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TITLE: Brief Cognitive Behavioral Therapy for Military Populations

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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. To date, all regulatory approvals have been obtained that are required for initiation of the study. Several staff positions have been filled, and hiring continues for the remaining positions. Database development and other study infrastructure requirements are under construction as planned. Enrollment is planned to begin within the next few months.

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

Most tasks outlined for the first year of the study have been accomplished. These accomplishments include obtaining IRB approvals from Brook Army Medical Center (BAMC), Madigan Army Medical Center (MAMC), the University of Utah, and the University of Texas Health Science Center at San Antonio (UTHSCSA). We have also obtained approvals from HRPO and CIRO. All legal documents and agreements (i.e., CRADA and SOW) have also been approved. Basic infrastructure development has been accomplished, including finalizing assessment packets, creation of database, data transfer policies, and initial staff hires. Specifically, the Project Director and one Independent Evaluator (IE) have been hired. The IE has been trained in study design, informed consent procedures, self-report assessment procedures, and structured interview administration. Practice cases have been initiated for the IE to ensure fidelity. Weekly supervision occurs between the Project Director and the IE. One of two therapists was also hired, but she resigned within a month of hire; advertising continues to fill the therapist positions. All quarterly reports have been submitted. Enrollment of participants has not yet been initiated, but is projected to occur within the next few months. As a result, no data have yet been collected. Specific tasks from the Statement of Work, along with current status are listed below.

Statement of work tasks and goals for months 0 to 6 (Quarters 1 to 2):

1. Initiate IRB proposals for primary and sub-contracts to all applicable military, VA, & civilian IRBs
2. Participate in first Investigators Meeting at Fort Carson, Colorado
3. Advertise for and hire grant staff for each of the sites (project coordinators, research associates, etc.)
4. Prepare flow sheet and data recording forms for telephone screening
5. Finalize assessment and individual project measurements for each site
6. Generate policy and procedures for data transfer from sites
7. Construct database to be used for data collection
8. Assign passwords-protected user profiles for data access
9. Conduct weekly research meetings with grant staff at individual sites
10. Conduct training of all staff to implement screens, intake evaluations, and therapist training
11. Initiate telephone conferences for project coordinators, therapists, and research assistants
12. Initiate monthly teleconference meetings with PIs, project coordinators and support staff
13. Complete quarterly technical progress reports for each site

Current status:

1. Accomplished – All IRB approvals have been obtained (Madigan AMC, UTHSCSA, Utah), and CIRO approval has been obtained. Upon completion of staff training, participants can begin to be enrolled

2. Accomplished
3. Accomplished
4. N/A – phone screening no longer utilized
5. Accomplished
6. Accomplished
7. Accomplished
8. Accomplished – Built into database design
9. Accomplished
10. Currently underway
11. Accomplished
12. Accomplished
13. Accomplished

Statement of work tasks and goals for months 7 to 12 (Quarters 3 to 4):

1. Facilitate hiring, training, supervision and fidelity checks as needed for attrition
2. Continue advertising confidential telephone screening
3. Initiate confidential telephone screenings
4. Enroll first of 150 participants in randomized clinical trials.
5. Initiate intake evaluations and follow-up assessments (1,3,6, 12,18 and 24 months)
6. Initiate enrollment and administering study treatments
7. Initiate entering research data into database useable tracking software program
8. Initiate 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. Initiate 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. One independent evaluator and one therapist were hired in August 2010, and have initiated inprocessing at EACH. Local orientation and training is scheduled for the end of September 2010. Study-specific training is scheduled for 11-22 October.
2. N/A phone screening no longer being used.
3. Item deleted because phone screening no longer being used.
4. N/A – No patients have been enrolled. First participant anticipated to be enrolled in November 2010.
5. N/A – No patients have been enrolled.
6. N/A – No patients have been enrolled.
7. N/A – No patients have been enrolled.
8. N/A – No patients have been enrolled.
9. Weekly telephone conferences have been initiated on Thursdays. The independent evaluator and therapist have also begun attending daily clinic meetings and weekly high risk meetings to coordinate with EACH staff and local investigators.
10. Telephone and email communication is occurring on weekly basis among all staff members.
11. N/A – No patients have been enrolled.
12. N/A – Annual reviews to occur between November 2010 – February 2011.
13. Accomplished
14. Accomplished
15. Accomplished – Principal Investigators meeting occurred on 23 June 2010 at Ft. Carson.

KEY RESEARCH ACCOMPLISHMENTS

- Hiring of Project Director and Independent Evaluator
- Obtaining all IRB and regulatory approvals
- Creation of electronic database

REPORTABLE OUTCOMES

Lessons learned from preparations for this study have also been useful in developing risk management protocols and approaches for other DOD-funded clinical trials. For example, the training curriculum developed for this study has been used for research staff on several other research studies in order to maximize participant safety and limit the need to exclude suicidal patients from other treatment studies.

CONCLUSION

No empirical results have yet been obtained from this study since enrollment has not yet begun. The first year of this study has resulted in the successful accomplishment of regulatory approvals required for the conduct of research with human subjects.

REFERENCES

None

APPENDICES

None

SUPPORTING DATA

None