

AWARD NUMBER: W81XWH-14-1-0005

TITLE: Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders

PRINCIPAL INVESTIGATOR: Mark Ilgen, Ph.D.

CONTRACTING ORGANIZATION: University of Michigan
Ann Arbor, MI 48109

REPORT DATE: January 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE January 2017		2. REPORT TYPE Annual		3. DATES COVERED 30 DEC 2015 – 29 DEC 2016	
4. TITLE AND SUBTITLE Intervening to Reduce Suicide Risk in Veterans with Substance Use Disorders				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-1-0005	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Mark Ilgen, Ph.D. E-Mail: marki@umich.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Regents of the University of Michigan 503 Thompson St. Ann Arbor, MI 48109-1340				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
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 continued participant recruitment and enrollment, delivery of the intervention, and participant follow-ups.					
15. SUBJECT TERMS Suicide, Veterans, Substance Use Disorders					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
U	U	U	UU	35	

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	16
5. Changes/Problems.....	16
6. Products.....	16
7. Participants & Other Collaborating Organizations.....	17
8. Special Reporting Requirements.....	23
9. Appendices.....	23

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 third 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 third year, our main objectives, activities, and accomplishments have focused on increasing participant recruitment towards reaching our overall RCT recruitment goal. A key objective during this third year has been the evaluation and monitoring of recruitment activities and strategies across all study sites to ensure that participant recruitment remains steady and that, as a project, we continue to progress towards the completion of recruitment within the next year. 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 third year, we have evaluated recruitment efforts weekly and have devised strategies to modify our recruitment plan, as needed, in an effort to overcome recruitment challenges while still maintaining the scientific integrity of the project and operating within our Statement of Work. During the first quarter, we continued to recruit from the Intensive Outpatient Substance Abuse Programs (IOPs) at the study sites, and project staff have continued to strengthen our relationships with staff at the study sites to ensure successful recruitment of participants. These relationships have proved vital in allowing study staff to consistently recruit and enroll participants in the study, and we will continue to maintain these relationships throughout the study. In addition, in January of 2016 we submitted amendments to our IRBs to expand study recruitment to include VA standard outpatient substance use treatment programs at the existing study sites. These outpatient SUD programs typically serve a larger number of patients compared to the IOP programs and also provide greater flexibility in scheduling. This modification to our recruitment approach was completed in an effort to increase the number of participants available to be approached and potentially recruited into the RCT each month. We received approval for this amendment from the Ann Arbor VA IRB and the University of Michigan IRBMED in February of 2016, and approval from the Colorado Multiple IRB in March of 2016. This amendment was submitted to HRPO for approval in March of 2016 and was acknowledged later that month which allowed for recruitment from the standard outpatient substance use clinics to begin in April, 2016.

Also during this first quarter, the annual renewal for the Colorado Multiple IRBs was approved in January, 2016 and was acknowledged by HRPO in April, 2016. Additionally, we held our first project Data and Safety and Monitoring Board (DSMB) meeting in February, 2016. DSMB members were presented with a report that included information regarding recruitment, intervention delivery, participant follow-up retention, unrelated adverse events including hospitalizations and some preliminary data. The Board had no concerns and recommended unconditional approval of the study. Additionally, in February of 2016, we submitted our Research & Development annual update to the Ann Arbor VA IRB, which was approved in March, 2016. In March, 2016, the Ann Arbor VA conducted a routine audit of project consent forms for the Ann Arbor site which found no errors, omissions or non-compliance in in VA Consent Documents. Through continued evaluation of recruitment, in March, 2016 we amended the protocol to redistribute the number of participants to be recruited at each site in order to match the pace of recruitment. Specifically, we increased the number of participants to be recruited into the RCT from the Ann Arbor VA Healthcare System to 100 participants (from the original 40), and reduced the amount to be recruited from the Colorado Springs CBOC to 50 participants (from the original 100). This amendment was approved in April, 2016 and acknowledged by HRPO in May, 2016.

During the second and third quarters, we continued all main project tasks as well as modified the project in order to increase recruitment efforts. In April, 2016 project staff including Principle Investigators and Project Coordinators presented a workshop at the 49th Annual Conference of the American Association of Suicidology in Chicago, IL. This workshop was designed to provide individuals a chance to understand the unique treatment needs of suicidal individuals seen in SUD treatment programs and be able to identify specific strategies for suicide risk assessment and management in the context of a research project. The workshop provided an overview of the research project, a description of the therapeutic conditions, and a presentation on the development and utilization of a suicide risk protocol with individuals receiving ongoing care within a large health system. In April, 2016 we submitted our initial VA Research & Development "Request to Review" application to the Detroit VA Clinical Investigation Committee for review. We received a request from the committee for minor modifications in June, 2016. We received requested materials back from Detroit VA staff in August of 2016 and re-submitted the materials for review in November, 2016. We submitted our Scheduled Continuing Renewal of the project to the University of Michigan IRBMED in May, 2016, which was subsequently approved in June, 2016 and acknowledged by HRPO in August, 2016. Our annual project renewal was submitted to the Ann Arbor VA IRB in August, 2016, approved in September, 2016, and acknowledged by HRPO in October, 2016. Additionally, during the second quarter in June, 2016, we submitted an amendment to the Ann Arbor VA IRB in order to add the Toledo Community Based Outpatient Clinic as an additional recruitment location under the VA Ann Arbor Healthcare System. This facility has a dedicated outpatient substance abuse treatment program that sees patients for both individual and group-based substance abuse treatment. The location was added in order to increase recruitment numbers and complete our research protocol with eligible participants throughout the Ann Arbor Healthcare System. We received contingent approval pending minor modifications for this amendment from the Ann Arbor VA IRB in July, 2016. We submitted the requested changes to the Ann Arbor VA IRB in August, 2016 and received amendment approval to begin recruitment at the Toledo CBOC in September, 2016. Recruitment began at the location in September, 2016 following HRPO acknowledgment of the amendment.

We have also continued the process of hiring additional study staff, including CBT and SPC therapists, Research Assistants, and Research Coordinators at both the Colorado and Michigan study sites to ensure that we have enough staff to accomplish all study tasks. Given the complex, complicated, and serious nature of the population being studied (suicidal Veterans in substance abuse treatment), we continued to spend an increased amount of time training staff members on our risk assessment and management protocols. Study staff participated in extensive training on the nature of suicide and its association with substance use disorders, as well as participated in role play. Key study staff also visited Denver, CO in November of 2016 for an additional meeting to discuss recruitment efforts, intervention delivery, and follow-up procedures to ensure that all study sites are following study protocols and procedures accurately. Also in November, 2016 the annual renewal for the Colorado VA recruitment sites was submitted to the Colorado Multiple IRB and was awaiting approval at the end of the reporting period. Throughout the reporting period, all study staff have continued to receive thorough trainings on how to identify, monitor, and manage emergency situations involving risk to participant safety. We have collaborated closely across study sites to ensure successful completion of a wide array of study-related tasks. We have continued regular project meetings between the Michigan sites and the sites in Colorado, via weekly or bi-weekly phone meetings and/or e-mail and have added regular clinical supervision meetings for both conditions across sites during this reporting period. During our meetings, we discuss 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,

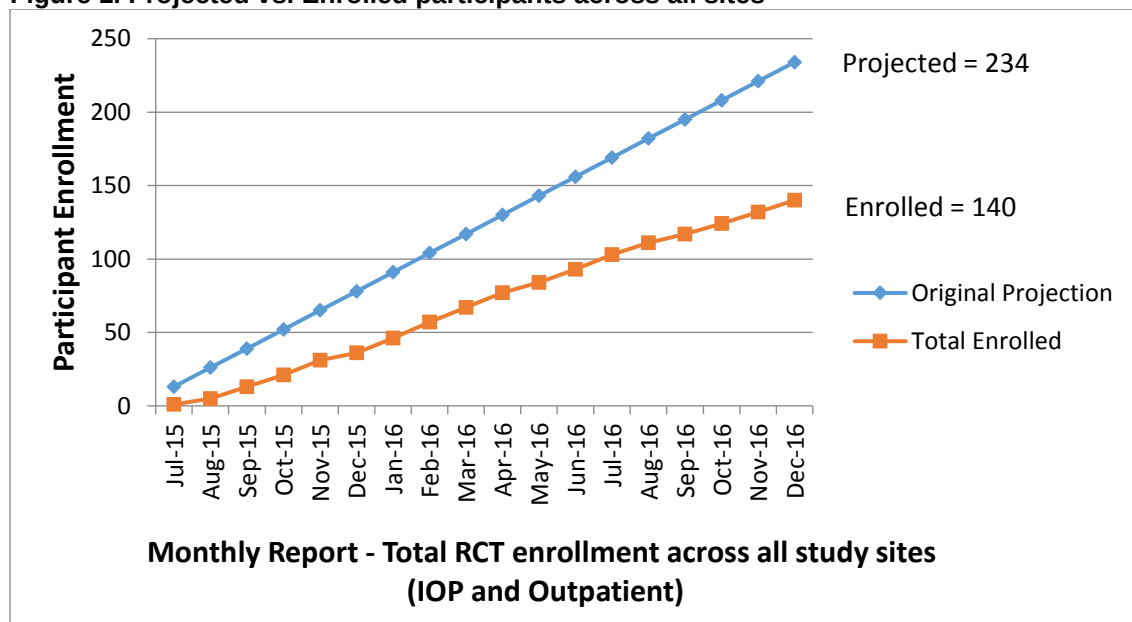
creating and finalizing study measures, and the creation of the study databases) and risk management issues.

Study recruitment

Recruitment has continued at the Ann Arbor VA Medical Center [including the Toledo Springs Community Based Outpatient Clinic (CBOC)], the Denver VA Medical Center, and the Colorado Springs CBOC throughout this third year. Through the end of this reporting period, there have been a total of 1175 patients who presented for SUD treatment at the study sites. Of those potential participants, we have approached 1084 (92.3%) for recruitment and consented 632 (58.3%) participants for the screening portion of the study, of which 573 (90.7%) participants completed the screening questionnaire. Of this screening sample, 95.5% were male (n=547) and the mean age was 48.2 years old. Across all study sites in both Michigan and Colorado, 155 participants (27.1%) 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]) (96.8%), having a legal guardian (0.2%), receiving methadone treatment for substance use within the past 6 month (0.7%), experiencing active psychoses (0.2%), and actively participating in substance abuse treatment at the site for at least 1 month prior to recruitment (1%), and actively participating in other randomized trial at the study site (1%). One hundred and forty participants (90.3%) 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. **Based on these recruitment numbers, through the end of this reporting period we have recruited 46.7% of our overall projected study sample (n=300) through approximately 18 months of recruitment.**

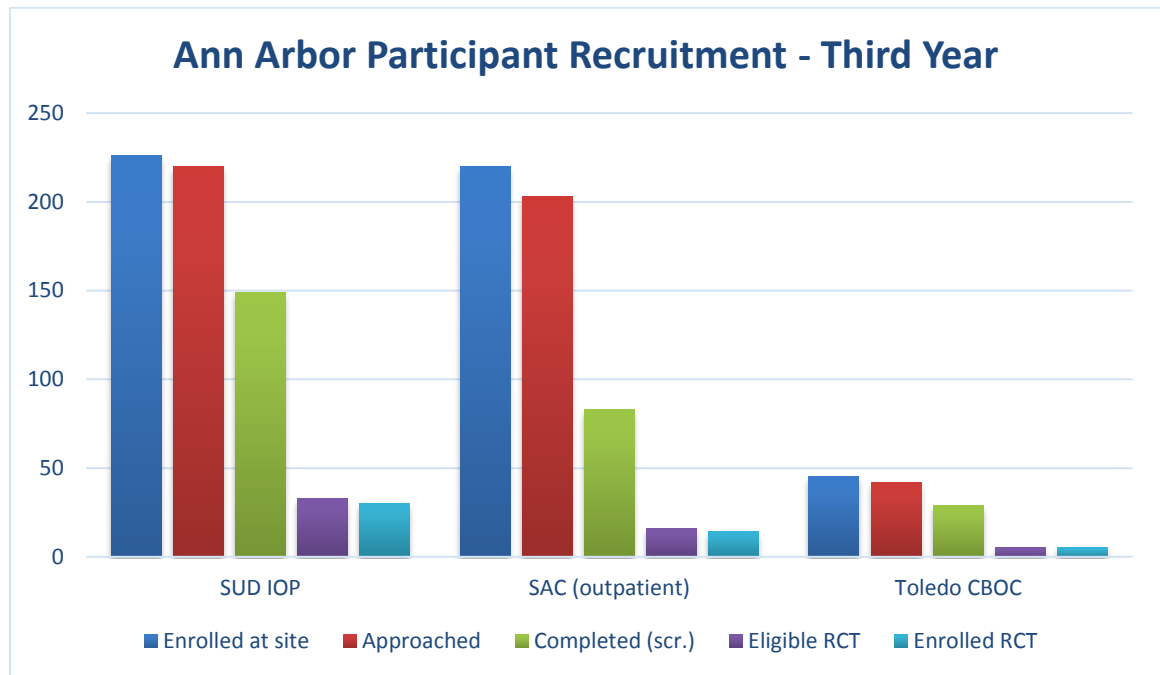
The Figure below reflects recruitment and enrollment numbers since recruitment began in 2015. Numbers reflect participant recruitment across all study sites for enrollment in the RCT. Projected numbers reflect an initially proposed total recruitment window of 24 months.

Figure 1. Projected vs. Enrolled participants across all sites



While the above statistics represent the recruitment progress of the study since recruitment began in 2015, the graphs below depict our recruitment efforts for the current reporting year only, for the study as a whole and then each individual recruitment site. The recruitment graphs for each individual site include recruitment from both outpatient clinics as well as intensive outpatient clinics that occurred during this reporting period.

Figure 2. Recruitment for Ann Arbor VA site (IOP and Outpatient): December 30, 2015 through December 31, 2016



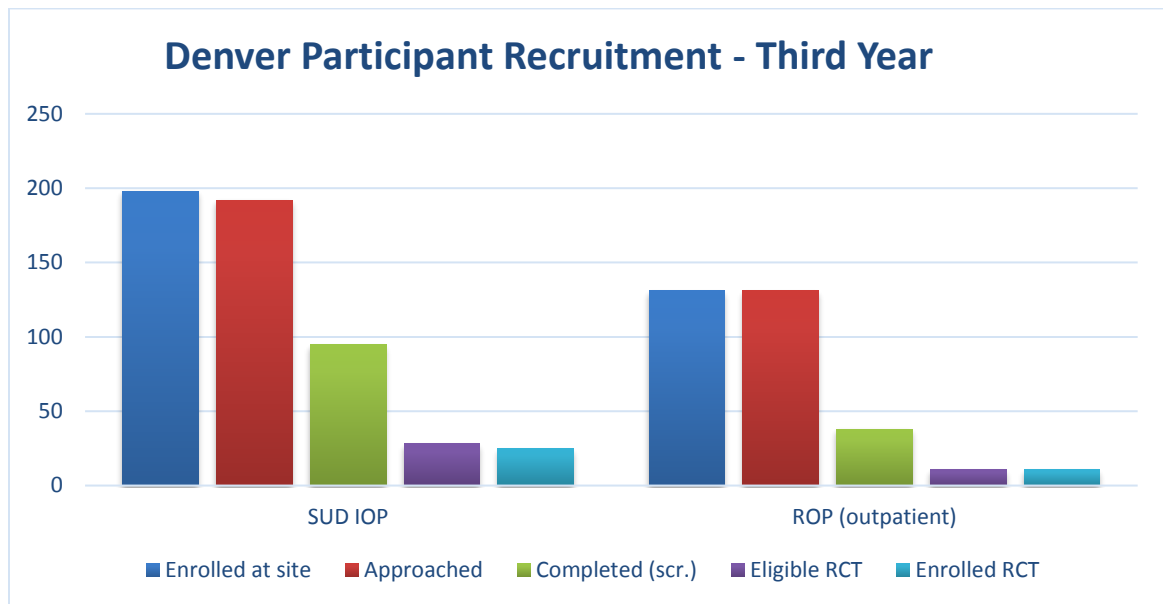
During this reporting period in Ann Arbor at the SUD IOP clinic, we approached 88.5% (n=200) of the 226 patients who came to the clinic for their intake appointment. Of those approached, 84.0% (n=168) agreed to participate and signed an informed consent form and were given a screening questionnaire to complete. Eighty-nine percent (n=149) of those consented completed the screening questionnaire, and of those 33 were eligible for the full RCT (22.1%). Of those eligible, 30 participants (90.9%) were enrolled into the full study. For those who were not enrolled, 2 participants declined and 1 terminated treatment at the study site before enrollment could occur.

We began recruitment in the Ann Arbor Substance Abuse Outpatient Clinic (SAC) in May, 2016. Since then, we have approached 91.8% (n=203) of the 220 patients who came to the clinic for their intake appointment. Patients were approached either in-person at the clinic (n=119; 58.6%) or by mail via the study approved recruitment letter (n=84; 41.4%). Of those approached, 107 patients agreed to participate (52.7%) and 83 patients completed the screening questionnaire (77.6%). There were 16 participants who were eligible for the full RCT based on their answers to the screening questions, which equates to an eligibility rate of 19.3%. Fourteen participants were enrolled into the full RCT (87.5%). One eligible participant was not enrolled due to the fact he did not show

up for 3 scheduled baseline appointments and discontinued treatment at the SAC clinic, while another eligible participant declined.

Recruitment at the Toledo Community Based Outpatient Clinic (CBOC) began in September, 2016. Since then, we have approached 42 patients out of the 45 enrolled in treatment at the clinic (93.3%) through presentations at the clinic groups or via recruitment letters. Of those patients, 69% completed the screening questionnaire (n=29) and five participants were eligible for the full RCT for an eligibility rate of 17.2%. All eligible participants were enrolled into the RCT (100%).

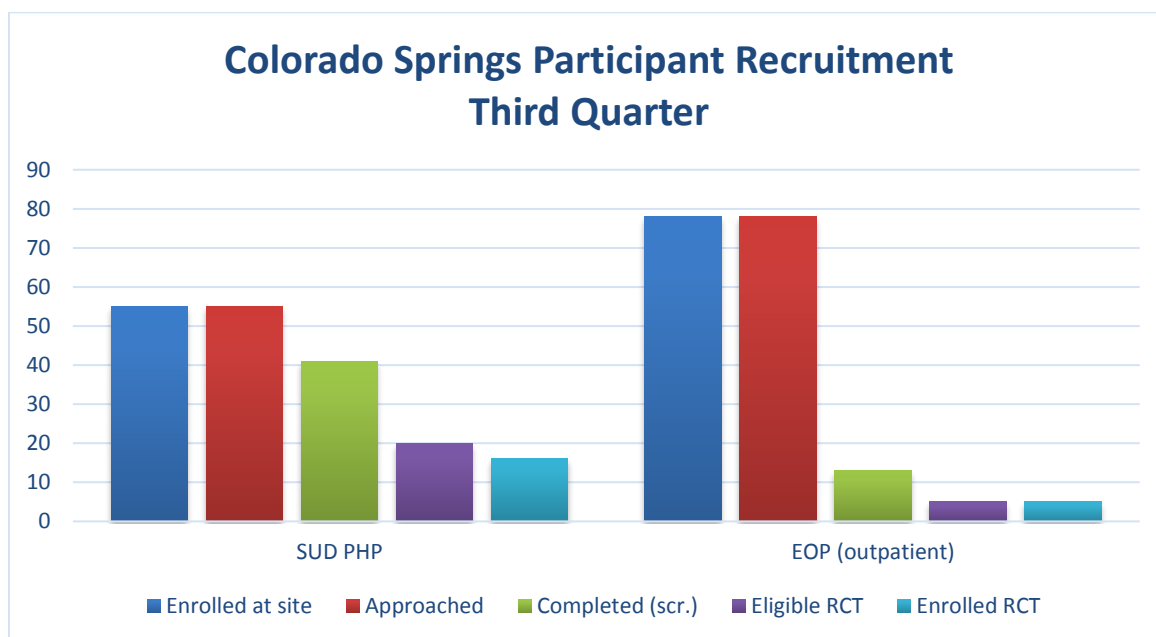
Figure 3. Recruitment for Denver VA site (IOP and Outpatient): December 30, 2015 through December 31, 2016



During this reporting period in Denver at the SUD IOP clinic, we approached 97.0% (n=192) of the 198 patients who came to the clinic for their intake appointment. Patients were approached either in-person at the clinic (n=136; 70.8%) or by mail via the study approved recruitment letter (n=56; 29.2%). Of those approached, 49.5% (n=95) 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=95), and of those 28 were eligible for the full RCT (29.5%). Twenty-five eligible participants were enrolled into the study (89.3%).

In the Denver Substance Abuse Outpatient Clinic (ROP), we approached 100% (n=131) of the patients who came to the clinic for their intake appointment. The majority of patients were approached via the recruitment letter mailing (n=91; 69.5%), while 30.5% were approached in-person at the clinic (n=40). Of those approached, 39 patients agreed to participate (29.8%) and 38 patients completed the screening questionnaire (97.4%). There were 11 participants who were eligible for the full RCT based on their answers to the screening questions, which equates to an eligibility rate of 28.9%. Eleven participants were enrolled into the full RCT (100%).

Figure 4. Recruitment for Colorado Springs CBOC site (IOP and Outpatient): December 30, 2015 through December 31, 2016



During this reporting period in Colorado Springs at the CBOC SUD PHP clinic, we approached 100% (n=55) of the patients who came to the clinic for their intake appointment. Forty-one (74.5%) of those were approached in-person at the clinic, while fourteen (25.5%) were approached via recruitment letter. Of those approached, 74.5% (n=41) 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=41), and of those 20 were eligible for the full RCT (48.8%). Sixteen eligible participants were enrolled into the study during this reporting period (80.0%).

In the Colorado Springs CBOC Substance Abuse Outpatient Clinic (EOP), we approached 100% (n=78) of the patients who came to the clinic for their intake appointment). The majority (88.5%; n=69) were approached via recruitment letter while 11.5% (n=9) were approached in-person via recruitment presentations. Of those approached, 14 patients agreed to participate (17.9%) and 13 patients completed the screening questionnaire (92.9%). There were 5 participants who were eligible for the full RCT based on their answers to the screening questions, which equates to an eligibility rate of 38.5%. All 5 participants were enrolled into the full RCT (100%).

The Table below provides 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.

Table 1. Preliminary baseline characteristics of the RCT sample

	Overall	Ann Arbor	Denver	Colorado Springs
<u>Demographics</u>				
% Male	93.8%	92.1%	95.2%	95.8%
% White	65.1%	68.2%	61.9%	62.5%
% Hispanic origin	13.2%	6.3%	19.0%	20.8%
% Employed (full or part-time)	16.1%	10.2%	21.9%	20.8%
% On Disability*	46.8%	50.8%	39.0%	50.0%
% Married	13.2%	9.5%	14.3%	20.8%
Age, yr. (M)	45.5	43.7	46.0	49.5
<u>Military History</u>				
% ever deployed	68.2%	69.8%	69.0%	62.5%
% history of combat (of total sample)	35.7%	36.5%	38.1%	29.2%
<u>Clinical Characteristics</u>				
Level of Suicidal Ideation (M) (BSS-SR; maximum score= 38)	14.3	15.0	11.3	17.6
Level of PTSD symptoms (M) (PCL-5; maximum score= 80)	51.7	51.2	52.8	50.8
Level of Depressive symptoms (M) (PHQ-8; maximum score = 24)	14.1	15.3	13.9	11.4
Self-efficacy to avoid suicide (M) (SEASA; maximum score = 54)	31.6	31.2	31.1	33.6
% Yes Alcohol use in prior 6 months (SAOM)	78.3%	76.2%	78.6%	83.3%
% Yes Drug use in prior 6 months (SAOM)	76.4%	80.3%	73.8%	70.8%
Prior suicide attempts (lifetime)				
No prior attempts (%)	33.1%	25.9%	42.9%	33.3%
1 prior attempt (%)	33.9%	43.1%	23.8%	29.2%
2+ prior attempts (%)	33.1%	31.0%	33.3%	37.5%

Intervention Delivery

We continue to deliver both the Cognitive Behavioral Therapy (CBT) and Supportive Psycho-educational Control (SPC) interventions at our study sites. During this reporting period, 53 (50.0%) participants have been randomized to receive the CBT intervention across sites, and 53 (50.0%) participants have been randomized to receive the SPC intervention, for a total enrollment of 68 participants into the CBT condition (48.6%) and 72 participants into the SPC condition (51.4%) since the beginning of project recruitment. For those randomized to the CBT intervention, 33 (63.5%) have completed all 8 sessions of the intervention. In the SPC intervention, 41 (68.3%) have

completed all 8 intervention sessions. Incomplete therapy sessions have been due to an inability to locate or contact participants using the contact information available, or an inability to complete the sessions due to the participant being in a controlled environment (e.g. incarcerated or at a treatment facility we are unable to visit) or moving out of state. Supervision of the CBT and SPC therapists has been ongoing throughout the reporting period to ensure fidelity of the intervention protocols. Study therapists have continued to monitor participant satisfaction and comprehension of the session content and participants have expressed high levels of satisfaction with the sessions. During this reporting period, we also hired additional study therapists in Michigan to prepare for expansion to the Detroit and Toledo site. Current study therapists and clinical supervisors have been involved in training these new study therapists, including reviewing manual content, conducting role plays, and completing fidelity measurements.

Participant Follow-up and Retention

During this reporting period, we have also continued conducting follow-up assessments. For this period, across all study sites the overall follow-up retention rate for all phone and in-person assessments is **78.0%**. For the 1-month post enrollment follow-up assessment, the retention rate is 85.3%. The follow-up rate for the brief 2-month phone follow-up assessment is 81.7%. The follow-up rate for the 3-month follow-up assessment is 77.5%. The 4-month and 5-month follow-ups are both brief phone assessments and the follow-up rates are 75.9% and 68.9% respectively. The follow-up rate for the 6-month assessment is 80.6%, and for the 12-month assessment the rate is 73.5%. These rates do not consider that some participants who are not counted as completed 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).

To date, we have had three participants request to withdraw from the study. Two participants have withdrawn from the Denver VA site due to increased stress, one in April, 2016 and one in August, 2016. One participant withdrew from the Ann Arbor VA site in October, 2016 due to a lack of time to participate.

During this reporting period, we had one participant death from the Colorado Springs CBOC site in July, 2016. The death was reported as a suicide. A report describing the details of the death was provided to the Research Monitor and it was determined by the Monitor that this event was unexpected and not study related. Because it was not study related, no additional reports to local IRBs or HRPO were deemed necessary based on reporting guidelines. The death was reported to the Colorado Multiple IRB at the continuing renewal which was submitted in November, 2016.

At this point, we do not have data to report regarding study aims since recruitment, baseline, and post-intervention follow-up assessments are ongoing. The Figures below provides more details regarding the follow-up assessment completion rates across all study sites and each individual site.

Figure 5. Follow-up retention statistics across all sites

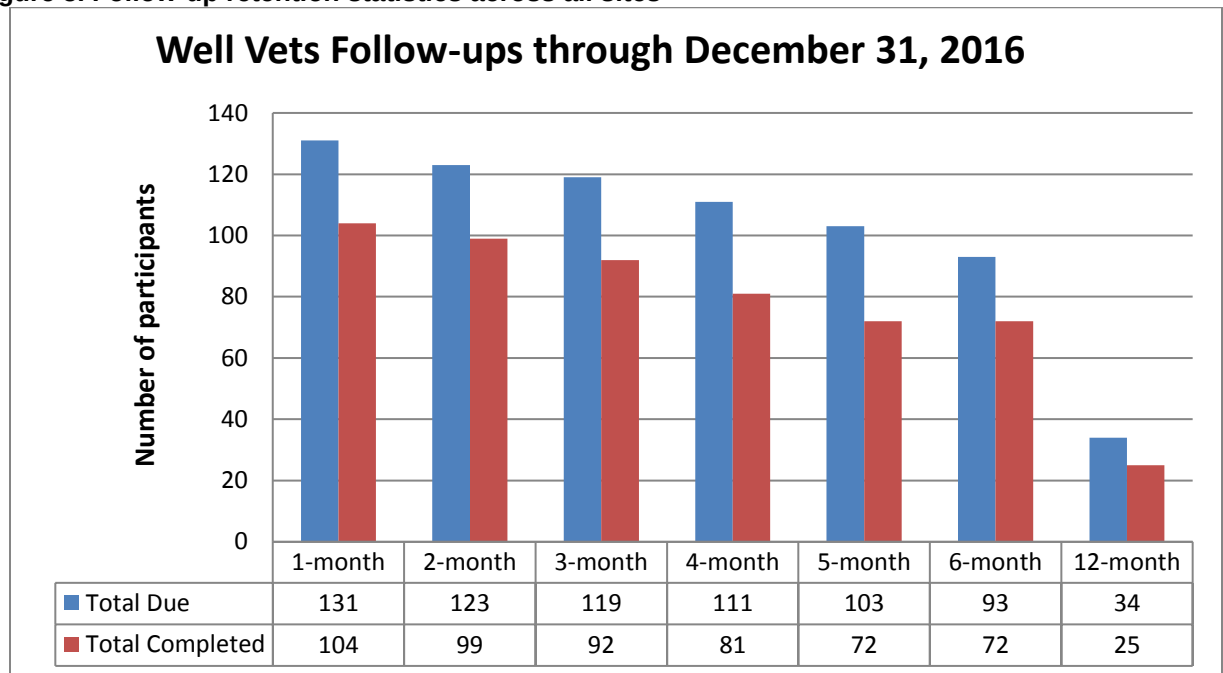
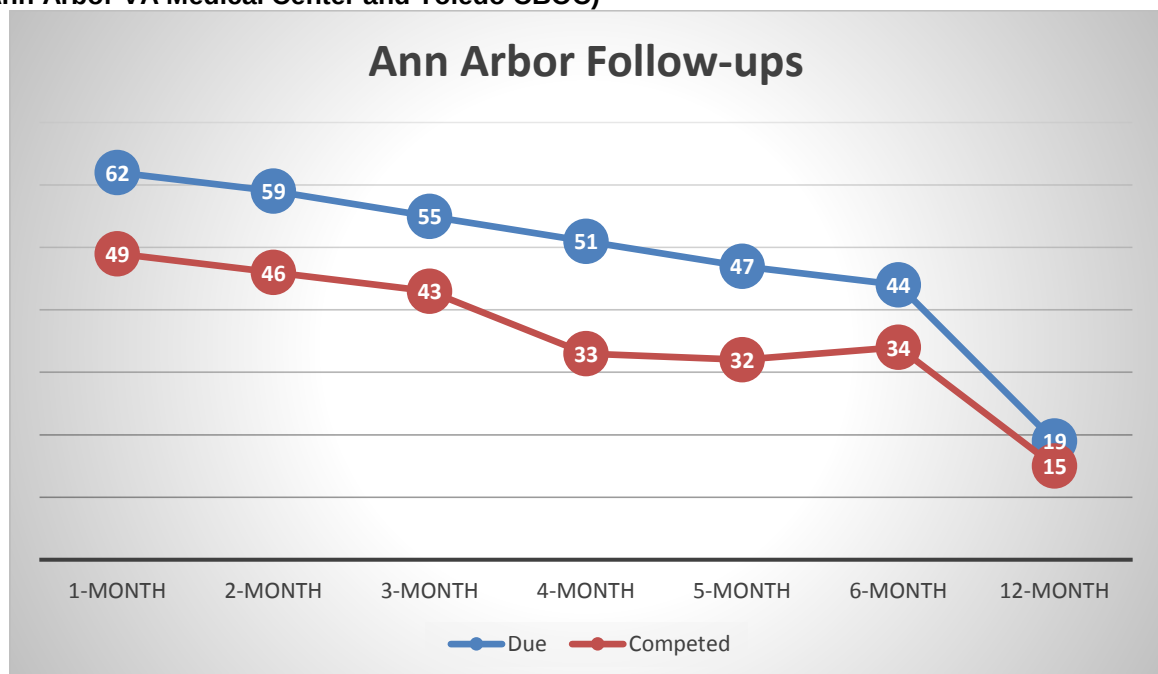
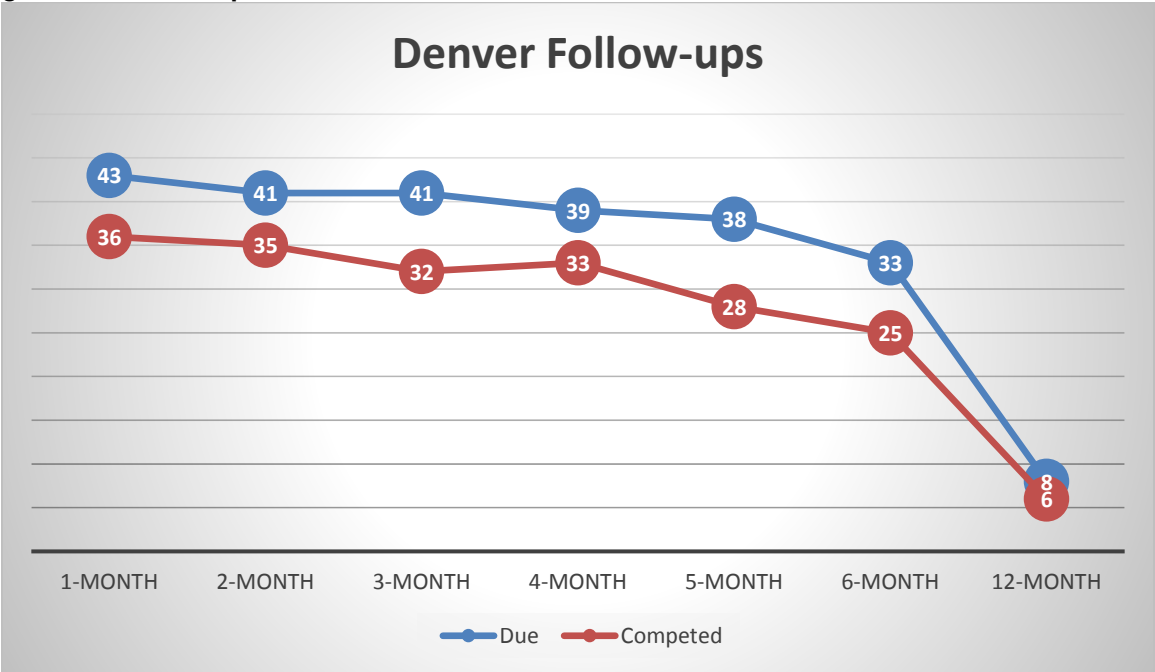


Figure 5a. Follow-up retention statistics – Ann Arbor sites
(Ann Arbor VA Medical Center and Toledo CBOC)



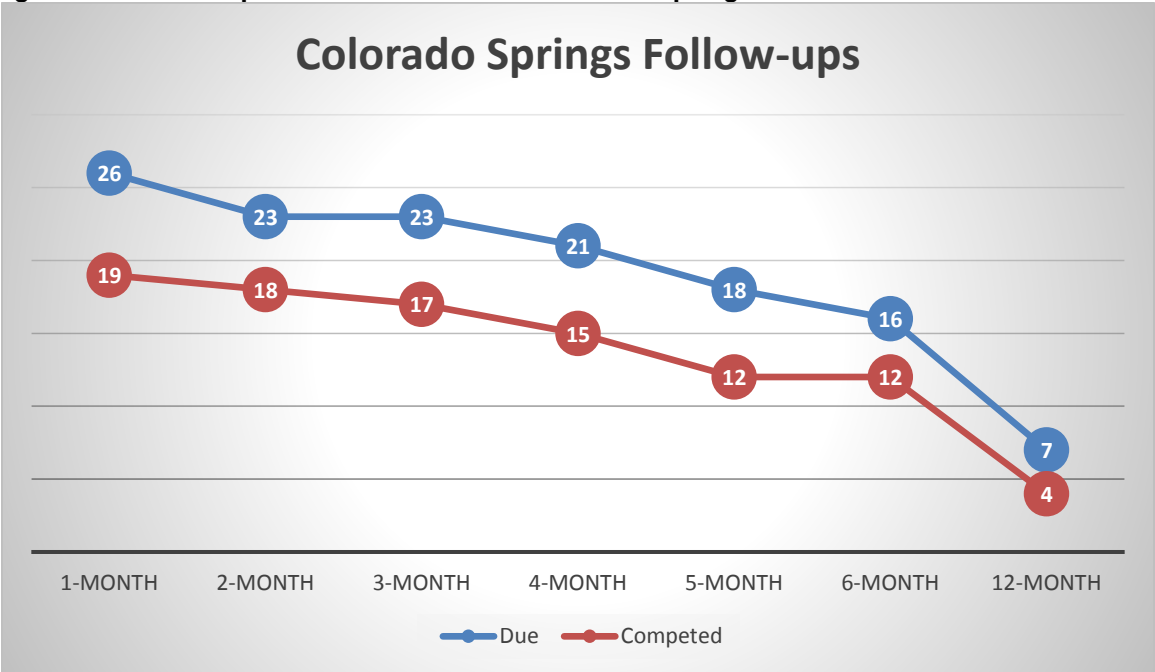
For the Ann Arbor site, the overall follow-up retention rate is **74.7%**, with the following rates at each respective time point: 1-month is 79.0%, 2-month is 78.0%, 3-month is 78.2%, 4-month is 64.7%, 5-month is 68.1%, 6-month is 77.3%, and 12-month is 79.0%.

Figure 5b. Follow- up retention statistics – Denver site



For the Denver site, the overall follow-up retention rate is 77.1%, with the following rates at each respective time point: 1-month is 83.7%, 2-month is 85.4%, 3-month is 78.0%, 4-month is 84.6%, 5-month is 73.7%, 6-month is 75.8%, and 12-month is 75.0%.

Figure 5c. Follow- up retention statistics – Colorado Springs site



For the Colorado Springs site, the overall follow-up retention rate is 72.4%, with the following rates at each respective time point: 1-month is 73.1%, 2-month is 78.3%, 3-month is 73.9%, 4-month is 71.4%, 5-month is 66.7%, 6-month is 75.0%, and 12-month is 57.1%.

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

In April, 2016 project staff including Principle Investigators and Project Coordinators presented a workshop at the 49th Annual Conference of the American Association of Suicidology in Chicago, IL. This workshop was designed to provide individuals a chance to understand the unique treatment needs of suicidal individuals seen in SUD treatment programs and be able to identify specific strategies for suicide risk assessment and management in the context of a research project. The workshop provided an overview of the research project, a description of the therapeutic conditions, and a presentation on the development and utilization of a suicide risk protocol with individuals receiving ongoing care within a large health system.

- *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 subject recruitment and enrollment at the study sites, as well as continue intervention delivery and follow-ups with enrolled participants. Participant enrollment into the RCT will be a main focus during the next reporting period as we continue to progress towards our recruitment goal of 300 participants enrolled. We will continue to be vigilant on the progress of recruitment at all study sites and will work to overcome challenges in order to keep recruitment at a steady pace. In addition, we will continue to deliver intervention sessions to participants and project therapists will continue to receive extensive monitoring and supervision to ensure that sessions are delivered consistently and at a high level of quality. Participant retention for follow-ups will also be a large 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. During this most recent reporting period, we were able to identify a site specific PI at the Detroit VA, Dr. Rielle Watson, PsyD, to oversee the project at that location, and worked with her to submit our project to their IRB for approval. During the next reporting period we anticipate receiving IRB and HRPO approval to begin recruitment at that site. Within the next reporting period we also will hold our second Data Safety and Monitoring Board meeting.

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 as recruitment, enrollment, intervention delivery, and follow-ups continue to increase in volume to ensure that all study protocols are being accurately followed. 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 subject recruitment, enrollment, and follow-up within the next reporting period.

4. IMPACT

Nothing to Report.

5. CHANGES/PROBLEMS

- *Changes in approach and reasons for change*

During this reporting period, we received approval from the Science Officer and Grants Officer to expand study recruitment to include VA outpatient substance use disorder treatment at the same study sites. Initially, recruitment of participants focused exclusively on those currently enrolled in the SUD Intensive Outpatient Programs (IOPs), which require patients to attend SUD treatment programming multiple days per week for several hours per day. While we found recruiting from these SUD IOPs successful in the short-term, we also encountered challenges with the relatively small size of the programs as well as the fact that participants were often busy with limited transportation options. This made it difficult for them to participate in research despite their interest in the project. In order to ensure that we will be able to achieve our recruitment goal in the timeframe outlined in our SOW, we feel that expanding the scope of the project to include VA outpatient SUD treatment was essential since outpatient SUD programs at the study sites serve a larger number of patients and provide for greater flexibility in scheduling participants. This modification did not result in any change to our budget or our SOW.

Additionally, in order to increase the volume of participants available to approach for recruitment, we expanded the Ann Arbor site to include the Toledo CBOC as a new recruitment location. This change will allow us to continue to recruit and enroll a higher number of participants each month in order to decrease the length of time needed to recruit our sample goal of 300 participants.

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) 1 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:	Stephen Chermack, Ph.D. Co-Investigator 1 Dr. Chermack has reviewed study materials, assisted in the revision of our intervention manuals, and provided training and clinical supervision to study therapists in both conditions.

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Amanda Price, MS Project Manager 11 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): Nearest person month worked: Contribution to the project:	Linda Mobley, MS IRB Coordinator 7 Mrs. Mobley assisted in revising the protocols and study materials, attended project meetings, completed paperwork for local IRB submissions and project submissions to USAMRMC HRPO, and completing documents for the Certificate of Confidentiality application.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Ariel Friese, MS, LPC Project Coordinator/Research Assistant (Denver & Colorado Springs) 9 Ms. Friese 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. Ms. Friese has also begun to transition to a research assistant role while another staff member takes over as Project Coordinator.

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Jill Trammel Project Coordinator (Denver & Colorado Springs) 2 Ms. Trammel has participated in measures and risk assessment training, in addition to all regulatory training. She has begun assisting with participant recruitment, screening, tracking and enrollment, including the provision of screening measures, baseline interviews and measures and follow-up interviews and measures. She will be transition to the role of Study Coordinator for Ms. Friese.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Emily Yeagley, MA SPC Clinical Supervisor (all sites) 3 Ms. Yeagley has been providing clinical supervision to both SPC therapists. She has participated in weekly supervision meetings and has been reviewing participant therapy session recordings for fidelity and adherence.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Amanda Regalia, LMFT Study Therapist – CBT condition (Denver & Colorado Springs) 12 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 & Detroit) 9 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, and helped prepare study-related materials for participants.

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Samantha Lindenauer, LLMSW Study Therapist – CBT Condition (Ann Arbor) 2 Ms. Lindenauer has participated in trainings regarding administration of the CBT condition which have included reviewing study materials, listening to session tapes, participating in risk management training, attending study meetings including clinical supervision and role playing study sessions.
Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Sarah Emeritz, LLMSW Study Therapist – CBT Condition (Ann Arbor) 6 Ms. Emeritz has participated in trainings regarding administration of the CBT condition which have included reviewing study materials, listening to session tapes, participating in risk management training, attending study meetings including clinical supervision and role playing study sessions.
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) 9 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:	Amanda Ciofu, MSW Study Therapist – SPC Condition (Ann Arbor) 2 Ms. Ciofu 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.

<i>Name:</i> <i>Project Role:</i> <i>Researcher Identifier (e.g. ORCID ID):</i> <i>Nearest person month worked:</i> <i>Contribution to the project:</i>	<i>Michelle Sanborn, MA</i> <i>Study Therapist – SPC condition (Ann Arbor & Detroit- previous)</i> <i>5</i> <i>Mrs. Sanborn has assisted in reviewing and editing the SPC therapist manual, participated in ongoing clinical supervision and training in the delivery of the SPC intervention, attended project meetings and trainings, and helped prepare study-related materials for participants. Please note, Mrs. Sanborn left the position in August, 2016.</i>
<i>Name:</i> <i>Project Role:</i> <i>Researcher Identifier (e.g. ORCID ID):</i> <i>Nearest person month worked:</i> <i>Contribution to the project:</i>	<i>Angela DeSantis, MSW</i> <i>Study Therapist – SPC Condition (Ann Arbor & Detroit)</i> <i>6</i> <i>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.</i>
<i>Name:</i> <i>Project Role:</i> <i>Researcher Identifier (e.g. ORCID ID):</i> <i>Nearest person month worked:</i> <i>Contribution to the project:</i>	<i>Mary Jannausch, MS</i> <i>Data analyst</i> <i>3</i> <i>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.</i>
<i>Name:</i> <i>Project Role:</i> <i>Researcher Identifier (e.g. ORCID ID):</i> <i>Nearest person month worked:</i> <i>Contribution to the project:</i>	<i>Kristen Enriquez, MA</i> <i>Research Assistant (Denver & Colorado Springs)</i> <i>9</i> <i>Ms. Enriquez has assisted in all aspects of data management, as well as participant recruitment, screening, tracking and enrollment, including the provision of screening measures, baseline interviews and measures and follow-up interviews and measures. Please note, Ms. Enriquez left the position in October, 2016.</i>

Name: Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to the project:	Karson Stevenson Research Assistant (Denver & Colorado Springs) 1 Ms. Stevenson has participated in measures and risk assessment training, in addition to all regulatory training. She has begun assisting with 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 & Detroit) 10 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 & Detroit) 10 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:	Jennifer Jordan, BS Research Assistant (Ann Arbor & Detroit) 5 Mrs. Jordan 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.

- *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

Changes in Other Support for Dr. Ilgen:

1. No Changes

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

University Of Michigan Projects:

(Ilgen, M.)	04/01/11-03/31/17	0.60 calendar
NIH/NIDA R01 DA029587		
Psychosocial Pain Management during Addictions		
Treatment to Improve Outcomes		

This randomized control trial is designed to determine the efficacy of a group based cognitive-behavioral pain management intervention in comparison to a Supportive Psychoeducation Control (SPC) group in individuals with co-occurring pain and substance use disorders recruited at the start of residential treatment program.

(Ilgen, M.)	05/01/13-02/28/17	1.38 calendar
NIH/NIDA R01 DA033397		
Medical Marijuana: Longitudinal Trajectories in Use,		
Pain and Functioning		

With the ongoing policy debate and the growing popularity of medical marijuana programs in the United States, it is essential to understand the ramifications of medical marijuana use for individuals who seek access to it. The proposed study will identify a cohort of 800 individuals who are seeking to obtain medical marijuana and examine their substance use (marijuana and other drug use), pain (pain level and behavioral pain tolerance), HIV risk profile, functioning (mental, physical, employment, and legal functioning), and health service use over the course of two years. The resulting data will inform the debate surrounding medical marijuana use and could help shape strategies to identify and intervene with individuals at risk for problems related to substance use.

(Ilgen, M.)	12/30/13-12/29/18	2.74 calendar
DoD/USAMRMC – W81XWH-14-1-0005		(1.2 calendar
Intervening to Reduce Suicide Risk in Veterans with		cost shared
Substance Use Disorders		with the VA)

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.

(Lantz, P.)	12/01/15-05/31/18	0.48 calendar
-------------	-------------------	---------------

Robert Wood Johnson Foundation #73217
University of Michigan Policies for Action Research Hub

The goals of this project are: 1) To actively collaborate with the Robert Wood Johnson Foundation, the National Coordinating Center and other Research Hubs in conducting transdisciplinary research that drives policy action and social change toward health equity; 2) To conduct three transdisciplinary research projects and one applied policy analysis methods project that will make important contributions to the existing evidence base and promote further action; and 3) To produce manuscripts, white papers, issue briefs, and other communications for wide audiences that will effectively translate our research results into policy, practice, and positive change to enhance the Culture of Health.

Veterans Health Administration Projects:

(Bohnert, A.)	07/01/15-06/30/19	1.6 calendar
VA Health Administration–HSR&D, IIR 13-322-2		
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.

(Ilgen, M.)	07/01/15-06/30/19	2.4 calendar
VA Health Administration–HSR&D, IIR 14-103-2		
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.

OVERLAP

None

Changes in Other Support for Dr. Blow:

1. Effort ended on NIH/NIAAA R01 AA018659 (PI – Blow)
2. Effort ended on VA IIR 09-333-2 (PI – Chermack)
3. Effort ended on VA IIR 12-144-2 (PI – Kales)
4. Effort started on NIH/NIDA R01 DA035331 (PI – Bohnert)

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:

(Blow, F.)	09/20/13-08/31/18	1.9 calendar
NIH / NIAAA / DoD R01 AA023122		(1.2 calendar
Preventing Alcohol/Prescribed Drug Misuse in the		cost shared
National Guard: Web and Peer BI		with the VA)

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.

(Ilgen, M.)	12/30/13-12/29/18	0.12 calendar
DoD/USAMRMC – W81XWH-14-1-0005		
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.

(Blow, F.)	09/01/14-08/31/19	3.0 calendar
Case Western Reserve University / DoD/USAMRMC–		
W81XWH-14-2-0007		
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.

(Bohnert, A.)
NIH/NIDA R34 DA035331
Developing a prescription opioid overdose prevention
intervention

03/01/14-02/28/17 0.12 calendar

This behavioral intervention development project aims to expand and refine a three session intervention to prevention prescription opioid overdoses among individuals in residential addictions treatment and to conduct a pilot randomized controlled trial of the intervention compared to an equal attention control condition.

Veterans Health Administration Projects:

(Bohnert, A.)
VA Health Administration–HSR&D, IIR 13-322-2
Primary are Intervention to Reduce Prescription Opioid
Overdoses: Prescription Opioid Safety Trial (POST)

07/01/15-06/30/19 0.6 calendar

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.

OVERLAP

None

Changes in Other Support for Dr. Bohnert:

1. Effort ended on NIH/NIDA R01 DA029587 (PI – Ilgen)
2. Effort ended on NIH/NAAA R01 AA023122 (PI – Blow)
3. Effort started on CDC R49 CE002099 (PI – Cunningham)

OTHER SUPPORT

BOHNERT, AMY

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:

(Bohnert, A.)	03/01/14–02/28/17	0.96 calendar
NIH/NIDA R34 DA035331		
Developing a prescription opioid overdose prevention intervention		

This behavioral intervention development project aims to expand and refine a three session intervention to prevention prescription opioid overdoses among individuals in residential addictions treatment and to conduct a pilot randomized controlled trial of the intervention compared to an equal attention control condition.

(Ilgen, M.)	12/30/13–12/29/18	0.19 calendar
DoD/USAMRMC – W81XWH-14-1-0005		
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.

(Bohnert, A.)	09/01/14–08/31/16	1.2 calendar
Center for Disease Control and Prevention - IPA		
14IPA1405517		

The assignment will allow CDC to gather crucial information to address the following key areas of the Prescription Drug Overdose team's strategic direction: 1) Effective monitoring and surveillance of opioid prescribing and associated health outcomes. 2) Analyses to determine key drivers of opioid pain reliever overdose and effective strategies to prevent opioid pain reliever overdose. In addition, the assignment will allow CDC and University of Michigan researchers to examine the relationship between opioid prescriptions and clinical outcomes in order to inform opioid prescribing guidelines as well as recommendations for coordinated care for patients with pain.

(Cunningham, R.)
CDC/NCIPC R49 CE002099
The University of Michigan Injury Center

08/01/12–07/31/17 0.6 calendar

The University of Michigan Injury Center is a comprehensive ICRC that integrates all phases of injury prevention and control, across the spectrum of age groups. 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, violence, and related disabilities particularly among vulnerable populations.

(Bohnert, A.)
NIH/NIDA R01 DA039159
Reducing Non-Medical Opioid Use: An automatically
adaptive mHealth Intervention

05/01/16–01/31/21 2.4 calendar

The first phase of this study will aim to develop a reinforcement learning (i.e., artificial intelligence) behavioral intervention delivered via interactive voice response with the goal of reducing non-medical opioid use among individuals identified at the UM emergency department (ED) as leaving the ED with a prescription opioid for pain and with recent non-medical opioid use. The second phase of this study will be to conduct a phase-III clinical trial of the intervention compared to an enhanced usual care condition with 600 ED patients. This study will also involve focus groups of patients and ED clinicians in order to understand issues related to implementation of the intervention.

Veterans Health Administration Projects:

(Bohnert, A.)
VA Health Administration–HSR&D, IIR 13-322-2
Primary Care Intervention to Reduce Prescription
Opioid Overdoses: Prescription Opioid Safety Trial
(POST)

07/01/15-06/30/19 3.0
calendar

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.

(Ilgen, M.)
VA Health Administration–HSR&D, IIR 14-103-2
Facilitating use of the Veterans Crisis Line in High-Risk
Patients

07/01/15-06/30/19 1.8 calendar

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.

OVERLAP

None

Changes in Other Support for Dr. Chermack:

1. Effort ended on NIH/NIDA R01 DA029587 (PI – Ilgen)
2. Effort ended on VA IIR 09-333-2 (PI – Chermack)

OTHER SUPPORT**CHERMACK, STEPHEN**

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:**

(Ilgen, M.)	12/30/13 – 12/29/18	1.46 calendar
DoD/USAMRMC W81XWH-14-1-0005		
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.

(King, C.)	08/11/14 – 07/31/19	0.96 calendar
NIH/NIMH R01 MH103244		
Electronic Bridge to Mental Health (eBridge) for College Students		

We propose to conduct a large-scale randomized controlled intervention trial across multiple universities to determine the impact of eBridge on college students' readiness to seek mental health treatment, linkage to mental health treatment, and mental health outcomes. We will also determine the extent to which the online counseling mediates intervention effectiveness.

Veterans Health Administration Projects:

None

OVERLAP

None

Changes in Other Support for Dr. Olson-Madden:

1. Effort started on HRSA Subcontract (PI – Olson-Madden)

OTHER SUPPORT

OLSON-MADDEN, JENNIFER

ACTIVE

University of Michigan Projects:

(Ilgen, M.)	12/30/13 – 12/29/18	6 calendar
DoD/USAMRMC W81XWH-14-1-0005		
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.

(Dettmer, Judy PI; Olson-Madden, Jennifer, University of Colorado Denver Site PI)

Funding Period: 06/2014 -06/2018

Effort: 0.6 calendar

Funding Source: Health Resources Services Administration (HRSA)

Award amount: (subcontract)

Title: *HRSA Implementation: Justice involved individuals with traumatic brain injury*

The major goal of this project is to develop and disseminate a resource/toolkit of information for justice-involved providers and support persons regarding best practices in screening, assessment, treatment and prevention of traumatic brain injury in adult and juvenile justice-involved settings.

OVERLAP

None

Changes in Other Support for Dr. Valenstein:

1. Effort ended on BCBSM Foundation (PI – Valenstein)
2. Effort ended on DoD/MSU RC102123A (PI – Kees)
3. Effort ended on Bristol-Meyers Squibb Foundation (PI – Kees)
4. Effort started on University of Washington/PCORI (PI – Valenstein)

OTHER SUPPORT

VALENSTEIN, MARCIA

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

1R01AA023122-01 (Blow)

National Institute on Alcohol Abuse and Alcoholism (NIAAA) 09/20/13-08/31/18 1.80 Calendar
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.

Log 11224006 (Ilgen)

DoD/USAMRMC 12/30/13 – 12/29/18 0.60 Calendar
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.

R34MH103447(Pfeiffer) 07/15/2014 - 05/31/2017 0.60 Calendar
NIMH R34

Peer mentorship to reduce suicide risk following psychiatric hospitalization

Risk of suicide is significantly elevated during the period of time immediately following inpatient psychiatric treatment. This study will develop and pilot test a peer mentorship intervention to reduce the risk of suicide among patients psychiatrically hospitalized at the University of Michigan.

State of Michigan Community Health HHS (Dalack) 10/1/2016-9/30/2017 0.72 Calendar

TaMMS: Evaluating the use of Peer Support Specialists in Collaborative CareCare

The goal of this project is to continue the implementation of a flexible, tailored model of mental health care management support in safety net clinics in Washtenaw County. TaMMS includes all of the essential elements of evidence-based collaborative care for depression and anxiety.

State of Michigan Department of Community Health (Marcus) 10/1/2016- 9/30/207 .12 Calendar
Enhancement of the Michigan Child Collaborative Care Model: Expanding Access and Monitoring Outcomes
DC

This project aims to develop an innovative care model to increase access to mental health treatment for underserved children and adolescents in Michigan to include ongoing follow up of patients, and the establishment of metrics that provide data on uptake of the program (utilization, changes in prescribing, provider and patient satisfaction, treatment recommendation follow through and adherence, changes in primary care provider confidence and competence), and changes in clinical outcomes, including symptom severity data.

R01-MH-096699 (Aikens/Piette) 9/18/12-6/30/17 .24 Calendar
National Institute of Mental Health

Telemonitoring Enhanced Support for Depression Self-Management.

This is an RCT to compare the effectiveness of telemonitoring support with care partners to usual care on depression severity outcomes among low-income primary care patients.

University of Washington/PCORI 1/1/16 – 12/31/20 1.08 Calendar
Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural FQHCs subcontract The central question examined by this study is whether it is better to support primary care providers' treatment of patients with Bipolar Disorder and PTSD through an integrated care model or to use telemedicine technology to facilitate referrals to offsite mental health specialists.

DEPARTMENT OF VETERANS AFFAIRS

IIR 12-109 (Pfeiffer) 01/01/2013 – 09/30/2017 1.09 Calendar
Department of Veterans Affairs, Health Services Research and Development
Veteran College Students Mental Health and Academic Achievement.

This project aims will be to 1) Assess cross-sectional and longitudinal prevalence of mental health symptoms, hazardous alcohol use, and levels of wellbeing among a *representative* sample of Veteran and comparison students. 2) Assess Veteran students' use of VA and non-VA mental health services (including college mental health services), treatment preferences, and perceived treatment barriers, and 3) Assess cross-sectional and longitudinal *associations* between Veteran students' mental health symptoms, treatment, and academic performance.

IIR13-310 10/1/14-3/31/18 0.6 Calendar
Department of Veterans Affairs, Health Services Research and Development
Veteran Peer-Assisted Computerized Cognitive Behavioral Therapy for Depression
The purpose of this study is to conduct a Hybrid Type I RCT of Peer-Supported cCBT (PS-cCBT) versus enhanced usual care (EUC) for 330 patients with new episodes of depression diagnosed in primary care at three VA sites and their CBOCs. Our Primary Specific Aims are to 1) compare PS-cCBT versus EUC on symptomatic, functional and recovery-oriented outcomes, and 2) compare PS-cCBT versus EUC on acquisition of depression coping skills, initiation and continuation of antidepressant medication, and initiation and completion of more intensive traditional psychotherapy (contingent on symptom level).

IIR 14-345 Pfeiffer (PI) 04/01/2016 - 3/31/2020 1.2 Calendar Months
HSR&D, Department of Veterans Affairs Total Direct Costs:
Incorporating Treatment Outcomes into Quality Measurement of Depression Care
The purpose of this project is to develop and assess outcome quality measures for depression and assess the relationships between outcomes and care processes, including a new measure of treatment intensification, and to determine the association between facility characteristics and depression care processes and outcomes.

IIR 14-324 Zivin (PI) 01/01/2016 - 6/30/2019 1.2 Calendar Months
HSR&D, Department of Veterans Affairs Total Direct Costs:
VA responses to guidance regarding risks of psychotropic medication use

The goal of this study is to examine multilevel responses to external warnings regarding psychotropic medications, specifically variation in the adoption of warnings by VISNs, VA facilities, and providers, and the effect of varying levels of pharmacy integration on response to warnings. The specific aims include 1) to assess and describe PBM and VISN-level responsiveness and variation in responsiveness to warnings regarding psychotropic medications, 2) to assess prescribing patterns before and after warnings regarding psychotropic medications, and 3) To understand specific strategies used by facilities and providers with high response to warnings and barriers encountered by facilities and providers with low response to warnings.

OVERLAP

None

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 all regulatory approvals, began project recruitment in both Michigan and Colorado sites, began participant enrollment and randomization into the randomized controlled trial, began 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

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 (*in progress*)
- ☐ Conduct baseline and follow-up interviews (*in progress*)
- ☐ Conduct therapy sessions (*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
- ☒ Submit regular progress reports

Budget Expenditure to Date

Projected Expenditure: \$4,466,674

Actual Expenditure: \$2,415,902

Updated: (Ann Arbor (MI), January 27, 2017)