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TITLE: Brief Cognitive Behavioral Therapy for Military Populations

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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. All staff positions have been filled, the database is completed and functioning as designed, and enrollment was initiated on January 31, 2011. To date, 52 subjects have consented to participate, of whom 41 have been randomized. 3-month and 6-month assessments have been initiated. Recruitment is occurring at an acceptable pace, with target enrollment (i.e., 150 participants total) projected to be achieved as planned.

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 second 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. All therapy sessions are reviewed by the Project Manager (Dr. Craig Bryan) and the PI (Dr. David Rudd), and weekly supervision occurs between Dr. Bryan and each therapist. On a monthly basis during site visits, Dr. Bryan also conducts group supervision with both therapists together. The independent evaluator also participates in supervision at least twice per month to ensure coding reliability and fidelity to inclusion/exclusion criteria. Several full assessments have been recorded and viewed by Dr. Bryan to ensure fidelity in administering clinician-administered interviews. The database is fully operational, and no major problems in data storage or maintenance have been 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 2011, 52 have provided informed consent for study enrollment, of which 41 have met study criteria and been randomized to treatment. Follow-up assessments have been initiated (3-month and 6-month). Recruitment has accelerated since the first participant was enrolled on 31 January 2011, with a current pace of 2 to 4 new participants per week. Based on this pace of recruitment, we project reaching target enrollment within the planned timeline of the project. All quarterly reports have been submitted. Two theory-based manuscripts involving study staff have been written and submitted for publication; both are currently in press. A paper presentation has been submitted to and accepted for the annual meeting of the Association for Behavioral and Cognitive Therapies, to be held in November 2011. This will entail the first quantitative data analysis for the study.

We have experienced minimal problems thus far, with the notable exception of obtaining annual renewal from the MAMC IRB prior to the study expiration date on 5 May 2011. The MAMC IRB failed to send a required checklist to the study's Medical Monitor (Dr. Harry Rauch) until after business hours on 4 May 2011. Although the IRB admitted to mistakenly overlooking this requirement, and agreed that this oversight was not due to the investigative team, they nonetheless temporarily suspended the study and directed the research team to discontinue all study procedures, to include treatment of actively suicidal patients. The investigators contacted the IRB to express grave concern about significantly increased risk to participants created by the IRB's actions and decisions; an exception to continue those procedures necessary for participant safety was then issued by the IRB. Approval for annual renewal was not received until 24 May 2011, the date of the next full IRB meeting. This oversight by the IRB significantly slowed study progress and set back recruitment from a pace of approximately 3 new participants per week to 1 per week. Over the subsequent 3 months, we have slowly been able to recover to our previous recruitment pace.

Locally at Ft. Carson, the current study is widely referred to as "the Rudd Study." In consultation with other clinical researchers, it was suggested that the project create and adopt a name that was more marketable and consumer-friendly, and that could provide a form of "brand recognition." As such, the

current project adopted the name Army Suicide Prevention and Intervention Research at Evans (ASPIRE).

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

12 to 24 months

1. Facilitate hiring, training, supervision and fidelity checks as needed for attrition
2. Continue advertising confidential telephone screening
3. Continue confidential telephone screenings
4. Continue intake evaluations and follow-up assessments (1,3,6, 12,18 and 24 months)
5. Continue enrollment and administering study treatments
6. Complete exit interviews with participants who have completed treatment
7. Continue entering research data into database using tracking software program
8. Continue verification and cleaning of data set
9. Continue telephone conferences for coordinators, therapists, and research assistants
10. Continue monthly teleconference meetings with PIs, project coordinators and support staff
11. Continue data analyses, manuscript preparation and professional scientific presentations
12. Complete annual IRB progress reports at each site
13. Continue to complete quarterly technical progress reports
14. Complete annual progress report to USAMRAA
15. Participate in Principal Investigators Meeting in Fort Carson, Colorado

Current status:

1. Accomplished – Two therapists were hired and have been trained in study procedures and the investigational therapy. No attrition of staff has occurred. 100% of psychotherapy sessions are recorded and viewed by the Project Manager and the PI for the purposes of fidelity monitoring. The Project Manager meets with study therapists weekly for supervision, and monthly for group supervision. The Project Manager meets with the independent evaluator at least twice per month for the purposes of supervision and coding fidelity. Several full administrations of clinician interviews have been videotaped and reviewed to ensure assessment fidelity.
2. N/A – phone screening no longer utilized
3. N/A – phone screening no longer utilized
4. Accomplished – 52 participants have participated in the intake assessment, of which 41 have been randomized for treatment. Our evaluator has conducted 3-month and recently initiated 6-month assessments on study participants.
5. Accomplished and ongoing
6. Accomplished and ongoing
7. Accomplished and ongoing
8. Accomplished and ongoing
9. Accomplished – telephone conferences occur on a weekly basis among research therapists, evaluator, and Project Manager.
10. Accomplished – telephone conferences occur at least twice per month with investigators and Project Manager.
11. Data analyses are planned to be initiated by October 2011, when a minimum of 50 participants have been randomized. Two non-quantitative manuscripts have been written and are currently in press. One conference presentation is planned for November 2011 at the Association for Behavioral and Cognitive Therapies.
12. Accomplished
13. Accomplished
14. Accomplished
15. The annual investigator meeting is scheduled for December 2011.

KEY RESEARCH ACCOMPLISHMENTS

- Hiring and training of 2 study therapists
- Obtaining IRB annual approval/renewal
- Initiation of enrollment
- Initiation of study treatment and assessments
- Fidelity monitoring of therapists and evaluator

REPORTABLE OUTCOMES

In terms of scholarly activity resulting from this project, two theory-focused manuscripts have been accepted and are currently in press, and one conference presentation is scheduled for November 2011 at the Association for Behavioral and Cognitive Therapies. The PI (Dr. David Rudd) and Project Manager (Dr. Craig Bryan) are additionally completing 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. Bryan and Dr. Rudd were recently awarded a grant from the Department of Defense-funded Military Suicide Research Consortium to conduct a randomized clinical trial of triage-based interventions for suicidal Soldiers at Ft. Carson; this new study will be initiated upon completion of this current project. A second project to research biomarkers of suicidal behaviors has additionally been submitted for funding, with the intent for this proposed study to be an "add-on" to the current funded study; no decision has yet been made regarding this opportunity. Finally, a third study proposal to investigate new methods for detecting suicide risk among Soldiers who intentionally deceive or conceal suicide risk has been submitted to MOMRP for consideration; no decision has yet been made regarding this proposal. All new study proposals are planned to be conducted at Ft. Carson using the current project's research staff and collaborative team.

Related to their efforts on this project, Dr. Rudd and Dr. Bryan have conducted a number of presentations and made several media appearances focused on military suicide. Dr. Bryan has also begun conducting workshops across the country for mental health professionals to teach them BCBT for suicidal patients.

Research staff members and collaborators have benefited from this project via increased opportunities for advanced training and professional development. Dr. Evelyn Wertenberger (site PI) attended an advanced training workshop in cognitive-behavioral therapy at the Beck Institute. Study therapists Sharon Stone and Kim Arne, and independent evaluator Sean Williams have participated in a dialectical behavior therapy workshop hosted at Ft. Carson and a cognitive processing therapy for PTSD workshop at nearby Peterson Air Force Base. Kim Arne and Sean Williams have received formal supervision hours required for licensure from Dr. Evelyn Wertenberger, and both have passed initial licensing examinations.

CONCLUSION

The second year of this study has resulted in the initiation of enrollment and study procedures, and has seen considerable success in recruitment despite some setbacks. The project has benefited significantly from careful selection of research staff familiar with the military culture and previous experience working in military settings, and from close involvement and collaboration of Army clinicians and leadership. The early decision to fully integrate our research team within the Army hospital and clinics has contributed directly to the fast pace of recruitment over the past few months, and has ensured that the results will be more directly translatable to Army settings. No empirical results have yet been obtained from this study since quantitative data analyses have not yet been initiated, however feedback from other medical providers involved in the treatment and care of our participants has been extremely positive.

REFERENCES

None

APPENDICES

None

SUPPORTING DATA

None