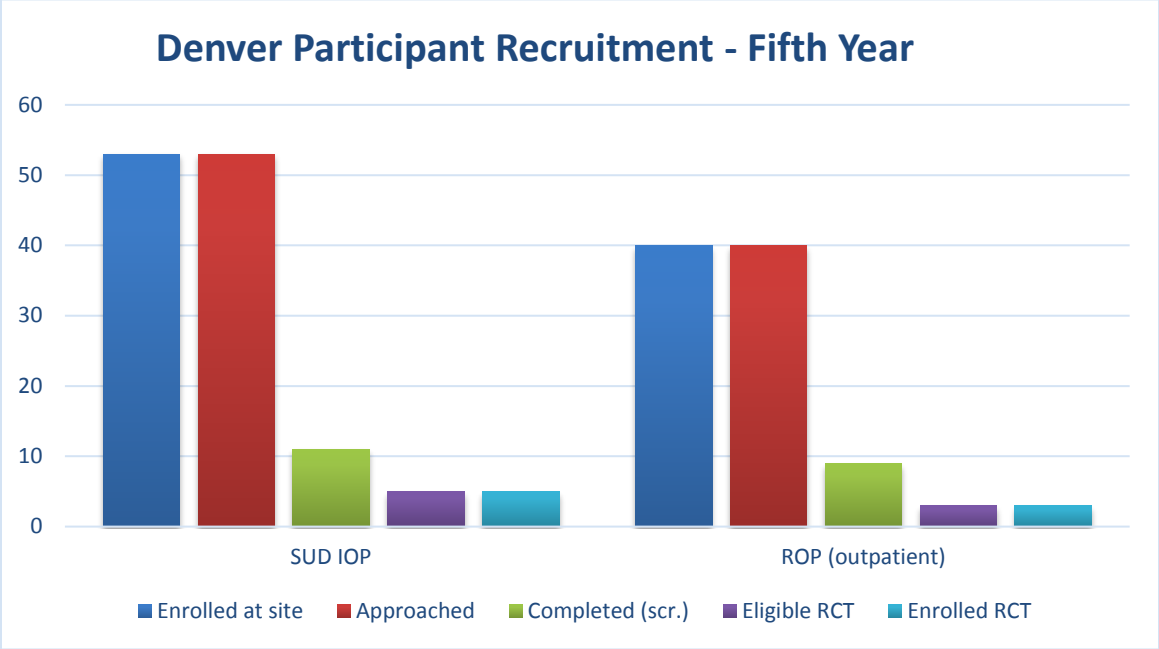


During this reporting period in Ann Arbor at the SUD IOP clinic, we approached 81.0% (n=68) of the 84 patients who came to the clinic for their intake appointment. Of those approached, 79.4% (n=54) agreed to participate and signed an informed consent form and were given a screening questionnaire to complete. Eighty-nine percent (n=48) of those consented completed the screening questionnaire, and of those 10 were eligible for the full RCT (20.8%). Of those eligible, 10 participants (100%) were enrolled into the full study.

In the Ann Arbor Substance Abuse Outpatient Clinic (SAC) during this reporting period, we have approached 91.6% (n=109) of the 119 patients who came to the clinic for their intake appointment. Of those approached, 47 patients agreed to participate (43.1%) and 37 patients completed the screening questionnaire (78.7%). There were 10 participants who were eligible for the full RCT based on their answers to the screening questions, which equates to an eligibility rate of 27.0%. Six participants were enrolled into the full RCT (60.0%). One eligible participant was not enrolled due to the fact they did not show up for 3 scheduled baseline appointments and discontinued treatment at the SAC clinic, while 3 additional eligible participants declined.

At the Toledo Community Based Outpatient Clinic (CBOC), we approached 47 patients out of the 50 enrolled in treatment at the clinic (94.0%) via recruitment letters. Of those patients, 21.3% completed the screening questionnaire (n=10) and four participants were eligible for the full RCT for an eligibility rate of 40.0%. All 4 eligible participants were enrolled into the RCT (100%).

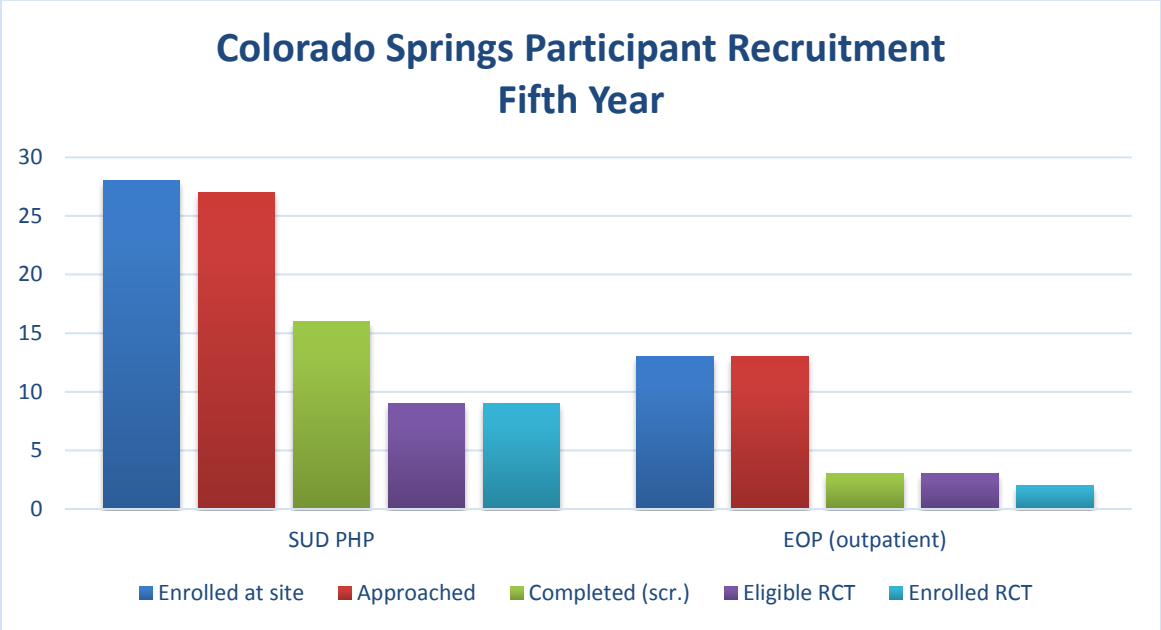
Figure 3. Recruitment for Denver VA site (IOP and Outpatient): December 31, 2017 through May 15, 2018.



During this reporting period in Denver at the SUD IOP clinic, we approached 100% (n=53) of the 53 patients who came to the clinic for their intake appointment. Of those approached, 20.8% (n=11) agreed to participate and signed an informed consent form and were given a screening questionnaire to complete. All consented participants completed the screening questionnaire (n=11), and of those 5 were eligible for the full RCT (45.5%). All 5 eligible participants were enrolled into the study (100%).

In the Denver Substance Abuse Outpatient Clinic (ROP), we approached 100% (n=40) of the patients who came to the clinic for their intake appointment. Of those approached, 9 patients agreed to participate (22.5%) and all 9 patients completed the screening questionnaire (100%). There were 3 participants who were eligible for the full RCT based on their answers to the screening questions, which equates to an eligibility rate of 33.3%. All eligible participants were enrolled into the full RCT (100%).

Figure 4. Recruitment for Colorado Springs CBOC site (IOP and Outpatient): December 31, 2017 through June 15, 2018.



During this reporting period in Colorado Springs at the CBOC SUD PHP clinic, we approached 96.4% (n=27) of the patients who came to the clinic for their intake appointment (n=28). Of those approached, 59.3% (n=16) agreed to participate and signed an informed consent form and were given a screening questionnaire to complete. All consented participants completed the screening questionnaire (n=16), and of those 9 were eligible for the full RCT (56.3%). All 9 eligible participants were enrolled into the study during this reporting period (100%).

In the Colorado Springs CBOC Substance Abuse Outpatient Clinic (EOP), we approached 100% (n=13) of the patients who came to the clinic for their intake appointment. Of those approached, 3 patients agreed to participate (23.1%) and all

patients completed the screening questionnaire (100%). There were 3 participants who were eligible for the full RCT based on their answers to the screening questions, which equates to an eligibility rate of 100%. Two participants were enrolled into the full RCT (66.7%). One eligible participant was not enrolled due to an inability to contact them to schedule the enrollment appointment.

Table 2 below provides preliminary demographic information for the screening sample, for each site individually and across all sites. No significant demographic differences were detected between sites for the screening sample.

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

		Site		
	Total	**Ann Arbor VA site**	**Denver VA site**	**Colorado Springs CBOC site**
N=	**1,125**	**670**	**309**	**146**
Demographics				
Age (yr.) (mean)	48.5	48.3	50.4	45.6
Male gender	1,033 *(91.8%)*	620 *(92.5%)*	279 *(90.3%)*	134 *(91.8%)*
Domestic status:				
Partnered (Married / Cohabitating)	313 *(27.8%)*	192 *(28.7%)*	79 *(25.6%)*	42 *(28.8%)*
Hispanic ethnicity	111 *(9.9%)*	32 *(4.8%)*	49 *(15.9%)*	30 *(20.5%)*
Race group				
White	761 *(67.6%)*	481 *(71.8%)*	184 *(59.5%)*	96 *(65.8%)*
African-American	256 *(22.8%)*	154 *(23.0%)*	82 *(26.5%)*	20 *(13.7%)*
Income before taxes, past year: $25,000 or less	529 *(47.0%)*	310 *(46.3%)*	155 *(50.2%)*	64 *(43.8%)*

The Figures below provide information on the prevalence of suicidal ideation (Figure 2) and suicidal behaviors (Figure 3) in the screening sample (Veterans presenting for substance abuse treatment). Data is presented from the Beck Scale for Suicidal Ideation – Self Report (BSS-SR), which was utilized to determine study eligibility for the RCT. Data is presented for the project, and by site. No statistical differences were detected between sites.

Figure 5. Suicidal ideation, screening sample – Total and by site

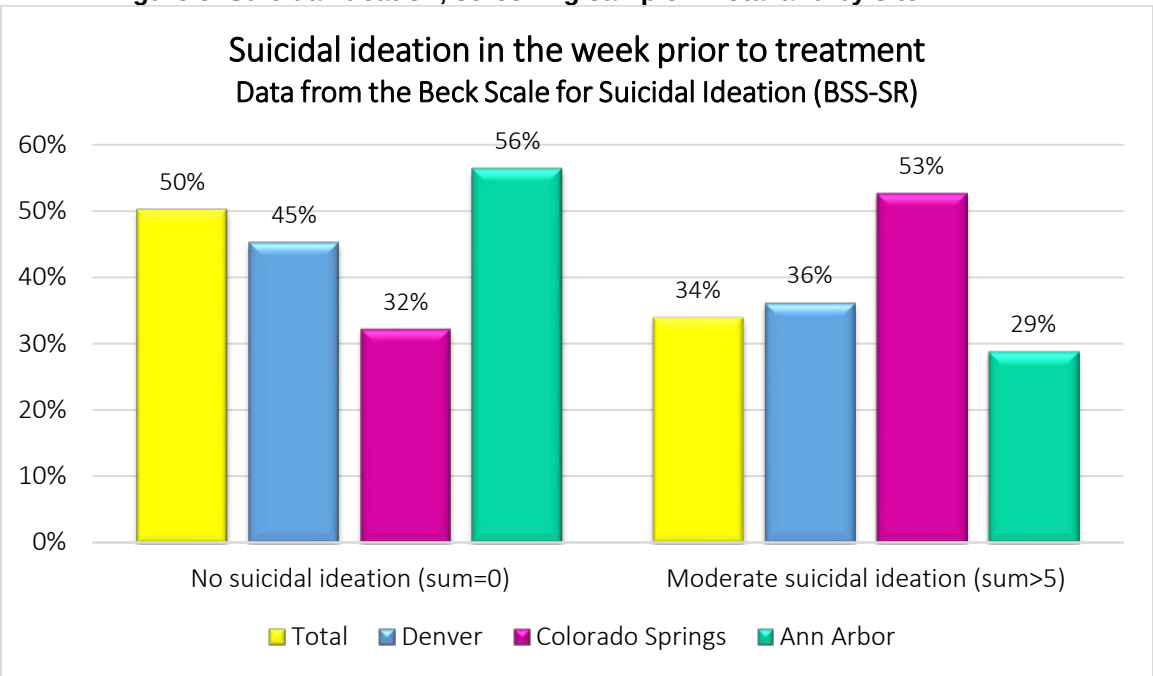


Figure 6. Suicidal behaviors, screening sample - Total and by site

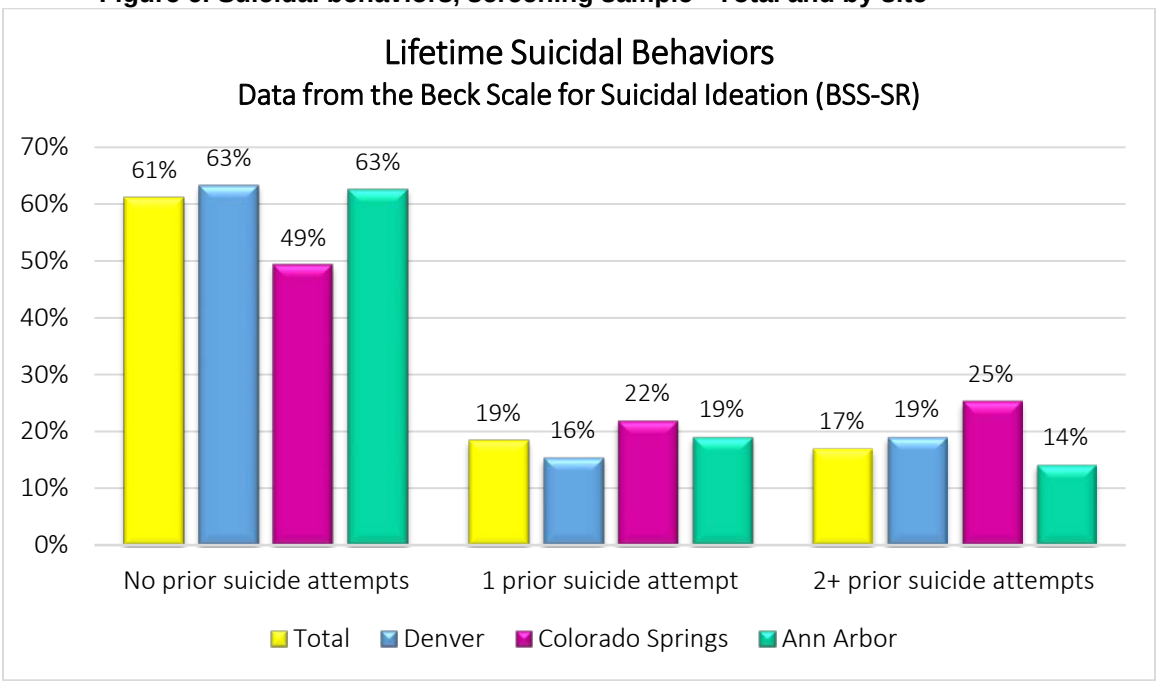


Table 3 below provides preliminary information on the frequency of recent substance use in the screening sample for the total sample and for each individual site. Data reported are the number and percentage of participants who endorsed using each substance for recreational use (e.g. not as a prescription) within the 6 months prior to completing the screening assessment.

Table 3. Substance use frequencies (data from the Substance Abuse Outcomes Module [SAOM]) – Total and by site

		Site		
	Total	**Denver**	**Colorado Springs**	**Ann Arbor**
N=	**1,125**	**309**	**146**	**670**
Past 6 months – any use				
Alcohol	887 (*79%*)	252 (*82%*)	111 (*76%*)	524 (*78%*)
Marijuana	448 (*40%*)	143 (*46%*)	66 (*45%*)	239 (*36%*)
Cocaine	226 (*24%*)	70 (*23%*)	26 (*18%*)	170 (*25%*)
Heroin	111 (*10%*)	21 (*7%*)	11 (*8%*)	79 (*12%*)
Amphetamines	115 (*10%*)	49 (*16%*)	35 (*24%*)	31 (*5%*)
Hallucinogens / Inhalants	35 (*3%*)	14 (*5%*)	7 (*5%*)	14 (*2%*)
Prescription opioids (misused)	244 (*22%*)	75 (*24%*)	39 (*27%*)	130 (*19%*)
Prescription sedatives (misused)	141 (*13%*)	41 (*13%*)	22 (*15%*)	78 (*13%*)
Tobacco	734 (*65%*)	205 (*66%*)	104 (*71%*)	425 (*63%*)

Table 4 and Table 5 below provide preliminary baseline characteristics of the RCT sample across all recruitment sites as well as each individual site. The data includes participants recruited from both IOP and standard outpatient SUD clinics. No statistically significant differences were noted between conditions on demographic variables or the clinical variables presented. **As noted earlier, because one participant withdrew before randomization, all remaining analyses are based on an N of 299.**

Table 4. Well Vets: Characteristics at Baseline.

		Condition	
	Total	**SPC**	**CBT**
N	299	149 (50%)	150 (50%)
Demographics			
Site [NS]			
Ann Arbor	150 (50%)	74 (50%)	76 (51%)
Denver	90 (30%)	45 (30%)	45 (30%)
Colorado Springs	59 (20%)	30 (20%)	29 (19%)
Age (yr.) (mean, SD) [NS]	45.5 (12.1)	45.3 (12.1)	45.7 (12.1)
Male gender [NS]	269 (90%)	133 (89%)	135 (91%)
Domestic status: Married/cohabitating [NS]	76 (25%)	35 (23%)	41 (27%)
Hispanic ethnicity [NS]	44 (15%)	27 (18%)	17 (11%)
Race group [NS]			
White	196 (66%)	94 (63%)	102 (68%)
African-American	52 (17%)	32 (22%)	20 (13%)
More than one race, or other race	50 (17%)	22 (15%)	28 (19%)
Education [NS]			
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 (77%)	119 (79%)
Employment [NS]			
Full time/part time/self-employed*	52 (17%)	28 (19%)	24 (16%)
Disabled	115(39%)	61 (41%)	54 (36%)
All others	131 (44%)	59 (40%)	72 (48%)
Income before taxes, past year: $25,000 or less [NS]	150 (50%)	78 (52%)	72 (48%)
Ever been homeless - yes [NS]	188 (63%)	89 (60%)	99 (66%)
Military service history			
Rank [NS]			
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%)
# Deployments, of any sort, in career [NS]			
None	86 (29%)	40 (27%)	46 (31%)
One	88 (29%)	46 (31%)	42 (28%)
Two or more	125 (42%)	63 (42%)	62 (41%)
Any combat experience - yes [NS]	127 (44%)	59 (40%)	68 (47%)
One combat tour	76 (62%)	35 (60%)	41 (63%)
Two or more combat tours	47 (38%)	23 (40%)	24 (37%)
Branch served [NS]			
Army	161 (57%)	81 (57%)	80 (58%)
Marine Corps, Navy, *or* Air Force	106 (38%)	52 (37%)	54 (39%)
More than one branch	13 (5%)	8 (6%)	5 (4%)

*includes retirees and disability, with part/full/self-employment. [NS] p not significant at 0.05

Table 5. Well Vets – substance use, and mental health – at Baseline

		Condition	
	N (%) or Mean (SD)	**SPC**	**CBT**
N	299	149 (50%)	150 (50%)
Substance use in the past 6 months (SAOM)			
Alcohol (any, in past 6 months) [NS]	250 (84%)	122 (83%)	128 (86%)
Any drug use [NS]	229 (77%)	116 (78%)	113 (75%)
Any illicit substances (street drugs and/or someone else's Rx meds)	209 (91%)	106 (91%)	103 (91%)
Misuse of own Rx medication(s)	83 (36%)	42 (36%)	41 (36%)
Mental health			
PHQ-8 score (mean, SD) [NS]	13.7 (5.6)	13.6 (5.9)	13.8 (5.3)
SEASA sum (mean, SD) [NS]	33.1 (11.7)	32.5 (11.4)	33.8 (11.9)
BSS-SR			
BSS-SR sum (items 1-19) (mean, SD) [NS]	11.5 (7.7)	11.5 (8.0)	11.5 (7.4)
CSS-RS			
Total Ideation, *past month* (mean, SD) [NS]	14.9 (6.4)	15.1 (8.1)	14.7 (6.4)
Highest Ideation, *past month* [NS]			
Zero	68 (23%)	34 (23%)	34 (23%)
1 or 2	102 (34%)	56 (38%)	46 (31%)
3 to 5	129 (43%)	59 (40%)	70 (47%)
Any past suicide attempt = ***YES*** (n, %) [NS]	189 (63%)	94 (63%)	95 (63%)

[NS] p not significant at 0.05

Table 6 below depicts the frequency of lifetime suicidal behaviors reported for the baseline sample. Data is reported from the Columbia Suicidal Severity Rating Scale (C-SSRS). Definitions for these behaviors were taken from the measure. A suicide attempt was defined as a potentially self-injurious act committed with at least some wish to die as a result of the behavior. An interrupted suicide attempt was defined as an instance when the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act, where if not for that interruption, an actual attempt would have occurred. Similarly, an aborted suicide attempt is defined as an instance when a person begins to take steps toward making a suicide attempt but stops themselves before they actually engage in any self-destructive behavior. Non-suicidal self-injurious behavior is defined as any self-injurious behavior done without any suicidal ideation, or without the intent to ends one life. Instead, the behavior is done for an alternative reason (e.g. to relive stress, feel better, get sympathy/help, etc.).

Table 6. Baseline suicidal behavior history: Lifetime and Past Month for all sites

		Site		
	Overall	**Ann Arbor**	**Denver**	**Colorado Springs**
N	**299**	**150 (50.2%)**	**90 (30.1%)**	**59 (19.7%)**
Suicide attempt	189 (63.2%)	98 (65.3%)	48 (53.3%)	43 (72.9%)
Interrupted suicide attempt	46 (15.3%)	22 (14.7%)	15 (16.5%)	9 (15.3%)
Aborted suicide attempt	59 (19.7%)	28 (18.7%)	14 (15.4%)	17 (28.8%)
Non-suicidal self-injurious behavior	93 (31.0%)	37 (24.7%)	36 (39.6%)	20 (33.9%)

Intervention Delivery

As previously noted, out of the 300 participants recruited across all study sites, 299 were randomized to a treatment condition; 150 participants were randomized to receive the CBT condition (50.0%), and 149 were randomized to receive the SPC condition (49.7%). One consented participant completed the interview portion of the baseline assessment before being withdrawn from the study. Therefore, this participant was not randomized to receive a condition. Figure 7 below displays the session completion percentages for all participants across all sites, by condition. Overall, approximately 70% of participants assigned to the CBT condition completed all 8 sessions, and a similar percentage of those participants assigned to the SPC condition completed all 8 sessions. There were no significant differences observed in session attendance between conditions. Table 7 below provides session feedback obtained from participants on questions regarding their feelings towards the sessions. Significant differences were detected between conditions on a few items and are represented in the table. Tables 8 and 9 present data on demographic characteristics and session attendance. Age and combat history were the only significant characteristics, with younger veterans being less likely to complete all 8 therapy sessions, and those with a history of combat being more likely to complete all 8 therapy sessions.

Figure 7. Session Completion data across all sites, by condition

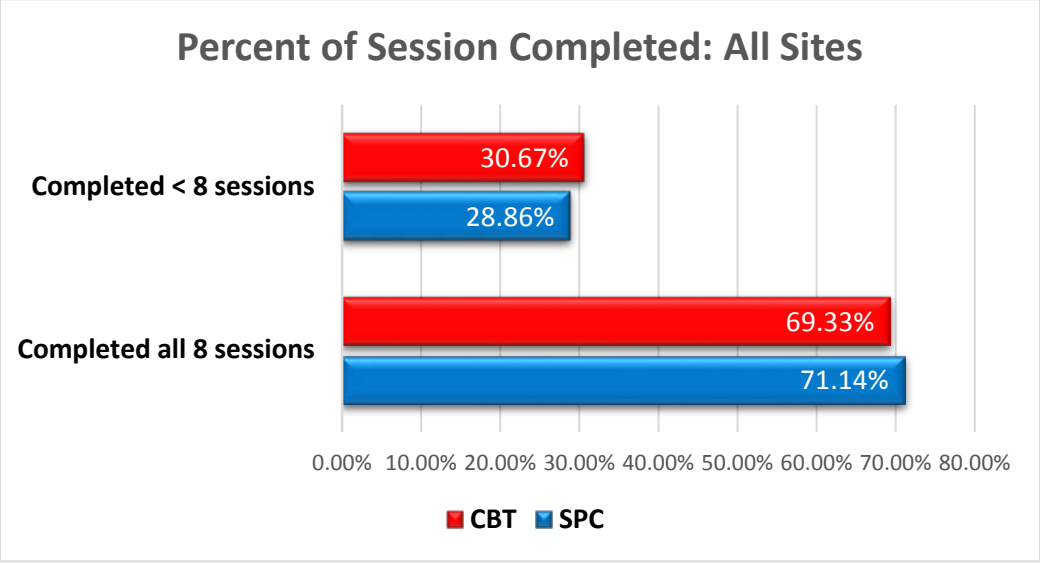


Table 7. Therapy Session Feedback Form: means, across 8 sessions, overall and by site and condition

			Condition A		Condition B	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
Session Feedback						
1. How helpful was the session for you?	8.3 [NS]	8.2 – 8.4	8.3	8.2 – 8.5	8.2	8.1 – 8.3
2. How actively did you participate in the session today?	9.0 [NS]	9.0 – 9.1	9.1	9.0 – 9.2	9.0	8.9 – 9.1
3. How comfortable did you feel discussing issues about suicide with your therapist?	8.2 [C]	8.1 – 8.3	8.4	8.3 – 8.6	8.1	7.9 – 8.2
4. How comfortable did you feel discussing issues around alcohol/drug use with your therapist?	8.9 [NS]	8.9 – 9.0	9.0	8.9 – 9.1	8.8	8.7 – 9.0
5. How well did your therapist explain the structure and purpose of today's session with you?	9.3 [C]	9.2 – 9.3	9.2	9.1 – 9.3	9.4	9.3 – 9.4
6. How helpful was today's session in helping you to feel better about yourself?	8.2 [NS]	8.1 – 8.3	8.3	8.2 – 8.4	8.1	7.9 – 8.2

[NS] p not significant at 0.05; [C] $p \leq 0.05$

Table 8. Well Vets: Characteristics at Baseline and their association with therapy session attendance, all conditions

		Sessions		Odds of <8 Sessions attended
	Total	All sessions	<8 Sessions	
N	299	210 (70%)	89 (30%)	OR (95% CI)
Demographics				
Condition B [NS]	150 (50%)	104 (50%)	46 (52%)	1.09 (0.66, 1.79)
Site [NS]				
Ann Arbor	150 (50%)	105 (50%)	45 (51%)	(referent)
Denver	90 (30%)	61 (29%)	29 (33%)	1.11 (0.63, 1.95)
Colorado Springs	59 (20%)	44 (21%)	15 (17%)	0.79 (0.40, 1.57)
Age (yr.) (mean, SD) [A]	45.5 (12.1)	47.7 (11.8)	40.4 (11.3)	**0.95 (0.93, 0.97)**
Male gender [NS]	269 (90%)	187 (89%)	82 (92%)	1.44 (0.59, 3.49)
Domestic status: Married/cohabitating [NS]	76 (25%)	52 (25%)	24 (27%)	1.12 (0.64, 1.97)
Hispanic ethnicity [NS]	44 (15%)	26 (12%)	18 (20%)	1.78 (0.92, 3.45)
Race group [NS]				
White	196 (66%)	140 (67%)	56 (63%)	(referent)
All others	103 (34%)	69 (33%)	33 (37%)	1.20 (0.71, 2.01)
Education [NS]				
H.S./GED, or less, or unspecified	66 (22%)	45 (21%)	21 (24%)	1.13 (0.63, 2.04)
At least some college, w/ or w/o degree(s)	233 (78%)	165 (79%)	68 (76%)	(referent)
Employment [NS]				
Disabled	52 (17%)	74 (35%)	41 (46%)	1.56 (0.94, 2.58)
All others	115(39%)	135 (65%)	48 (54%)	(referent)
Income before taxes, past year: $25,000 or less [NS]	150 (50%)	111 (53%)	39 (44%)	0.70 (0.42, 1.15)
Military service history				
Ever deployed [C]	213 (71%)	142 (68%)	71 (80%)	**1.89 (1.04, 3.42)**
Any combat experience - yes [C]	127 (44%)	81 (39%)	46 (52%)	**1.70 (1.03, 2.81)**

*includes retirees and disability, with part/full/self-employment. [NS] p not significant at 0.05
[A] $p \leq 0.005$; [B] $p \leq 0.01$; [C] $p \leq 0.05$;

Table 9. Well Vets – substance use, and mental health – at Baseline: n = 299 and their association with therapy session attendance

		Sessions		Odds of <8 Sessions attended
	Total	**All sessions**	**<8 Sessions**	
N	299	210 (70%)	89 (30%)	OR (95% CI)
Substance use in the past 6 months (SAOM)				
Alcohol (any, in past 6 months) [NS]	250 (84%)	180 (86%)	70 (80%)	0.60 (0.31, 1.16)
Any drug use [NS]	229 (77%)	155 (74%)	74 (83%)	1.75 (0.93, 3.30)
Any illicit substances (street drugs and/or someone else's Rx meds) [NS]	209 (70%)	139 (66%)	70 (79%)	2.01 (0.65, 6.25)
Misuse of own Rx medication(s) [NS]	83 (28%)	61 (29%)	22 (25%)	0.65 (0.36, 1.18)
Mental health				
PHQ-8 score (mean, SD) [NS]	13.7 (5.6)	13.6 (5.5)	14.1 (5.8)	1.02 (0.97, 1.07)
SEASA sum (mean, SD) [NS]	33.1 (11.7)	32.4 (11.4)	35.0 (12.2)	1.02 (0.99, 1.04)
BSS-SR				
BSS-SR sum (items 1-19) (mean, SD) [NS]	11.5 (7.7)	11.3 (7.6)	11.8 (7.9)	1.01 (0.98, 1.04)
CSS-RS				
Total Ideation, *past month* (mean, SD) [NS]	14.9 (6.4)	14.6 (6.8)	15.6 (5.3)	1.02 (0.98, 1.07)
Highest Ideation, *past month* [NS]				
Zero	68 (23%)	41 (19%)	27 (30%)	(referent)
1 or 2	102 (34%)	73 (35%)	29 (33%)	1.66 (0.87, 3.17)
3 to 5	129 (43%)	96 (46%)	33 (37%)	1.92 (1.02, 3.58)
Any past suicide attempt = ***YES*** (n, %) [NS]	189 (63%)	131 (63%)	58 (65%)	1.13 (0.67, 1.89)

[NS] p not significant at 0.05; [B] $p \leq 0.01$; [C] $p \leq 0.05$;

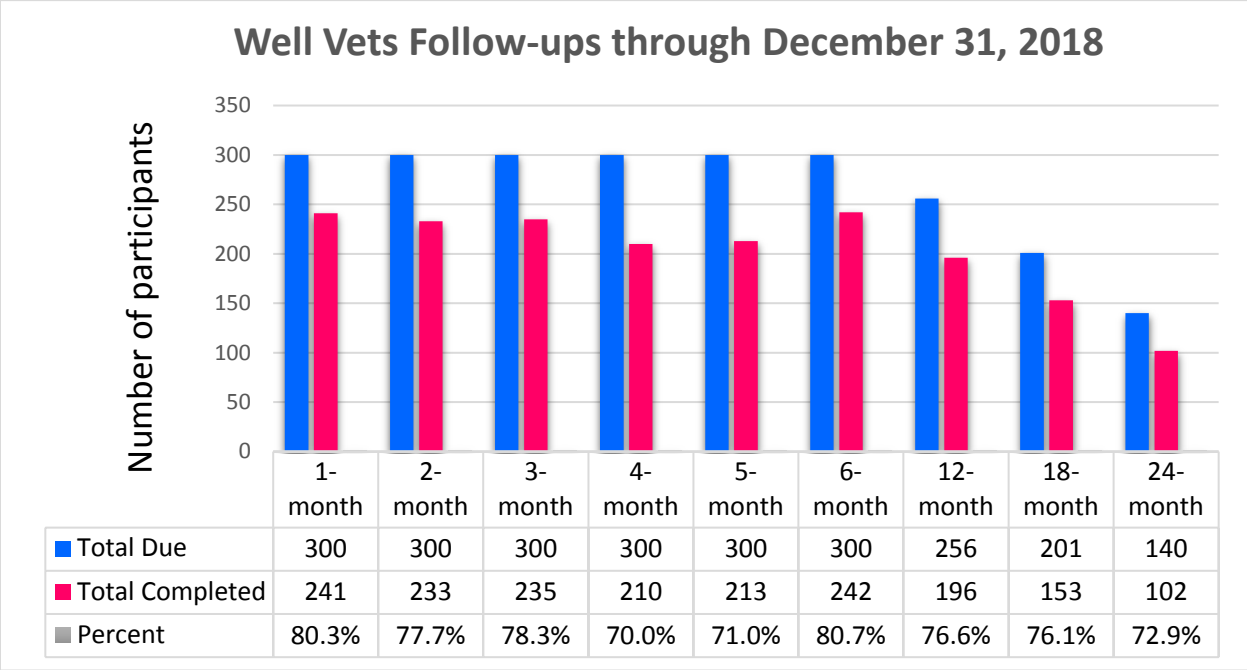
Participant Follow-up and Retention

During this reporting period, we have also continued conducting follow-up assessments. We are now completing follow-ups for all assessment points, including the 2-year (24-month) final follow-up. **To date, there have been a potential 2,397 follow-up assessments due for all participants, including all time points. We have completed 1,825 follow-up assessments out of those that are due for completion.** Based on these numbers, across all study sites, the overall follow-up retention rate is **76.1%**. At this point, we have completed all possible follow-ups for the following assessment time points: 1-month in-person 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 in-person follow-up. For the 1-month post enrollment follow-up assessment, the retention rate is 80.3% across all sites. The follow-up rate for the brief 2-month phone follow-up assessment is 77.7%. The follow-up rate for the 3-month post enrollment follow-up assessment is 78.3%. The 4-month and 5-month follow-ups are both brief phone assessments and the follow-up rates are 70.0% and 71.0% respectively. The follow-up rate for the 6-month assessment is 80.7%, and for the 12-month assessment, the rate is 76.6%. For the 18-month follow-up assessments, the completion rate is 76.1%. Finally, the 24-month follow-up assessment completion rate is 72.9%. 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. 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).

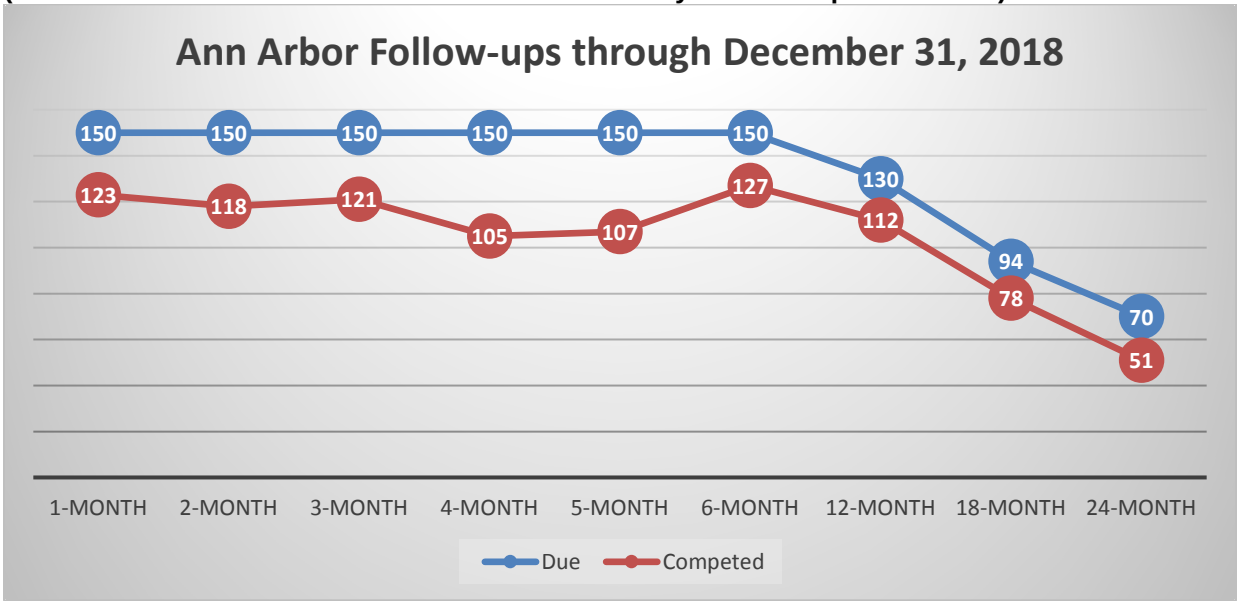
The Figures below (Figures 8, 9,10, and 11) provides more details regarding the follow-up assessment completion rates across all study sites and each individual site.

Figure 8. Follow-up retention statistics across all sites



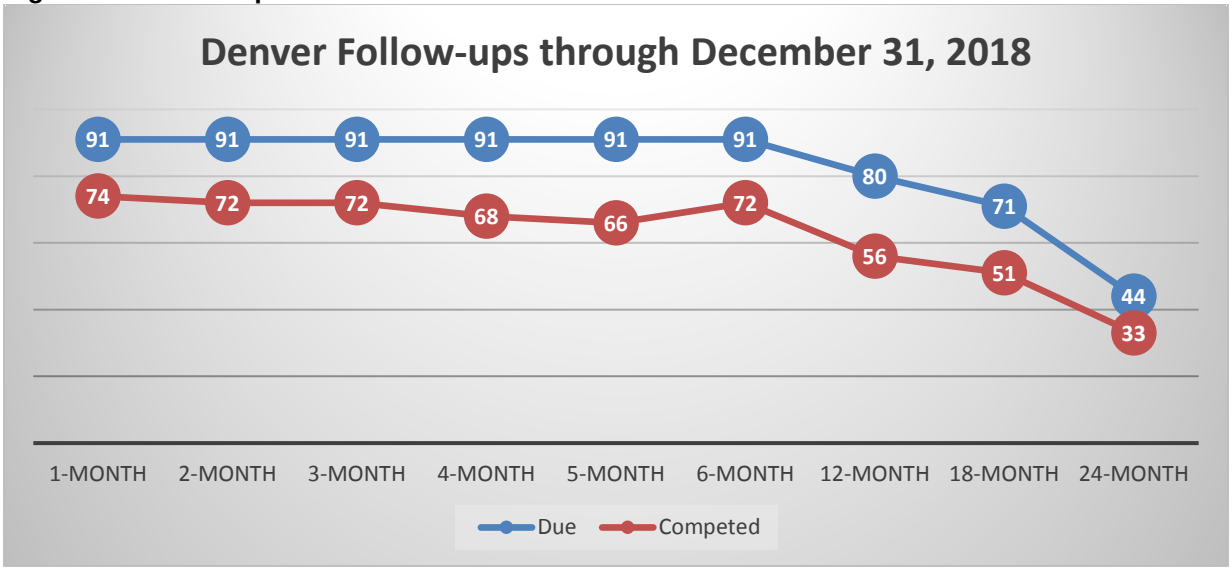
	1-month	2-month	3-month	4-month	5-month	6-month	12-month	18-month	24-month
Total Due	300	300	300	300	300	300	256	201	140
Total Completed	241	233	235	210	213	242	196	153	102
Percent	80.3%	77.7%	78.3%	70.0%	71.0%	80.7%	76.6%	76.1%	72.9%

Figure 9. Follow-up retention statistics – Ann Arbor sites
(Ann Arbor VA Medical Center and Toledo Community Based Outpatient Clinic)



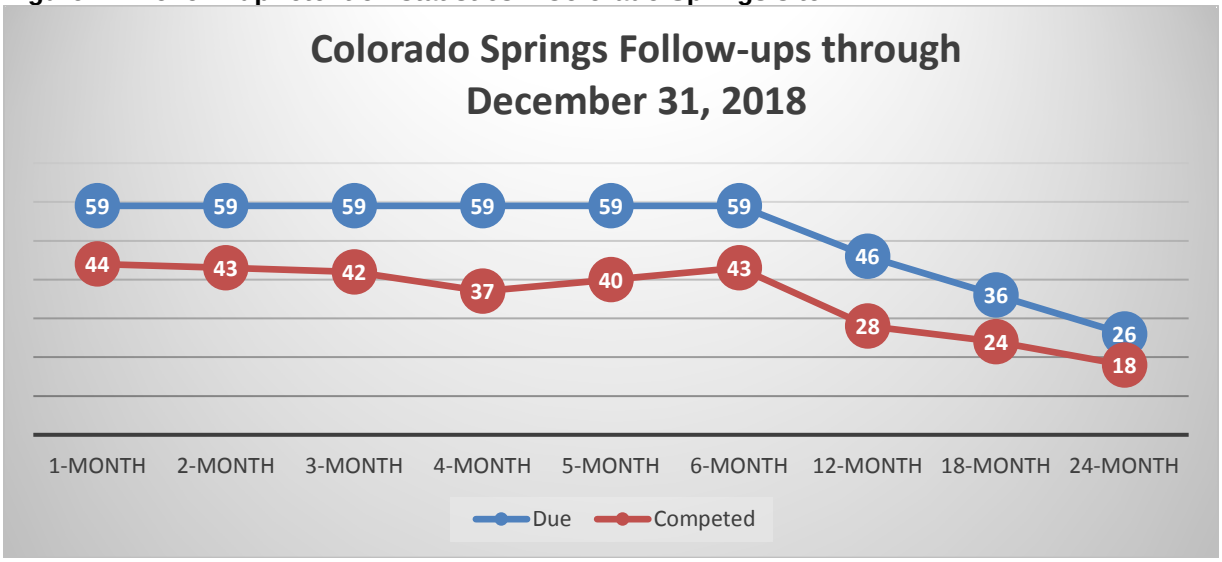
For the Ann Arbor site, the overall follow-up retention rate is 78.9%, with the following rates at each respective time point: 1-month is 82.0%, 2-month is 78.7%, 3-month is 80.7%, 4-month is 70.0%, 5-month is 71.3%, 6-month is 84.7%, 12-month is 86.2%, 18-month is 83.0%, and 24-month is 72.9%.

Figure 10. Follow- up retention statistics – Denver site



For the Denver site, the overall follow-up retention rate is 76.1%, with the following rates at each respective time point: 1-month is 81.3%, 2-month is 79.1%, 3-month is 79.1%, 4-month is 74.7%, 5-month is 72.5%, 6-month is 79.1%, 12-month is 70.0%, 18-month is 71.8%, and the 24-month is 75.0%.

Figure 11. Follow- up retention statistics – Colorado Springs site



For the Colorado Springs site, the overall follow-up retention rate is 69.0%, with the following rates at each respective time point: 1-month is 74.6%, 2-month is 72.9%, 3-month is 71.2%, 4-month is 62.7%, 5-month is 67.8%, 6-month is 72.9%, 12-month is 60.9%, 18-month is 66.7%, and the 24-month follow-up is 69.2%.

Patient Safety Monitoring

SAEs and AEs

As of December 31, 2018, we have had fourteen participants request to withdraw from the study across all the sites. We have had four participant deaths from the Ann Arbor site and two participant deaths from the Colorado Springs site, for a total of 6 deceased over the course of the study. The cause of death for one participant from Colorado Springs was reported as a suicide. The causes of death from the 5 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, 2018, we have submitted 18 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 10 outlines the reports made and the outcomes.

Table 10: Research Monitor Notifications and outcomes – All Sites

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

Colorado Springs	1/72018	Participant death	No changes proposed.
Ann Arbor	6/14/2018	Participant death	No changes proposed.

At this point, we do not have data to report regarding study aims since recruitment, baseline, and 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?*

  Nothing to Report.

- *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 anticipate that this will be an ongoing training, where staff will continue to meet regularly throughout the study to process and refine the management of these issues. 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 continue follow-up within the next reporting period.

4. IMPACT

Nothing to Report.

5. CHANGES/PROBLEMS

Nothing to Report.

6. PRODUCTS

Nothing to Report.

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* *4* *Dr. Ilgen has reviewed study materials, assisted in the refining and revision of measures and intervention manuals, provided oversight in protocol and study procedures, reviewed regulatory documents, participated in clinical supervision for intervention conditions, aided in hiring and training of new staff, provided risk management for all phases of the project, and attended project meetings.*

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* *4* *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* *10* *Ms. Price has facilitated the overall protocol and study coordination of the study sites, including management and coordination of participant recruitment, enrollment, intervention delivery, and follow-up assessments, participation in subject recruitment and consenting, conducting enrollment interviews, randomization of eligible participants, facilitation of intervention delivery, and conducting follow-up assessments, 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.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Neared person month worked:* *Contribution to the project:*	*Suzanne Thomas* *Project Coordinator (Denver & Colorado Springs)* *10* *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:*	*Emily Yeagley, MA* *Lab Manager (Ann Arbor)* *2* *Ms. Yeagley has participated in team meetings and provided guidance and supervision to study staff.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Amanda Regalia/Turecek, LMFT* *Study Therapist – CBT condition (Denver & Colorado Springs)* *6* *Ms. Regalia has participated in weekly clinical supervision and training for the CBT treatment condition. She has been providing therapy sessions to participants enrolled in the CBT condition and managing all aspects of treatment, risk management in sessions and follow-up.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Erin Goldman, LMSW* *Study Therapist- CBT condition (Ann Arbor)* *4* *Mrs. Goldman has assisted in reviewing and editing the CBT therapist manual, participated in ongoing clinical supervision and training in the delivery of the CBT intervention, attended project meetings and trainings, helped prepare study-related materials for participants, helped in the training of new CBT therapists, and provided CBT therapy sessions to participants enrolled in the CBT condition.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Jennifer Powers, LCSW* *Study Therapist – SPC condition (Denver & Colorado Springs)* *7* *Ms. Powers has participated in weekly clinical supervision and training for the SPC treatment condition. She has been providing therapy sessions to participants enrolled in the SPC condition and managing all aspects of treatment, risk management in sessions and follow-up.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Angela DeSantis, MSW* *Study Therapist – SPC Condition (Ann Arbor)* *7* *Mrs. DeSantis has participated in trainings regarding administration of the SPC condition which have included reviewing study materials, listening to session tapes, participating in risk management training, attending study meetings including clinical supervision, and providing SPC therapy sessions to participants enrolled in the SPC condition.*

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 has reviewed study measures, continues to develop systems for project databases and electronic data and storage and analysis, and has provided preliminary data analyses.*
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 been conducting participant recruitment, screening, tracking and enrollment, including the provision of screening measures, baseline interviews and measures and follow-up interviews and measures.*
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, participated in intervention role play sessions as a mock client, and participated in participant recruitment, consenting, enrollment, and follow-up.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Oluchi Uju-Eke, MPH* *Research Assistant (Ann Arbor)* *6* *Ms. Uju-Eke has participated in study-specific procedures training including consent and measures administration, completed VA required trainings and paperwork, participated in the creation of study databases, participated in intervention role play sessions as a mock client, and participated in participant recruitment, consenting, enrollment, and follow-up.*

Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Jazmine Wells, BS* *Research Assistant (Ann Arbor)* *12* *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*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Doctor Ashe, MPH* *Data Manager* *6* *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)* *6* *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:*	*Trevor Bak* *Research Assistant (Ann Arbor)* *7* *Mr. Bak 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.*
Name: *Project Role:* *Researcher Identifier (e.g. ORCID ID):* *Nearest person month worked:* *Contribution to the project:*	*Yang Ni* *Research Assistant (Ann Arbor)* *2* *Ms. Ni has participated in training on data entry and management. She has begun cleaning and finalizing data, and attended meetings to discuss data needs.*

Name:	*Nick Shaughnessy*
Project Role:	*Research Assistant (Denver & Colorado Springs)*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*3*
Contribution to the project:	*Mr. Shaughnessy has continued training on project activities including data entry. He has also attended project meetings.*

• *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

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

OTHER SUPPORT

ILGEN, M.

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

University of Michigan Projects:

W81XWH-14-1-0005 (Ilgen) 12/30/2013-12/29/2019 2.74 calendar
DoD-USAMRMC (1.2 cost share by VA)

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.

R44 AA026119 (Fan) 08/10/2017-07/31/2019 NIH- 0.24 calendar
Arborsense, Inc.
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.

R21 AT 010106 (Ilgen) 09/20/2018-09/19/2019 NIH- 1.86 calendar
DHHS
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 DA 047466 (Ilgen, Arnedt) 09/30/2018-07/31/2021 0.96 calendar
NIH-NIDA

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.

Veterans Health Administration Projects:

IIR 15-348-2 (Bohnert) 07/01/2016-06/30/2020 0.25 calendar
VA Health Administration-HSR&D
Cannabis Use and Health among VHA Primary Care Patients

The proposed project will characterize patterns of regular cannabis use and determine how patters 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.

IIR 13-322-2 (Bohnert) 07/01/2015-06/30/2019 0.15 calendar
VA Health Administration-HSR&D
Primary Care Intervention to Reduce Prescription Opioid Overdoses: Prescription Opioid Safety Trial (POST)

This project aims to determine the safety of high-dose opioid use among Veterans presenting to primary care and mental health clinics, it is of critical importance to involve researchers who have expertise in overdose risk, opioid use, primary care and mental health care settings, pharmacoepidemiology, and longitudinal data analysis, as well as sufficient support staff.

IIR 14-103-2 (Ilgen) 07/01/2015-06/30/2019 0.35 calendar
VA Health Administration-HSR&D
Facilitating use of the Veterans Crisis Line in High-Risk Patients

This study will be a randomized controlled trial of the impact of a new brief intervention, called Crisis Line Facilitation, compared to enhanced usual care on utilization of the Veterans Crisis Line and other mental health services use as well as on suicide attempt(s) in participants who are currently treated for a suicidal crisis in a VHA inpatient psychiatric unit.

IIR 15-298 (Ilgen, Timko) 09/01/2017-08/31/2021 0.75 calendar
VA Health Administration-HSR&D
Improving Outcomes among Medical/Surgical Inpatients with Alcohol Use Disorders

This project aims to help Veterans who are in the hospital and have untreated alcohol problems. We will adapt a Decision Aid that explains alcohol-related treatment options and their risks and benefits. Then, we will determine the effectiveness of an intervention called DO-MoST (for Drinking Options-Motivate, Shared Decisions, Telemonitor), whereby a Decision Coach helps Veterans make decisions about alcohol-related behaviors and treatments they prefer, and keeps in contact by phone to continue to help with drinking and treatment decisions. DO-MoST is designed to increase rates at which Veterans decide to reduce or quit drinking, and begin and remain in treatment, and to improve drinking- and medical-related outcomes over time. It may also decrease Veterans' use of expensive health services such as hospitalizations and emergency visits. Finally, we will study how VA can use DO-MoST on an ongoing, more widespread basis.

IIR 13-350 (Piette) 10/01/2014-12/31/2019 0.15 calendar
VA Health Administration-HSR&D

Patient-Centered Pain Care Using Artificial Intelligence and Mobile Health Tools

This study will evaluate an intervention that increases Veterans' access to effective CBT pain management services while allowing VA to maximize program expansion given constrained resources. The intervention is designed to be fundamentally patient-centered – learning automatically "what works" for each Veteran based on ongoing feedback regarding their pain-related functioning. If successful, the study will establish a new approach for using artificial intelligence to improve Veterans' pain care. Similar methods could be used to improve the efficiency of chronic disease management services for patients with depression, hypertension, diabetes, and other priority conditions.

R34 (Ilgen, Arnedt) 09/01/2018-08/31/2021 1.2 calendar
NIH-NIDA
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.

Pending

University of Michigan Projects:

(Mahmoudi, Peterson) 09/30/2018-09/29/2021 0.24 calendar
ACL-DHHS
Opioid Use Disorder Among People with Disabilities: Rigorous Evaluation of Risk Factors, Health Outcomes, and Policies

The goal of this DRRP is to develop a better understanding of prevalence estimates, individual and environmental risk factors, treatment patterns, and associated health and healthcare use outcomes of opioid use disorder among people with disabilities.

R01 AA 027223 (Bohnert, K.) 07/01/2019-06/30/2024 1.2 calendar
NIH
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 DA (Ilgen) 07/01/2019-06/30/2024 0.6 calendar
NIH/Oregon Health & Science Univ.
Impact of Cannabis Use in Older Adults Prescribed Long-term Opioid Therapy for Chronic Pain

Given the escalating use of cannabis, particularly as more states legalize its use, and the need to make evidence-based recommendations for pain management, clinicians need empirical data about pain treatment and adverse outcomes among patients who use cannabis in conjunction with long-term opioid therapy. We propose a prospective cohort study that will assemble and follow a national sample of U.S.

Veterans with musculoskeletal pain for two years, to examine trajectories of use and benefits and harms associated with co-occurring use of cannabis and prescription opioids.

R01 (Ilgen) 04/01/2019-03/31/2024 3.0 calendar
NIH
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.

R49 (Cunningham) 08/01/2019-07/31/2024 1.2 calendar
CDCP
University of Michigan Injury Prevention Center 2019-2024

The University of Michigan Injury Prevention Center is a comprehensive ICRC that integrates all phases of injury prevention and control across the spectrum of age groups. The Center is supplemented by the vast educational, research, outreach, and policy resources of the University of Michigan (U-M), whose injury faculty and practitioners are ready to address the burden of injury in Michigan, across the great lakes region (including the states of Illinois, Indiana, Ohio, and Wisconsin), and be a resource nationally. The Center has a decade of experience in conducting injury prevention research, outreach and translation, and educating the next generation of injury scientists and practitioners. The mission of the Center is to conduct high-quality research and training, to translate scientific discoveries into practice and policy, and to reduce injuries and violence.

R01 AA (Ilgen, Arnedt) 07/01/2019-06/30/2024 3.0 calendar
NIH-DHHS
CBT for insomnia (CBT-I) plus bright light therapy to improve sleep and abstinence in alcohol use disorders (AUD)

The goals of this project are to evaluate the effects of combination CBT for insomnia (CBT-I) and bright light therapy (BLT) on sleep and relapse among treatment-seeking adults with AUD and insomnia.

UM1 DA (Bohnert, Cunningham) 05/01/2019-04/30/2023 2.4 calendar
NIH-DHHS
HEALing Communities Across Michigan

The rate of drug overdose mortality, after adjusting for age, climbed by 256% between 1999 and 2017 in the United States. This increase occurred despite parallel reductions in nearly all major causes of death and numerous policy changes and funding programs to address the problem during this time period. Michigan ranked 7th nationally among states in the number of overdose deaths in 2017. This project will test the impact of a combined community engagement and implementation support strategy focused on the 15 counties in Michigan with the highest overdose rates to serve as a model for national efforts.

Veterans Health Administration Projects:

HX-15-026 (Ilgen, Timko) 01/01/2016-12/31/2019 1.2 calendar
VA Health Administration-HSR&D
Motivational Shared Decision Making to Improve Outcomes among Medical/Surgical Inpatients with Alcohol Dependence

The proposed research is a randomized controlled trial and formative evaluation of a patient-centered practice that integrates patients' informed preferences for their own health care, as a new intervention with Veteran patients as they transition from inpatient medical/surgical care to AUD treatment in primary and specialty care settings, thereby improving Veterans' AUD and medical outcomes and decreasing VA health care costs. The research will show if this new intervention approach is an additional tool, which can improve treatment and decrease Veterans' costs.

IIR I01 HX002024 (Timko, Ilgen) 01/01/2017-12/31/2020 2.4 calendar
VA Health Administration-HSR&D
Improving Outcomes among Medical/Surgical Inpatients with Alcohol Use Disorders

This project aims to help Veterans who are in the hospital and have untreated alcohol problems. We will adapt a Decision Aid that explains alcohol-related treatment options and their risks and benefits. Then, we will determine the effectiveness of an intervention called DO-MoST (for Drinking Options-Motivate, Shared Decisions, Telemonitor), whereby a Decision Coach helps Veterans make decisions about alcohol-related behaviors and treatments they prefer, and keeps in contact by phone to continue to help with drinking and treatment decisions. DO-MoST is designed to increase rates at which Veterans decide to reduce or quit drinking, and begin and remain in treatment, and to improve drinking- and medical-related outcomes over time. It may also decrease Veterans' use of expensive health services such as hospitalizations and emergency visits. Finally, we will study how VA can use DO-MoST on an ongoing, more widespread basis.

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

BLOW, FREDERIC C

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

University Of Michigan Projects:

R01 AA023122 (Blow, F.) 09/20/13-08/31/19 1.42 calendar
NIH / NIAAA / DoD
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 (Ilgen, M.) 12/30/13-12/29/19 0.72 calendar
DoD/USAMRMC
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.

W81XWH (Blow, F.) 09/01/14-08/31/19 1.8 calendar
Case Western Reserve 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.

Veterans Health Administration Projects:

(Bohnert, A.) 07/01/15-06/30/19 0.35 calendar
VA Health Administration–HSR&D, IIR 13-322-2
Primary are Intervention to Reduce Prescription Opioid Overdoses: Prescription Opioid Safety Trial (POST)

This project aims to determine the safety of high-dose opioid use among Veterans presenting to primary care and mental health clinics, it is of critical importance to involve researchers who have expertise in overdose risk,

opioid use, primary care and mental health care settings, pharmacoepidemiology, and longitudinal data analysis, as well as sufficient support staff.

(Bohnert, K) 10/01/16-09/30/20 0.35 calendar
VA Health Administration–HSR&D IIR 15-348-2
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, F & Pfeiffer, P) 04/1/17-03/31/22 1.3 calendar
SDA, VA Office of Research & Development
Precision Medicine in Mental Health Care (PRIME Care)

This project is a multi-site study designed to evaluate the utility of PGx testing in treating Major Depressive Disorder.

(Maust, D) 09/02/17-08/31/22 .75 calendar
VA Health Administration-HSR&D, IIR 16-210
Addressing Inappropriate Benzodiazepine Prescribing among Older Veterans

Use of benzodiazepines (BZDs) is associated with health problems for older adults, including falls, fractures, automobile accidents, difficulty thinking, and even death.

(Blow, F) 06/01/18-5/31/22 2.25 calendar
VA Health Administration-HSR&D, IIR 16-235
Improving Outcomes for Emergency Patients with Alcohol Problems

This study is a randomized controlled trial of an alcohol to facilitate reductions in alcohol use and to link Veterans with alcohol problems to needed primary and specialty care including other needed services such as homeless outreach and case management where needed. The project will help Veterans with hazardous drinking who may have difficulty engaging in needed care that potentially improve their mental and physical health outcomes.

PENDING

(Birditt, K.) 09/01/18-08/31/21 0.9 calendar
NIH / NIAAA R01
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 psychosocial factors that exacerbate the effects of alcohol use on cardiovascular health.

R01 AA027223 (Bohnert, K.) 07/01/19-06/30/24 0.6 calendar
NIH-DHHS
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 (Ilgen, M.) 04/01/19-03/31/24 NIH-DHHS 1.2 calendar
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.

(Birditt, K.) 07/01/19-06/30/23 0.9 calendar
NIH-DHHS
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.

UM1 DA (Bohnert, A., Cunningham, R.) 05/01/19-04/30/23 2.4 calendar
NIH-DHHS
HEALing Communities Across Michigan

The rate of drug overdose mortality, after adjusting for age, climbed by 256% between 1999 and 2017 in the United States. This increase occurred despite parallel reductions in nearly all major causes of death and numerous policy changes and funding programs to address the problem during this time period. Michigan ranked 7th nationally among states in the number of overdose deaths in 2017. This project will test the impact of a combined community engagement and implementation support strategy focused on the 15 counties in Michigan with the highest overdose rates to serve as a model for national efforts.

Veterans Health Administration Projects:

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

CONROY, D.

Active

W81XWH-14-1-0005 (Ilgen) 12/30/2013-12/29/2019 1.8 calendar
DoD-USAMRMC
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.

168-SR-17 (Arnedt) 04/04/2017-04/04/2019 1.8 calendar
American Sleep Medicine Foundation
Cognitive Behavioral Therapy for Insomnia Delivered Via AASM SleepTM or Face-to-Face: A Non-Inferiority Trial

The goal of this project is to compare the effectiveness of telemedicine CBT for insomnia (via the AASM SleepTM platform) to gold standard face-to-face CBT for insomnia.

(Kratz, Braley) 04/01/2018-08/01/2022 1.2 calendar
Patient-Centered Outcomes Research Institute
(PCORI)
A randomized controlled trial of telephone-delivered cognitive behavioral-therapy, modafinil, and combination therapy of both interventions for fatigue in multiple sclerosis

(Aim 1); test whether depression, sleep disturbances, or MS disability level modify comparative treatment responsiveness across treatment arms in terms of fatigue impact (i.e., heterogeneity of treatment effects) (Aim 2); and compare adverse events, side effects, treatment adherence, and patient dropout rates among the three treatment arms and patient subgroups of interest (Aim 3).

R34 DA 047466 (Ilgen/Arnedt) 09/30/2018-07/31/2021 0.36 calendar
NIH-DHHS
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.

033255 (Swanson) 08/01/2018-07/31/2020 1.2 calendar
American Sleep Medicine Foundation
The Clinical Utility of DLMO in the Treatment of Delayed Sleep-Wake Phase Disorder: A Randomized Trial

The objective of the proposed study is to test the clinical utility of obtaining DLMO in the treatment of delayed sleep-wake phase disorder (DSWPD).

Pending

R01 AA (Ilgen/Arnedt) 07/01/2019-06/30/2024 1.2 calendar
NIH-DHHS
CBT for insomnia (CBT-I) plus bright light therapy to improve sleep and abstinence in alcohol use disorders (AUD)

The goals of this project are to evaluate the effects of combination CBT for insomnia (CBT-I) and bright light therapy (BLT) on sleep and relapse among treatment-seeking adults with AUD and insomnia.

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.

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 28, 2019)

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 (October 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: $5,008,345