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14. ABSTRACT Reducing suicide is a national priority and an urgent concern within the Department of Defense and the Department of Veterans Affairs. Indeed, rates of suicide among active duty service members have increased dramatically since 2005, and there is great concern that elevated risk will carry over following discharge from active service. The goal of the proposed study is to improve initiation of behavioral health (i.e., mental health, substance use) treatment services among untreated, at-risk U.S. military service members. The goal to facilitate behavioral health treatment is consistent with recommendations provided in reports by the Department of Defense, U.S. Army, U.S. Surgeon General, and the Institute of Medicine.					
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Abstract

Increasing Treatment Seeking Among At-Risk Service Members Returning from Warzones

PI: Tracy Stecker, PhD, Co-PI: Kenneth Conner, PsyD

Background: Reducing suicide is a national priority and an urgent concern within the Department of Defense and the Department of Veterans Affairs. Indeed, rates of suicide among active duty service members have increased dramatically since 2005, and there is great concern that elevated risk will carry over following discharge from active service. The goal of the proposed study is to improve initiation of behavioral health (i.e., mental health, substance use) treatment services among untreated, at-risk U.S. military service members. The goal to facilitate behavioral health treatment is consistent with recommendations provided in reports by the Department of Defense, U.S. Army, U.S. Surgeon General, and the Institute of Medicine

Objective/Hypothesis:

Test the effectiveness of the intervention on attitudes toward behavioral health treatment among at-risk service members.

Hypothesis 1a: Participants receiving the cognitive-behavioral (CB) intervention will have significant increases in positive attitudes about treatment at 1-month follow-up compared to controls.

Hypothesis 1b: Participants receiving the CB intervention will have significant increases in the intention to initiate behavioral health treatment compared to controls.

Test the effectiveness of the intervention on the initiation of and adherence to behavioral health treatment.

Hypothesis 2a: Participants receiving the CB intervention will be more likely to initiate behavioral health treatment than participants in control group during 6-month follow-up.

Hypothesis 2b: Participants receiving the CB intervention will attend more behavioral health treatment sessions than participants in the control group over 6-month follow-up.

Study Design: We propose a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves the initiation of treatment. Participants assigned to the treatment condition will be presented an individualized CB intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants will be assessed at baseline and at 1-month, 3-month, and 6-month follow-up. Analyses are based on logistic and mixed effect models.

Relevance: Reducing suicide among our service members is a national priority. The passage of the Joshua Omvig Veterans Suicide Prevention Act highlights the importance that stakeholders place on developing and implementing a comprehensive program to reduce suicide among U.S. service members and Veterans.

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1. INTRODUCTION

Reducing suicide is a national priority and an urgent concern within the Department of Defense and the Department of Veterans Affairs. The passage of the Joshua Omvig Veterans Suicide Prevention Act highlights the importance that stakeholders place on developing and implementing a comprehensive program to reduce suicide among U.S. service members and Veterans. Rates of suicide among active duty service members have increased dramatically since 2005, and there is great concern that elevated risk will carry over following discharge from active service. ***The goal of this study is to improve initiation of behavioral health (i.e., mental health, substance use) treatment services among untreated, at-risk U.S. military service members.*** The goal to facilitate behavioral health treatment is consistent with recommendations provided in reports by the Department of Defense, U.S. Army, U.S. Surgeon General, and the Institute of Medicine.

We are conducting a randomized controlled clinical trial of 1,200 military service members who are at increased risk for suicide but not currently in behavioral health treatment for the purpose of determining if a brief intervention improves attitudes toward behavioral health treatment and initiation of treatment. Advertisements are used to recruit service members who report current suicidal ideation or a history of suicide attempt on standard screening items, suggesting they are at risk for suicide. Participants assigned to the treatment condition are presented an individualized cognitive-behavioral (CB) intervention. The CB intervention takes 45-60 minutes, is delivered by phone, and has been shown to promote treatment-seeking including in a preliminary study of OEF/OIF Veterans with elevated posttraumatic stress disorder (PTSD) symptoms. Participants are assessed at baseline and at 1-month, 3-month, 6-month, and 12-month follow-up. Analyses are based on logistic and mixed effect models. **Specific Aims are as follows:**

- 1) *Test the effectiveness of the intervention on attitudes toward behavioral health treatment among at-risk service members.*
Hypothesis 1a: Participants receiving the CB intervention will have significant increases in positive attitudes about treatment at 1-month follow-up compared to controls.
Hypothesis 1b: Participants receiving the CB intervention will have significant increases in the intention to initiate behavioral health treatment compared to controls.
- 2) *Test the effectiveness of the intervention on the initiation of and adherence to behavioral health treatment.*
Hypothesis 2a: Participants receiving the CB intervention will be more likely to initiate behavioral health treatment than participants in control group during 6-month follow-up.
Hypothesis 2b: Participants receiving the CB intervention will attend more behavioral health treatment sessions than participants in the control group over 6-month follow-up.

The brief (45-60 min), practical (delivered by phone), and promising nature of the CB intervention (favorable preliminary data in OEF/OIF Veterans with elevated PTSD symptoms) indicate its potential for wider implementation to reduce suicide risk among service members.

2. KEYWORDS

Suicide, mental health treatment engagement, cognitive-behavioral intervention

3. OVERALL PROJECT SUMMARY

Recruitment for this trial began on March 2, 2013 and was initially awarded to Dr. Tracy Stecker at Dartmouth Medical School. The trial remained at Dartmouth for over a three year period and was very successful in terms of recruitment and study activities. During that time, we recruited 788 participants. Of the 788 participants, 651 of them were separated from the service, 109 were active in the National Guard or Reserves, and 28 were Active Duty.

The PI, Dr. Stecker, transferred from Dartmouth to the Medical University of South Carolina during the summer of 2016 and due to a restructuring of funding at Dartmouth Medical School, a transfer of the award to the Medical University of South Carolina was requested. The transfer request was approved and the award officially transferred to MUSC in April 2017. In April, we were allowed to begin the process of hiring and training new study staff to serve as research personnel. Active advertising and recruitment activities began in July 2017. Since that time, we have recruited an additional 162 participants. Of these, 151 are separated from service, 9 are in the Guard/Reserves, and 2 are Active Duty. We have recruited an additional 17 females since at MUSC, resulting in a total of 97 females. Thus, we have a total of 950 participants, with 802 separated from the service, 118 in the Guard/Reserves and 30 Active Duty.

Baseline characteristics.

Characteristics of the participant sample that have been entered into the data management system are presented in Tables 1-3 in the Appendix. The mean age of participants is approximately 31 years old, and 90% of the sample is male. The majority of participants (67%) identify their race as white, non-Hispanic. The vast majority (70%) reported service in the Army. Baseline symptom severity scores indicate that both the intervention and control groups reported moderately severe symptoms of depression (mean score = 18) as measured by the PHQ9, and insomnia (mean score = 18) as measured by the ISI. Further, PTSD (mean score = 62) as measured by the PCL, were well above suggested clinical cutoffs. The mean pain severity score, as measured by four items from the BPI, was 14 which indicates that while this sample reports extensive symptoms of depression, sleep disturbance and ptsd, they are not reporting physical pain.

Alcohol and substance use characteristics are also presented in Table 1 in the Appendix. Most participants (75%) reported drinking at least once over the past 30 days. Of those who reported drinking, 71% reported consuming five or more drinks on at least one occasion. The average number of days that participants who consumed alcohol reported having five or more drinks was 7. Individuals who reported drinking spent on average \$120 on alcohol during the past 30 days. Finally, of those who consumed alcohol, 20% reported having problems with alcohol.

In our sample, 39% reported using marijuana at least once over the past 30 days (M days using = 20) and 6% reported their use as causing a problem. Outside of marijuana, the class of drugs most used was opiates. Over the past 30 days, 2% reported using heroin at least once, 1% reported using methadone, and 17% reported using other opiates. For those using opiates, the average number of days using was 15. Further, 14% reported opiates were causing problems for them.

Suicidality

During the baseline assessment, 46% reported current suicidal ideation, 25% reported a wish to be dead, 11% reported nonspecific active suicidal thoughts, 14% reported active suicidal ideation

without a plan and without intent to act, 3% reported active suicidal ideation with some intent to act but without specific plan, and 1% reported active suicidal ideation with specific intent and plan.

In our sample, 44% reported having at least one prior suicide attempt and 61% of attempters reported multiple attempts. While the number of attempts ranged from zero to 100, only one person reported 100 suicide attempts. The next highest number of lifetime attempts was 30. The average number of lifetime suicide attempts for previous attempters was 3.

We have had five participants die during the trial. One participant died from heart failure related to the use of fentanyl, four died as a result of drug overdose. One of these overdoses was categorized as a suicide. All of these outcomes were reported to all IRB's involved and were judged to be unrelated to study participation.

SAE's

No SAE's have occurred during this trial period.

Recruitment activities

Our goal this year was to increase recruitment of Active Duty and female participants. To do this, we engaged with Colonel McKnight and emphasized targeted recruitment of Active Duty participants through social media, Craigslist ads near bases, targeted FaceBook ads near bases, and an advertisement in Military Times. We have received many calls from potential participants who currently serve in the Armed Forces, but they hesitate to participate due to concerns about their "confidentiality" and the "risk to job if it were discovered they were talking about seeking help". We've had more than 60+ calls of this nature from Active Duty individuals who ultimately resisted participating in the trial due to these concerns.

While these concerns are difficult to address, we have also had enormous difficulty spreading the word about this trial to Active Duty personnel. Targeted advertisements are costly, although we do receive callers. Traditional avenues within DoD of communicating about the trial might improve both the number of potential Active Duty participants who enroll AND address concerns about risk to job and confidentiality.

We have continued to enroll female participants at similar proportions to their presence in the U.S. Armed Forces.

Completers

Currently, we have 788 participants who have completed the trial. An additional 160 are currently active in the trial. Of the 788 participants who have completed the trial, we have 12 month follow up data on 412, and no 12 month data on 377 participants. The majority of these were lost during the one year transfer period while the study was moving from Dartmouth to the Medical University of South Carolina. During this inactive time, we were not allowed to contact participants. Attempts were made to contact these individuals once the trial became active at MUSC; however, the majority are classified as lost to follow up. We either do not have active phone numbers and working addresses on many while the others chose to not respond.

Treatment utilization

At month 1, we had data available for 261 participants from the intervention condition and 266 from the control condition. In the intervention condition, 34% of the sample had scheduled a treatment session, 23% had attended a session, and those who attended a session attended an

average of 3 sessions. In the control condition, 27% of the sample had scheduled a treatment session, 11% had attended a session, and those who attended a session attended an average of 2 sessions. ***This is preliminary data suggesting that the intervention is effective to modify treatment seeking behavior.***

Next Steps

We will continue to conduct study activities with the goal of reaching 1,200 participants. The overall N is critical to our analyses on modifying treatment seeking behavior as we intend to conduct sub-analyses on the multiple paths of resistance to treatment. For example, participants who engage in substance use to medicate symptoms often present with a specific thought process toward help seeking and the modification of this thinking differs from those who resist treatment due to worries over the consequences to their job or security clearance or those with concerns over stigma. For these analyses to occur, we would need adequate numbers in each cell. These nuanced analyses will provide critical information to improve the uptake of treatment among those in need.

4. RESEARCH KEY ACCOMPLISHMENTS

- We have recruited 950 participants as of April 2018. Of the 950 participants, 802 of them are separated from the service, 118 are active in the National Guard or Reserves, and 30 are Active Duty. Of these, 788 have completed the trial.
- Of those participants receiving the intervention to improve treatment seeking behavior, 22% sought treatment within a month of participating in the trial versus only 10% of the control condition. This provides preliminary evidence that the intervention improves the uptake of treatment among those reporting suicidal thoughts and behaviors not in treatment.

5. CONCLUSION

Nothing to report.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

Publications in Press

We have had the following four manuscripts published in peer reviewed journals.

1. Allan, N. P., Conner, K. R., Pigeon, W. R., Gros, D. F., Salami, T. K., & Stecker, T. (2017). Insomnia and suicidal ideation and behaviors in former and current U.S. service members: Does depression mediate the relations? *Psychiatry Research*, 252, (296-302). <http://dx.doi.org/10.1016/j.psychres.2017.03.009>
2. Allan, N. P., Gros, D. F., Hom, M. A., Joiner, T. E., & Stecker, T. (2016). Suicide ideation and interpersonal needs: Factor structure of a short version of the Interpersonal Needs Questionnaire in an at-risk military sample. *Psychiatry: Interpersonal and Biological Processes*, 79, 249-261. doi:10.1080/00332747.2016.1185893
3. Gómez, J. M., Allan, N. P., Santa Ana, E. J., & Stecker, T. (in press). Depression and intention to seek treatment among Black and White suicidal military members who are not engaged in mental health care. *Military Behavioral Health*.
4. Allan, N. P., Gros, D. F., Lancaster, C. L., Saulner, K. G., & Stecker, T. (in press). Heterogeneity in short-term suicidal ideation trajectories: Predictors and projections to suicidal behavior. *Suicide and Life Threatening Behavior*.

Publications under Review

We have the following 4 manuscripts under review in peer reviewed journals. Several manuscripts are also in preparation.

1. Allan, N. P., Holm-Denoma, J., Conner, K. R., Zuromski, K. L., Saulnier, K. G., & Stecker, T. Profiles of risk for suicidal behavior: Latent profile analysis of current risk factors. *Revise and Resubmit*.
2. Gros, D. F., Silva, C., Allan, N. P., Lancaster, C. L., Conner, K. R., & Stecker, T. Relations between thwarted belongingness, perceived burdensomeness, and acquired capability and readiness for mental health treatment in high risk veterans. *Revise and Resubmit*.
3. Law, K. C., Allan, N. P., Kolnogorova, K., & Stecker, T. An examination of PTSD symptoms and their effects on suicidal ideation and behavior in non-treatment seeking veterans. *Manuscript under review*.
4. Raines, A. M., Allan, N. P., Franklin, C. L., Huet, A., Constans, J. I., & Stecker, T. Correlates of suicidal ideation and behaviors among former military personnel not enrolled in the Veterans Health Administration. *Manuscript under review*.

Presentations

1. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. HSRD VA Conference, February 2014
2. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. Psychiatric Research Center, Dartmouth Medical School, March 2014
3. Stecker: Increasing Treatment Seeking Among Suicidal Veterans. VA cyberseries, September 2015
4. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. Ralph H Johnson VA Grand Rounds, September 2015

5. Stecker: Increasing Treatment Seeking Among Suicidal Military Members. Ralph H Johnson VA COIN presentation, September 2015
6. Allan, N. Insomnia and suicidal ideation and behaviors in former and current U.S. service members: Does depression mediate the relations? Annual Anxiety and Depression Association of America conference, San Francisco, CA, April 2017
7. Gros, D. Predictors of treatment discontinuation during prolonged exposure for PTSD. Annual Anxiety and Depression Association of America conference, San Francisco, CA. April 2017
8. Saulnier, K. Suicidal ideation in high-risk veterans: Using growth mixture modeling to identify heterogeneous trajectories. Annual Anxiety and Depression Association of America conference, San Francisco, CA. April 2017
9. Zuromski, K. Insomnia and suicidal ideation among military personnel: Exploring joint symptom trajectories. Annual Associated Professional Sleep Societies, Boston, MA, June 2017
10. Allan, N. Examining longitudinal relations between PTSD symptoms and risk factors for suicide in at-risk military personnel. Annual Association for Behavioral and Cognitive Therapies, San Diego, CA. November 2017
11. Huet, A. The interactive effects of insomnia and substance use on suicidal ideation and behavior on an at-risk military population. Annual Association for Behavioral and Cognitive Therapies, San Diego, CA. November 2017

7. INVENTIONS, PATENTS, AND LICENSES

Nothing to report.

8. REPORTABLE OUTCOMES

Nothing to report.

9. OTHER ACHIEVEMENTS

Study activities have prompted a critical understanding of risk factors among service members and Veterans that contribute to suicidal thoughts and behaviors as well as treatment utilization. One of the most commonly reported symptoms that emerge during the cognitive-behavioral intervention session is sleep disturbance. Likewise, sleep treatment is reported as the treatment most preferred by those who otherwise would resist seeking help. This knowledge has resulted in subsequent intervention refinement for those most in need of help, and key investigators are currently seeking additional funding to test whether a combination of a brief cognitive behavioral therapy for insomnia along with the treatment intervention session would help improve sleep disturbance, mental health symptoms, decision making, and treatment utilization.

10. REFERENCES

None

11. APPENDIX

Table 1: Baseline characteristics of the sample

Characteristic	Intervention Participants (<i>n</i> = 402)		Control Participants (<i>n</i> = 394)	
	<i>n</i>	%	<i>n</i>	%
Male	357	89.6	354	89.8
Female	42	10.4	40	10.2
Ethnicity				
White, non-Hispanic	270	67.2	259	65.7
White, Hispanic	30	7.5	35	8.9
Black, non-Hispanic	49	12.2	40	10.2
Black, Hispanic	4	1.0	2	.5
Native American	5	1.2	9	2.3
Asian/Pacific Islander	12	3.0	12	3.0
Other/or mixed race/ethnicity	29	7.2	35	8.9
Missing	3	0.7	2	.5
Branch of Service				
Army	274	68.7	277	70.3
Navy	39	9.8	40	10.2
Airforce	34	8.5	29	7.4
Marine	69	17.3	61	15.5
Coast Guard	0	0	1	0.3
Refused	1	0.3	0	0
Drug Use (past 30 days)				
Alcohol	301	75.1	296	75.1
Marijuana	155	38.7	154	39.1
Barbituates	0	0.0	1	0.3
Sedatives	38	9.7	37	9.4
Cocaine/Crack	13	3.2	18	4.6
Stimulants	25	6.2	17	4.3
Hallucinogens	8	2.0	8	2.0
Heroin	6	1.5	9	2.3
Methadone	3	0.7	1	0.3
Other Opiates	68	17.0	64	16.2
Inhalants	1	0.2	0	0.0
	Mean	Range	Mean	Range
Age	31.60	21-58	31.08	21-67
PHQ-9 score <i>at Baseline</i>	17.69	4-27	18.39	4-27
PCL score <i>at Baseline</i>	61.66	18-85	61.95	21-85
ISI score <i>at Baseline</i>	18.28	0-28	18.12	0-28
BPI score <i>at Baseline</i>	13.46	0-40	13.61	0-35

Table 2: Suicidal Ideation and Behavior

	Intervention Participants (<i>n</i> = 402)		Control Participants (<i>n</i> = 394)	
	<i>n</i>	Percentage (%)	<i>n</i>	Percentage (%)
Prior Suicide Attempt	174	43.3	172	43.7
Nonsuicidal Self Injury	121	30.1	99	25.1
Current Suicidal Ideation				
No current suicidal ideation	187	46.5	180	45.7
Wish to be Dead	100	24.9	97	24.6
Nonspecific active thought	43	10.7	42	10.7
Active Ideation, no plans or intent	53	13.2	58	14.7
Active ideation with some intent	12	3.0	14	3.6
Active ideation, intent and plan	7	1.7	3	0.8
Lifetime Suicidal Ideation				
No suicidal ideation	3	0.7	0	0.0
Wish to be Dead	48	11.9	67	17.0
Nonspecific active thought	61	15.2	43	10.9
Active Ideation, no plans or intent	66	16.4	69	17.5
Active Ideation with some intent	70	17.4	79	20.1
Active ideation, intent and plan	154	38.3	136	34.5

Table 3: Treatment at 1 month follow-up

Characteristic	Intervention Participants (261)		Control Participants (266)	
	<i>n</i>	%	<i>n</i>	%
Scheduled Appointment	89	34.1	73	27.4
Attended treatment	59	22.6	29	10.9
Number of sessions attended	2.6		1.9	