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TITLE: Brief cognitive behavioral therapy for military populations

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Salt Lake City, Utah 84122

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The purpose of this study is to compare a brief-cognitive behavioral therapy (B-CBT) to usual care in the treatment of active duty Service Members who report suicidal ideation with intent to die or those who make a suicide attempt. Enrollment, assessment, and treatment of study participants continues as planned without problems. To date, 161 subjects have consented to participate, of whom 140 have been randomized. 3-, 6-, 12-, and 18-month assessments have been initiated. Recruitment is occurring at a fast pace, with target enrollment (i.e., 150 participants total) projected to be achieved within the next month.					
15. SUBJECT TERMS Suicide, military, cognitive-behavioral therapy, psychotherapy					
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INTRODUCTION

The primary purpose of this study is to compare the effectiveness of brief cognitive-behavioral therapy (B-CBT) for the treatment of suicidality, including suicidal ideation and attempts (regardless of Axis I or II diagnosis) among active duty military personnel. The standard null hypothesis will involve tests conducted comparing improvement following B-CBT (treatment duration of 12 weeks) to treatment as usual (TAU). The primary outcome comparisons will include both direct markers of suicidality (i.e. suicide, suicide attempts) and indirect markers including associated symptomatology (i.e. suicidal ideation, intent, anxiety, depression, hopelessness, substance abuse, and sleep disturbance), along with remission of psychiatric diagnoses. Secondary purposes include the prospective investigation of suicide risk factors and warning signs to explore these variables' ability to predict subsequent suicidal behavior following an index attempt.

BODY

All tasks outlined for the third year of the study have been accomplished. We hired two research therapists and have trained them to provide Brief Cognitive Behavioral Therapy (BCBT) for suicidal patients. We have continued to enroll participants, provided the experimental treatment, and conducted all follow-up assessments. Therapy sessions are reviewed by the Project Manager (Dr. Craig Bryan), with weekly supervision occurring between Dr. Bryan and each therapist. The independent evaluator also participates in supervision at least twice per month to ensure coding reliability and fidelity to inclusion/exclusion criteria. The database has been fully operational with no major problems in data storage or maintenance experienced. We have obtained annual renewal of IRB approvals from Madigan Army Medical Center (MAMC), the University of Utah, and the University of Texas Health Science Center at San Antonio (UTHSCSA). As of 1 September 2012, 164 have provided informed consent for study enrollment, of which 140 have met study criteria and been randomized to treatment. During the past year, we initiated the first 12- and 18-month follow-up assessments. Recruitment has accelerated over the past year, and we now anticipate closing enrollment within the next month. We submitted a request for a no-cost extension, which has been approved, to complete follow-up assessments for additional year, consistent with original study goals. All quarterly reports have been submitted. Several empirical manuscripts have been written and published, and several presentations at scientific conferences have been made based on the study findings, along with a host of additional manuscripts being planned. A treatment manual is being completed, will be published as a book, and will be widely distributed.

We experienced minimal problems during the past year, and the study has been quite successful, despite the high-risk nature of the target population. As we approach the conclusion of this study, local mental health professionals at Fort Carson have expressed a strong desire for the study to continue as a designated treatment program (due to perceptions of significant benefit to the patient population).

Specific tasks from the Statement of Work, along with current status are listed below.

24 to 36 months

1. Continue intake evaluations and follow-up assessments (1,3,6, 12,18 and 24 months)
2. Continue enrollment and administering study treatments
3. Continue entering research data into database useable tracking software program
4. Continue verification and cleaning of data set
5. Continue telephone conferences for coordinators, therapists, and research assistants
6. Continue monthly teleconference meetings with PIs, project coordinators and support staff
7. Continue data analyses, manuscript preparation and professional scientific presentations
8. Complete annual IRB progress reports at each site
9. Complete final IRB progress report at each site.
10. Complete quarterly technical progress reports

11. Complete final quarterly technical progress report
12. Complete final annual progress report to funding agency
13. Participate in final Principal Investigators Meeting in Fort Carson, Colorado

Current status:

1. Intake evaluations and follow-up assessments have continued. As of 1 September 2012, we have evaluated 164 Soldiers for eligibility, of whom 140 have met inclusion criteria and have been randomized to one of the treatment conditions. 3-, 6-, 12-, and 18-month follow-up assessments have been continued with only five dropouts and four withdrawals thus far (i.e., a 94% retention rate thus far) .
2. 140 participants have been enrolled and randomized to one of the two treatments. Treatments are being delivered as planned.
3. Self-report data continues to be entered directly by participants into our electronic database, and our evaluator continues to enter clinician interview data within 24 hours of assessment.
4. Data has been screened and reviewed periodically, and identified errors have been corrected within 72 hours of identification.
5. Telephone conferences continue weekly for the coordinator, therapists, and evaluator.
6. Telephone conferences continue monthly to twice per month for investigators and coordinators.
7. Two quantitative analysis papers have been published during the past year, and seven conference proposals have been presented or are scheduled to be presented in the coming months at scientific meetings.
8. The annual IRB progress reports have been on schedule.
9. N/A – study is still ongoing.
10. Quarterly reports have been submitted on time.
11. N/A – study is still ongoing.
12. N/A – study is still ongoing.
13. N/A – study is still ongoing, but a final investigators meeting is tentatively scheduled for this winter.

KEY RESEARCH ACCOMPLISHMENTS

- Obtaining IRB annual approval/renewal
- Nearing completion of enrollment
- Continuation of study treatment and assessments
- Fidelity monitoring of therapists and evaluator
- Publication of first quantitative analyses
- Nearing publication of treatment manual and launching of related training effort

REPORTABLE OUTCOMES

In terms of scholarly activity resulting from this project in the past year, two quantitative analyses have been written up and subsequently published. A number of additional manuscripts are in process, with an emphasis on those targeting treatment outcome and effectiveness. Seven conference proposals have been accepted at the following scientific conferences: Association of Behavioral and Cognitive Therapies, November 2011 (2 presentations); American Association of Suicidology, April 2012 (2 presentations); Association of Behavioral and Cognitive Therapies, November 2012 (1 presentation scheduled); American Association of Suicidology, April 2013 (2 presentations scheduled). The PI (Dr. David Rudd) and Project Manager (Dr. Craig Bryan) are additionally nearing completion of the final version of the treatment manual and manuscript to be published in the form of a text book.

Based on the initial success and outcomes of the current project, Dr. Rudd and Dr. Bryan have regularly been featured in the media to discuss military suicide. A full list of media appearances within the past year can be found at www.veterans.utah.edu/media.html. Dr. Bryan continues to conduct workshops

across the country for mental health professionals to teach BCBT for suicidal patients, and Dr. Rudd continues to work with Congressional leaders to improve treatment options and mental health care for suicidal service members. A follow-up treatment study focused on acute interventions for suicidal Soldiers was funded last year, and has just recently received IRB approval. It is expected that the new study will begin at Fort Carson within the next few months, following the close of the current study, using the same staff and personnel involved in the current study. The possibility of additional treatment studies is being explored.

Research staff members and collaborators have benefited from this project via increased opportunities for advanced training and professional development. Study therapists Sharon Stone and Kim Arne received intensive training in military mental health and prolonged exposure therapy for PTSD at the Center for Deployment Psychology in Bethesda, MD. Kim Arne and Sean Williams have continued to receive formal supervision hours required for licensure from Dr. Evelyn Wertenberger, and both are scheduled to take their final examinations for independent licensure by the end of this year.

CONCLUSION

The third year of this study has resulted in the continuation of enrollment and study procedures, and has seen considerable success in recruitment that has brought the project to near completion. A no-cost extension was requested and approved, which will enable us to finish enrollment within the next month and continue follow-up assessments for another year. The project has benefited significantly from the close involvement and collaboration of Army clinicians and leadership, who have continued to support the study. Results of several initial empirical analyses have yielded important information about the primary motivations behind Soldiers' suicide attempts and the most common stressors experienced by Soldiers on the day of their suicide attempts. Subsequent analysis will explore treatment outcomes across a broad range of markers, examining the utility and effectiveness of a brief intervention for suicidality. In addition to improvement in soldier overall mental health and related functioning, the fiscal implications and potential savings will be explored. These results have had a direct impact on Army leadership, and have provided scientific data to support Army initiatives related to supporting the mental health needs of Soldiers. Feedback from other medical providers involved in the treatment and care of our participants has continued to be extremely positive, and it is expected that a larger-scale roll-out of training in BCBT at Fort Carson and other sites would be welcomed.

REFERENCES

Bryan, C.J., & Rudd, M.D. (2012). Life stressors, emotional distress, and trauma-related thoughts occurring within 24 hours of suicide attempts among active duty U.S. Soldiers. *Journal of Psychiatric Research*, 46, 843-848.

Bryan, C.J., Rudd, M.D., & Wertenberger, E. (in press). Reasons for suicide attempts among active duty Soldiers: a functional approach. *Journal of Affective Disorders*

APPENDICES

Current financial report.

SUPPORTING DATA

None

ANNUAL REPORT 2

Report Date 9/5/12

Reporting period from 9/8/11 to 9/7/12

PI M. David Rudd

Telephone No. 801-581-8620

Institution The University of Utah

Project Title: Brief Cognitive Behavioral Therapy for Military Populations

Current staff, with percent effort of each on project.

<u>Rudd, M. David</u>	<u>17%</u>	<u>Williams, Sean</u>	<u>50%</u>
<u>Bryan, Craig</u>	<u>75%</u>	<u>Arne, Kimberly</u>	<u>50%</u>
<u>Stone, Sharon</u>	<u>50%</u>		

Award expenditures to date (as applicable):

This Qtr/Cumulative	This Qtr/Cumulative
Personnel <u>44,761.15</u> / <u>446,927.26</u>	Travel <u>2,850.07</u> / <u>41,988.70</u>
Fringe Benefits <u>13,997.52</u> / <u>133,586.59</u>	Equipment/Facility Rental/User Fees <u>0</u> / <u>4,101.40</u> non-capital
Materials/Supplies <u>0</u> / <u>11,466.80</u>	Participant/Trainee Support <u>0</u> / <u>0</u>
Subject Costs <u>0</u> / <u>0</u>	Sub-award costs <u>34,411.08</u> / <u>538,515.65</u>
Consultant Services <u>0</u> / <u>1,500.00</u>	Other Direct Costs <u>0</u> / <u>2,566.55</u>

This Qtr/Cumulative
Subtotal <u>96,021.82</u> / <u>1,180,652.95</u>
Indirect Costs <u>30,496.36</u> / <u>333,343.83</u>
Fee <u>0</u> / <u>0</u>
Total <u>126,518.18</u> / <u>1,513,996.78</u>

Comments on administrative and logistical matters.

Award expenditures as of 8/31/12, based on University financial reporting systems.

Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work.

Use additional page(s) to present a brief statement of plans or milestones for the next quarter.