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TITLE: Pilot Trial of Inpatient Cognitive Therapy for the Prevention of Suicide in Military Personnel with Acute Stress Disorder or Post-Traumatic Stress Disorder

PRINCIPAL INVESTIGATOR: Marjan G. Holloway, Ph.D.

CONTRACTING ORGANIZATION:

Henry M. Jackson Foundation
Rockville, Maryland 20852

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT This study delivers a brief and targeted intervention to military personnel and family members diagnosed with a trauma-related condition who are admitted for psychiatric inpatient care following a suicide attempt. The intervention is named Post Admission Cognitive Therapy (PACT), consists of six 90-minute individual cognitive behavioral therapy sessions delivered by a doctoral level clinician. If PACT demonstrates to be clinically feasible, acceptable, and associated with preliminary evidence of improvement in symptoms relative to the control condition, its efficacy can be definitively determined through the conduct of a larger randomized controlled trial. This report provides a summary of research activities and preliminary results based on the study's Year 5 performance period. A total of 36 participants (16 over last year) have been enrolled. A no cost extension request of 6 months has been requested to complete the follow-up assessments and to write up the final study results.					
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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	5
Key Research Accomplishments.....	16
Reportable Outcomes.....	17
Conclusion.....	19
References.....	20
Appendix A (CONSORT Flowchart, All Years).....	21
Appendix B (CONSORT Flowchart, Last Year).....	23
Appendix C (DSMB Meeting Agenda).....	25

Introduction

Background: Posttraumatic stress disorder (PTSD) and suicide-related behaviors are significant public health problems. Existing literature provides strong support for the relationship between PTSD and suicide ideation, attempts, and deaths. PTSD, in fact, shows the strongest association with suicide-related behaviors of any of the anxiety disorders and has equal or greater odds ratio than mood disorders for resulting in impulsive suicide attempts. However, to date, no evidence-based interventions have been developed for individuals with PTSD who attempt suicide. Therefore, we aim to develop, implement, and evaluate an inpatient based cognitive behavioral care plan for service members and beneficiaries, with symptoms of either Acute Stress Disorder (ASD) or PTSD, who are admitted for hospitalization following a recent suicide attempt.

Specific Aims: (1) To develop and evaluate a new manual of Post-Admission Cognitive Therapy (PACT) as a targeted inpatient treatment for individuals admitted for a recent suicide attempt to a military hospital. (2) To assess the feasibility of the study's assessment procedures by monitoring the completion rate of outcome measures during face-to-face as well as follow-up phone and web-based administrations. (3) To evaluate the degree of change and variability of response to Post-Admission Cognitive Therapy in comparison to Enhanced Usual Care at post-intervention and follow-up (1-, 2-, and 3-Month) on subsequent suicide attempt behavior (primary outcome) as well as on levels of depression, hopelessness, suicide ideation, and posttraumatic stress symptoms (secondary outcomes). (4) To examine in a preliminary manner whether improvements on primary and secondary outcome measures are associated with enhanced problem solving abilities which is viewed as a potential mechanism of change in cognitive therapy for the reduction of suicide behavior and PTSD symptoms.

Objective: The broad objective of this research is to effectively utilize a unique window of opportunity during the hospitalization period following a recent suicide attempt to deliver a brief and targeted intervention for traumatized individuals.

Study Design: We plan to randomize 50 traumatized patients hospitalized at the Walter Reed National Military Medical Center (WRNMMC) for a recent suicide attempt to one of two conditions: (1) Post-Admission Cognitive Therapy + Enhanced Usual Care (PACT+EUC) or (2) Enhanced Usual Care (EUC). Individuals who are over the age of 18, able to communicate in English and willing to provide informed consent will be recruited. The PACT+EUC condition will consist of six 60-90 minutes individual cognitive therapy sessions administered over 3 days. The EUC condition will consist of the usual care patients receive at an inpatient facility during their hospitalization in addition to assessment services provided by independent evaluators who work directly with our research team. The primary outcome variable is the number of subsequent suicide attempts. We expect that patients in the control condition will reattempt suicide at an earlier date and at a higher frequency as compared to patients enrolled in the intervention condition. Secondary outcome measures include the severity of depression, hopelessness, suicide ideation, and posttraumatic symptoms. Patients in both conditions will be assessed on the dependent measures at baseline and at 1-, 2-, and 3- month follow-up intervals. Data analyses will provide estimates of the statistical power of PACT relative to EUC over time via the usage of repeated observation data. Our preliminary effect size estimates will be used for future sample size calculations to conduct a larger randomized controlled trial to definitively determine the efficacy of PACT.

Body

Overview of Year 5

Study recruitment was initiated on April 4, 2011. To date, a total of thirty-six out of the initially proposed fifty participants have been recruited. During the period of July 28, 2012 and August 27, 2013 (5th Year Performance Period), a total of ninety-two individuals were considered for referral to the study. Forty six (50%) individuals were ineligible due to the following reasons: (1) ten were not recommended by WRNMMC staff; (2) six were approached by WRNMMC staff and declined to be referred to the study; (3) twenty two were referred and/or recruited into different studies; and (4) eight were already enrolled in a different study and were readmitted to the hospital. A total of forty six individuals were ultimately referred to the study and assessed for eligibility by our research team. Thirty of these individuals were excluded due to reasons including active psychosis, early discharge, other reasons, and declining to participate. Sixteen individuals consented to participate in the study of which seven were randomly assigned to the PACT condition and nine were randomly assigned to the control condition. Please refer to Appendix A and B for the Consolidated Standards of Reporting Trials (CONSORT) flow diagram which also provides the follow-up information on the trial.

In terms of regulatory-related issues, since the last annual report, we received (a) IRB approval for 2 amendments to the core/lead protocol, (b) initial IRB approval for the Fort Belvoir Community Hospital (FBCH) local recruitment site, (c) initial IRB approval for the WRNMMC local recruitment site (required by the WRNMMC IRB after the overall study added a second recruitment site), and (d) continuing review approval for the project as a whole. All of these submissions also received secondary concurrence from the USUHS IRB and approval from HRPO.

Over the past year, a number of clinical research activities have taken place. The guides to consenting, baseline assessment, and follow-up assessments have been prepared and continually updated for staff training and study implementation. A data management plan including computer configuration and database creation has been continually updated. In addition to the described tasks, we continue to develop and modify our existing treatment protocol based on weekly treatment meetings, review of evidence-based literature, and experiences with participants. One member of our research team regularly attends the morning report at the inpatient unit in order to recruit participants for the study, to maintain a presence there, and to stay in communication with the hospital staff members who are in the best position to refer patient.

On August 30, 2013, a request was sent from HJF to the MOMRP contracting office in order to request a no cost extension of an additional 6 months. Please note that the study end date was proposed to be modified from August 27, 2013 to February 27, 2014. It was also requested that the study recruitment end at the current 36 out of 50 in order to allow any future patients to be recruited into the MOMRP funded well-powered RCT which is a continuation of this pilot study.

The approval for an additional no cost extension for 6 months will allow us to complete the following:

1. 1, 2, and 3-month telephone follow-up assessments for existing participants
2. Data analysis and interpretation
3. Preparation of report for the sponsor
4. Preparation of at least one empirical manuscript in order to disseminate the findings associated with the study

The revised statement of work which was submitted with this no cost extension request outlined the following activities during the next two quarters of this study:

YEAR 6 – Q1: Performance Period between July 28, 2013 to October 27, 2013

- ☐ Prepare and submit applicable CDMRP and regulatory board reports
- ☐ Conduct follow-up phone and web-based assessments
- ☐ Maintain contact with the study's Medical Monitor
- ☐ Maintain and regularly update study regulatory binders
- ☐ Monitor adverse events and follow WRNMMC guidelines for reporting
- ☐ Continue with ongoing training and supervision of study follow-up assessors
- ☐ Continue review of audiotaped assessment and therapy sessions for reliability & integrity checks
- ☐ Continue data entry with the usage of scannable forms and begin data cleanup
- ☐ Begin data analysis and generate preliminary tables & figures to summarize study findings
- ☐ Monitor and problem solve web-based assessment procedures
- ☐ Make adjustments to standard operating procedures, assessment, & treatment protocols as needed

YEAR 6 – Q2: Performance Period between October 28, 2013 to February 27, 2014

- ☐ Prepare and submit applicable CDMRP and regulatory board reports
- ☐ Maintain and regularly update study regulatory binders
- ☐ Monitor adverse events and follow WRNMMC guidelines for reporting
- ☐ Continue review of audiotaped assessment and therapy sessions for reliability & integrity checks
- ☐ Continue data entry with the usage of scannable forms and begin data cleanup
- ☐ Make adjustments to standard operating procedures, assessment, & treatment protocols as needed
- ☐ Disseminate study findings – send out at least 1 paper to summarize the primary study findings
- ☐ Finalize PACT manual and highlight trauma related components
- ☐ Submit treatment manual for publication

Activities and Milestones

Below is a summary of study related milestones:

July 28, 2008	Award Date
November 19, 2008	WRAMC IRB Submission
November 21, 2009	WRAMC/CIRO IRB Approval
January 27, 2010	USUHS IRB Approval
March 10, 2010	HRPO Defers to CIRO
June 25, 2010	HRPO Overturns Deferral to CIRO
November 25, 2010	Protocol Amendment
March 7, 2011	IRB Approvals for Amendment
April 4, 2011	Recruitment Begins (21 Months from Receipt of Funding Date)
August 31, 2011	Base Realignment& Closure
February 21, 2012	Revision of Inclusion Criteria
April 26, 2012	1 st Continuing Review Progress Report Submission:
July 16, 2012	Continuing Review WRNMMC IRB Approval: Expiration (June 20, 2013)
July 16, 2012	Continuing Review USUHS IRB Approval
July 17, 2012	Continuing Review HRPO Acceptance
November, 2013 – February, 2013	Credentialing Renewal Problems, Recruitment Stopped
April 26, 2013	2 nd Continuing Review Progress Report Submission
May 31, 2013	Continuing Review WRNMMC IRB Approval: Expiration (May 8, 2014)
July 15, 2013	Continuing Review USUHS IRB Approval
July 24, 2013	Continuing Review HRPO Acceptance

Below is a list of the tasks we have made progress on during the Year 5 reporting period from August 28, 2012 to August 27, 2013.

1. Regulatory Related Tasks

Summary of IRB Activity

Since the last annual report, we received (a) IRB approval for 2 amendments to the core/lead protocol, (b) initial IRB approval for the Fort Belvoir Community Hospital (FBCH) local recruitment site, (c) initial IRB approval for the WRNMMC local recruitment site (required by the WRNMMC IRB after the overall study added a second recruitment site), and (d) continuing review approval for the project as a whole. All of these submissions also received secondary concurrence from the USUHS IRB and approval from HRPO.

As detailed in the Y5Q1 report, the first amendment was made in order to (a) maximize recruitment for the study, including adding FBCH as a new recruitment site for the study, (b) increase the effectiveness of the therapy sessions, (c) increase compliance with follow-up assessments, (d) and make logistical changes to the study to clarify procedures.

The second amendment, detailed in the Y5Q2 report, was made after we learned that all USUHS staff lost their WRNMMC credentials due to procedural changes that went into effect after WRNMMC went from being overseen by the Army to the Navy. In response, we changed the WRNMMC site PI to LTC Geoffrey Grammer, M.D., Chief of Inpatient Psychiatry at WRNMMC. Dr. Holloway remains the overall study PI.

We received initial approval to begin recruitment at the FBCH and a formal start letter from FBCH command. We also received initial approval for the WRNMMC local recruitment site.

Finally, we received Continuing Review (CR) approval from the IRBs overseeing the two local recruitment sites as well as the core/lead site. The three projects are now being reviewed on the same continuing review schedule and as a group rather than individually. Secondary concurrence was obtained from USUHS on 7/15/2013 and CR approval was obtained from HRPO on 7/24/2013.

Maintained and Updated Study Regulatory Binder

A regulatory binder was put together for this study and contains the most up-to-date IRB approved versions of the protocol and consent form. In addition, this binder contains all relevant study documentation including study personnel certifications and IRB approval letters.

Mr. Robert Wheeler has served as the IRB Coordinator for the study. With his assistance, we maintain an electronic regulatory binder. An abbreviated printed version has been placed at WRNMMC inpatient psychiatry for availability for site PI, Dr. Grammer.

On March 9, 2013, the clinical coordinator attended the WRNMMC IRB Research Round Table meeting. This meeting is facilitated by Col Molly Klote and Mary Kelleher, directors of the IRB. The WRNMMC IRB was recently audited and came to the meeting with several proposed changes to documentation. WRNMMC IRB provided a Study Regulatory Binder Checklist of suggested information to keep in electronic Regulatory Binder. They also provided an example of Deviation Log and a "Note to File" to be included in the Regulatory Binder. This will adequately capture and deviations or changes to the protocol and the reasons for the changes.

Maintained and Updated Risk Management Protocol

The research team revised and implemented a risk management protocol that defines imminent risk and details proper procedures when imminent risk is encountered both on the inpatient unit and during follow-ups. Based on our experiences at the inpatient unit, we revised the risk management protocol to better reflect the safety needs of the participants.

Created a Plan for Adverse Event Reporting

The research team has maintained communication with the WRNMMC, USUHS, and HRPO regulatory boards to create and maintain an adverse event reporting policy. We have encountered several adverse events, and after consulting with the medical monitor and PI, we have classified all adverse events discovered as *unrelated*, serious, and expected to study participation. After a conference call with the director of the IRB Mary Kelleher on July 3, 2013 and Director of IRB Operations Debarati Dasgupta on July 31, 2013, we received guidance to only report *unrelated* adverse events at the time of continuing review.

Maintained contact with the study Medical Monitor

Contact with the study Medical Monitor, Dr. Russell Carr is maintained via email and IRBNet as well as by phone as needed.

Prepared report for DSMB and conducted DSMB meeting #1

During this reporting period, the first Data Safety Monitoring Board (DSMB) meeting was held on April 14, 2013. The members of the DSMB included Dr. Sunil Bhar (Swinburne University), Dr. Walter Matweychuk (University of Pennsylvania), and Dr. Jeffrey Goodie (USUHS). The board members were provided with an agenda, a DSMB report, and the last report submitted to the sponsor (see Appendix C for a copy of the DSMB meeting agenda). The board reviewed the study-related activities and discussed the adverse events that have occurred during recruitment. All three members voted to continue the study. A letter stating such will be developed and signed by all three members and submitted to the IRB during the next reporting period. We have problem solved payment related issues pertaining to the honorarium and it will be disseminated to the members of the DSMB during the next reporting period.

Attended WRNMMC IRB Research Round Table Meetings

On March 9, 2013, the clinical coordinator attended the WRNMMC IRB Research Round Table meeting. This meeting is facilitated by Col Molly Klote and Mary Kelleher, directors of the IRB. They provided several updates outlined below:

- Col Molly Klote asked that coordinators hold off on amendments, unless it is a change in PI or sponsor directed. The WRNMMC IRB is short staffed and facing furloughs and cutbacks which will severely impact their ability to process submissions.
- The WRNMMC IRB was recently audited and came to the meeting with several proposed changes to documentation. The following documents will be incorporated into the infrastructure of this study:
 - Adverse Event Tracking Log
 - Staff Signature and Delegation of Authority Log
 - Study Regulatory Binder Checklist - WRNMMC IRB provided a check list of suggested information to keep in electronic Regulatory Binder
 - Deviation Log / Note to File (For Regulatory Binder)
 - Subject Enrollment Log

Updated Clinical Trials.gov

On March 27, 2013, the PI Dr. Marjan Holloway updated this study on ClinicalTrials.gov.

2. Study Personnel

Conducted Ongoing Training and Supervision of Study Personnel

Study assessors and therapists received ongoing training and supervision. The following trainings were conducted during the reporting period in order to train personnel on various components of the study:

- February 7 – 2 hour training for all personnel PACT intervention delivery
- February 12 – 1 hour training for research assistants on how to gather patient information during morning report for recruitment while maintaining PHI and confidentiality
- February 19 - 1 hour training for all personnel on Safety on an Inpatient Unit
- February 20 – The clinical coordinator trained both post-doctoral fellows for 1.5 hours on administration and logistical issues regarding the baseline assessment
- February 28 - 2 hour training for all personnel PACT intervention delivery
- February 28 - 2 hour training for all personnel on follow up procedures meeting
- March 27 – 2 hour training for all personnel on the administration, scoring, and interpretation of the Clinician Administered PTSD Scale (CAPS) conducted by Dr. Frank Weathers.
- March 28 – 1 hour VPN Training for all personnel to become familiar with and learn how to review the electronic medical record
- April 3 – 1 hour training for all personnel on End Note to assist in manuscripts

- Each person received an individualized 2 hour training on Consenting Procedures
- Supervision for clinical personnel was held weekly for 1-2 hours to discuss cases from the pilot trials and the application to the PACT RCT delivery

3. Infrastructure for Pilot Trial

Maintained a Regular Presence at the Inpatient Psychiatric Unit, Participated in Meetings with Key Personnel, and Problem Solved Implementation Challenges

Over the past year, in order to continue our ongoing relationship with the WRNMMC inpatient psychiatric team, to ensure support for the study, to communicate effectively, and to problem solve implementation related challenges, we arranged for several meetings with Dr. Geoffrey Grammer (Chief of Inpatient Psychiatry) and Major Robert Duprey (Acting Chief of Psychiatric Nursing Service). During these meetings, we updated on study procedures, generated new ideas to best enhance the study implementation, and problem solved challenges. For instance, we discussed and implemented a monthly training session for all incoming psychiatry residents in order to educate them on our research study and to facilitate patient recruitment. Furthermore, we attend morning report five days a week and maintain regular meetings and phone calls with various WRNMMC staff members who have served as points of contact or attending physicians for patients whom we plan to recruit into the study. We have found that our consistent presence on the ward has increased visibility and awareness about our study. We will continue to maintain a presence at the unit and to enhance our communication with the unit staff so that we are continually evolving as part of their team. We were very pleased by the kind reception we have received and have had staff members approach us with patient referrals – some of whom did not fully meet the study inclusion criteria.

Standard Operating Procedure (SOP) Maintained

SOPs have been written for both consenting participants into the study and assessment to ensure adherence to study protocol. The SOP outlines study procedures, recommendations for working with this population, risk management procedures, adverse event reporting guidelines, and general information about the inpatient unit at WRNMMC. We have updated these SOPs accordingly when we receive new information.

4. Meetings and Dissemination of Scientific Knowledge Gained from Pilot Trial

Treatment and Administrative Meetings

We hold weekly Clinical Trials Management and Treatment meetings. The weekly meetings are generally 2-3 hours in length and include the study PI and study personnel. The goals of the weekly meetings are the following: (1) to address any adverse events or unforeseen administrative issues; (2) to discuss recruitment, retention, and regulatory issues; (3) to provide supervision of study personnel and allow for an opportunity to consult on challenging clinical research topics; (4) to review treatment components and discuss ways to refine the existing treatment model; and (5) to make plans for the transition from the pilot trial stage to the full blown randomized controlled trial to be conducted upon the completion of this study. Two times per month, the entire lab met to discuss the progress being made on various studies including this pilot trial.

Participated in the In-Progress Review (IPR) and North Atlantic Treaty Organization (NATO) Meetings

The study was presented at the IPR annual meeting held in Ft. Detrick, MD during May 2013. This provided an opportunity to exchange ideas with other investigators involved in military suicide prevention research. The NATO meetings were either co-chaired or chaired by the study PI during which time the topic of military suicide across various NATO and partner countries was discussed. Attendance in these meetings were not supported by funding provided by this grant – however, the knowledge gained has

been valuable in better understanding the unique needs of this highly vulnerable military population and the best practices employed by other nations.

5. Treatment Development

Developed Treatment Protocol and Published Treatment Components

The PI has continued to gain knowledge about various cognitive behavioral interventions for the treatment of suicidal individuals as well as inpatient treatment protocols. The research in this area has consisted of reading scientific literature, consulting with national and international subject matter experts, as well as informal communication with patients and providers about perceived treatment needs and gaps in inpatient care for individuals following a suicide attempt. A manuscript which outlines the components of the Post Admission Cognitive Therapy via a case study was accepted in 2013 for publication in *Clinical Case Studies*. CDMRP was mentioned as a source of funding support for the project.

Conducted competency and adherence ratings

We have continued to transcribe the psychotherapy sessions for competency and adherence ratings. The Cognitive Therapy Rating Scale has been modified for usage to rate therapist competency and adherence to Post Admission Cognitive Therapy. Please see below for a description of the status of transcription.

- ❖ 18 Participants x 6 Sessions = 108
- ❖ Withdrew or Audio File Missing = 29
- ❖ Sessions Available for Transcription = 79
- ❖ Total Transcribed Sessions = 33
- ❖ Total Sessions Half Completed or In Progress = 5
- ❖ Total Assigned = 2
- ❖ Total Incomplete = 39
- ❖ (33/79 = 41.77% complete)

Continued with Refinements in the Study Treatment Protocol

The research team continued to revise the treatment protocol, based upon our experiences working with participants in the study. In addition, we are making changes based upon the latest outcome data in the suicide prevention literature. The PI has continued to gain knowledge about various cognitive behavioral interventions for the treatment of suicidal individuals as well as evidence based inpatient treatment strategies. The research in this area has consisted of reading scientific literature, consulting with national and international subject matter experts, as well as informal communication with patients and providers about perceived treatment needs and gaps in inpatient care for individuals following a suicide attempt. The PI has participated as a member of the Defense Health Board's Task Force on the Prevention for Suicide by Members of the Armed Forces, the North Atlantic Treaty Organization's working group on military suicide, the Tragedy Assistance Program for Survivors Conference for Military Survivors and the DoD Suicide Prevention and Risk Reduction committee suicide nomenclature workgroup. All these activities, in addition to participation in national and international suicide meetings, have been instrumental in the scientific conceptualization, planning, and implementation associated with this clinical trial.

6. Study Recruitment and Retention

Our research staff attends morning report five times per week to discuss the eligibility of newly admitted patients for the study and to maintain consistent communication with the head social worker and the head of Inpatient Psychiatry. This communication has helped ensure that WRNNMC staff is aware and knowledgeable about our study, and that our research team is aware of patients that may be eligible for recruitment. In March of 2012 we received approval of a submitted amendment to make our inclusions criteria less stringent and to include individuals with Posttraumatic Stress Disorder (PTSD) or Acute Stress Disorder (ASD) who are hospitalized for (1) a suicide attempt or (2) suicide ideation with a history

of attempt. Follow-up assessments are also ongoing for the study with a success rate of 48% completion for 1-month follow-ups; 33% completion for 2-month follow-ups; and 72% completion for 3-month follow-ups. Study retention rates are due to a number of factors, 5 participants withdrew before a 1 month could be complete and 1 participant was deceased before the 1 month could be complete. Additionally, 8 participants were unable to complete at least 1 time point due to the study being on-hold for IRB approval. Active duty military service members are often relocated to a different duty station when discharged from the hospital. Two of the participants have been re-located overseas making follow-up difficult to coordinate. Despite some of the difficulties with retention, of the 27 participants that have completed the study 19 (70%) of participants have completed at least 1 time point.

CDMRP Follow-up Status as of 08.22.13

Study ID	1 Month	2 Month	3 Month
101	Complete	Complete	Complete
102	Complete	Expired	Complete
103	Withdrew	Withdrew	Withdrew
104	Complete	Expired	Expired
105	Complete	Complete	Complete
106	Expired	Expired	Expired
107	Complete	Complete	Complete
108	Expired	Expired	Expired
109	Expired	Expired	Withdrew
110	Complete	Expired*	Complete
111	Complete	Expired*	Complete
112	Expired*	Complete	Complete
113	Expired*	Expired*	Complete
114	Expired*	Expired	Complete
115	Expired*	Complete	Complete
116	Expired*	Expired	Complete
117	Expired*	Expired	Complete
118	Complete	Complete	Complete
119	Withdrew	Withdrew	Withdrew
120	Withdrew	Withdrew	Withdrew
121	Expired	Complete	Complete
122	Complete	Complete	Complete
123	Complete	Expired	Complete
124	Complete	Expired	Complete
125	Complete	Expired	Complete
126	Expired	Expired	ACTIVE
127	Withdrew	Withdrew	Withdrew
128	Expired	Expired	ACTIVE
129	Withdrew	Withdrew	Withdrew
130	Expired	Expired	ACTIVE
131	Complete	Complete	PENDING
132	Expired	Expired	ACTIVE
133	Deceased	Deceased	Deceased

134	PENDING	PENDING	PENDING
135	ACTIVE	PENDING	PENDING
136	PENDING	PENDING	PENDING
Total:	(13) Complete (20) Missing 13/27 = 48% + (2) Pending + (1) Active	(9) Complete (23) Missing 9/27 = 33% + (3) Pending	(18) Complete (10) Missing 18/25 = 72% + (4) Pending + (4) Active

*Follow-Up expired due to IRB Pending

Preliminary Data

Study recruitment was initiated on April 4, 2011. During the period of April 4, 2011 and August 27, 2013, one hundred ninety-two individuals were referred to the study and assessed for eligibility. One hundred six individuals were excluded due to the following reasons: (6) active psychosis; (15) expected early hospital discharge; (21) not recommended by WRNMMC staff; (9) declined when approached by WRNMMC Staff; (11) currently enrolled in another study; (4) currently enrolled in this study; (4) unable to recruit, awaiting IRB Continuing Review; (5) no coverage; (13) declined to participate when approached by our staff and (65) referral to different study. Thirty six individuals consented to participate in the study, eighteen were randomly assigned to treatment and eighteen were randomly assigned to the control condition. Of the participants who have not withdrawn, deceased, and/or are pending evaluation, 13 participants (48%) have completed their 1-month follow up assessments; 9 participants (33%) have completed the 2-month follow up assessment and 18 participants (72%) have completed the 3-month follow up assessments. Appendix A and B present the CONSORT flow diagrams.

Table 1: Demographic Characteristics of Sample (N = 36)*		
	Usual Care (n = 18)	Cognitive Therapy (n = 18)
Age, mean (SD), years	33.0 (10.8)	28.9 (8.6)
Gender		
Male	13 (72.2)	12 (66.7)
Female	5 (27.8)	6 (33.3)
Race/Ethnicity		
American Indian/Alaska Native	0	2 (11.1)
Asian	2 (11.1)	0
Black/African-American	2 (11.1)	5 (27.8)
Hispanic/Latino	3 (16.7)	2 (11.1)
White	11 (61.1)	8 (44.4)
Other	0	1 (5.6)
Education		
High school diploma/equivalent	4 (22.2)	3 (16.7)
Some college, no degree	9 (50.0)	8 (44.4)
Higher studies	5 (27.8)	7 (38.9)
Marital Status		
Never married	5 (27.8)	9 (50.0)
Married	10 (55.6)	4 (22.2)
Separated/Divorced/Widowed	3 (16.7)	5 (27.8)
Military rank[^]		
E1 - E4	7 (43.8)	11 (61.1)
E5 - E9	6 (37.5)	5 (27.8)
Officer (O1 - O10)	1 (6.2)	2 (11.1)
Cadet/Midshipman	2 (12.5)	0

* Data presented as No. (%), except as noted

[^] 2 participants were civilians

Table 2: Clinical Characteristics of Sample (N = 36)*		
	Usual Care (n = 18)	Cognitive Therapy (n = 18)
Major Depressive Episode		
Current	14 (77.8)	14 (77.8)
Recurrent	9 (50.0)	15 (83.3)
With melancholic features (current)	11 (61.1)	11 (61.1)
Substance Use Disorder		
Alcohol dependence	4 (22.2)	9 (50.0)
Alcohol abuse	3 (16.7)	4 (22.2)
Substance dependence (non-alcohol)	2 (11.1)	1 (5.6)
Post-Traumatic Stress Disorder		
Current	9 (50.0)	2 (11.1)
Lifetime	9 (50.0)	8 (44.4)
Suicide Attempts		
None	2 (11.1)	3 (16.7)
Once	4 (22.2)	4 (22.2)
Twice	5 (27.8)	4 (22.2)
Thrice or more	7 (38.9)	6 (33.3)
Unknown	0	1 (5.6)

* Data presented as No. (%)

Table 3: Secondary Outcome Measures*				
	Assessment Period, months			
	Baseline	1	2	3
Beck Depression Inventory II	<i>N</i> = 36	<i>N</i> = 13	<i>N</i> = 9	<i>N</i> = 18
Usual care	34.1 (12.2)	21.4 (16.7)	25.6 (15.4)	13.0 (11.1)
Cognitive therapy	30.5 (12.3)	22.8 (8.7)	19.7 (15.0)	13.1 (6.9)
Beck Hopelessness Scale	<i>N</i> = 36	<i>N</i> = 13	<i>N</i> = 9	<i>N</i> = 17
Usual care	9.9 (6.2)	7.9 (8.2)	9.6 (6.3)	6.3 (7.2)
Cognitive therapy	10.2 (6.3)	8.8 (6.6)	4.3 (1.5)	5.8 (3.8)
Suicide Ideation Score - current	<i>N</i> = 36	<i>N</i> = 13	<i>N</i> = 9	<i>N</i> = 18
Usual care	5.0 (6.7)	5.4 (7.4)	4.3 (5.5)	0.4 (0.7)
Cognitive therapy	5.7 (6.0)	1.8 (2.6)	1.7 (2.9)	1.0 (1.6)
Suicide Ideation Score - worse day	<i>N</i> = 36	<i>N</i> = 12	<i>N</i> = 9	<i>N</i> = 18
Usual care	24.7 (8.4)	8.3 (12.2)	9.6 (10.7)	7.1 (9.3)
Cognitive therapy	24.6 (6.3)	15.8 (12.6)	9.0 (15.6)	10.1 (12.2)

* Data presented as Mean (SD)

NB: The high attrition rate after baseline is due to time lapsing whilst waiting for IRB approval

Key Research Accomplishments

As reported at the most recent In-Progress Review meeting held at Ft. Detrick, Maryland, we have completed the following activities:

- ✓ Submitted Proposal for Stage II RCT in May 2010 AND Secured USAMRMC Funding
- ✓ Completed Retrospective Chart Review (2001-2006; N = 1477 Psychiatric Inpatients)
- ✓ Developed Documentation Template for DoD Inpatient Suicide-Related Admissions
- ✓ Provided Multiple Trainings Across DoD
- ✓ Prepared the following Peer-Reviewed Publications:
 - Dennis, J., **Ghahramanlou-Holloway, M.**, Cox, D., & Brown, G. (2011). A guide for the assessment and treatment of suicidal patients with traumatic brain injuries. *Journal of Head Trauma Rehabilitation*, 26, 244-256.
 - **Ghahramanlou-Holloway, M.**, Cox, D., & Greene, F. (2012). Post-admission cognitive therapy: A brief intervention for psychiatric inpatients admitted after a suicide attempt. *Cognitive and Behavioral Practice*, 19, 233-244.
 - Neely, L., Irwin, K., Carreno Ponce, J. T., Perera, K., Grammer, G., & **Ghahramanlou-Holloway, M.** (in press). Post Admission Cognitive Therapy (PACT) for the prevention of suicide in military personnel with histories of trauma: Treatment development and case example. *Clinical Case Studies*.

Deliverables:

- ✓ Session by Session Treatment Guide
 - Therapy Handouts – Worksheets
- ✓ Skills Workbook for Military Service Member
 - Treatment Summary Template for Service Member
- ✓ Provider Competency Measure
 - Adaptation of Cognitive Therapy Rating Scale (Young & Beck, 1980)
- ✓ Consenters, Assessor, & Provider Training Materials
- ✓ Risk Management Guide
- ✓ Report on Clinical Lessons Learned
 - Based on Transcribed Sessions
- ✓ Immediate Transition to Stage II Research

Goals Not Met

- Completion of Recruitment; Startup at 2nd recruitment site – Ft. Belvoir Community Hospital
Please note that we have not yet been able to start recruitment at FBCH. In addition to challenges associated with regulatory boards, clinical privileging/credentialing, within the past two weeks, we have been told that our staff members do not have the type of security clearance which is expected for FBCH staff – we have been working with the USUHS and HJF security officers to obtain a higher level clearance for our staff.

Reportable Outcomes

Publications Since Last Annual Report

Neely, L., Irwin, K., Carreno Ponce, J. T., Perera, K., Grammer, G., & **Ghahramanlou-Holloway, M.** (in press). Post Admission Cognitive Therapy (PACT) for the prevention of suicide in military personnel with histories of trauma: Treatment development and case example. *Clinical Case Studies*.

United States Air Force Medical Operations Agency. (2013). Air Force guide for suicide risk assessment, management, and treatment. San Antonio, Texas. (Prepared with funding provided by the United States Air Force to Dr. Ghahramanlou-Holloway for project titled, “Enhancing United States Air Force Suicide Prevention Efforts.”)

Presentations Since Last Annual Report

❖ Invited Talks & Presentations

Ghahramanlou-Holloway, M. (2012, August). Laboratory for the treatment of suicide-related ideation and behavior: Organization and current activities. Invited presentation at the Defense Suicide Prevention Office, Staff Educational Series, Arlington, VA.

Ghahramanlou-Holloway, M. (2012, September). Managing suicidal behaviors. Invited webinar presented with Dr. Peter Gutierrez, organized by the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, podcast available by visiting (<http://www.dcoe.health.mil/Training/MonthlyWebinars/2012Webinars.aspx>)

Ghahramanlou-Holloway, M. (2012, December). Post Admission Cognitive Therapy (PACT) for the inpatient treatment of military personnel with suicidal behaviors: A multi-site randomized controlled trial. Invited presentation at the Henry Jackson Foundation for the Advancement of Military Medicine Council of Director’s Meeting, Rockville, MD.

Ghahramanlou-Holloway, M. (2013, March). Cognitive behavior therapy for the prevention of suicide. Invited presentation for behavioral health providers, Ft. Meade, MD.

Ghahramanlou-Holloway, M. (2013, May). The role of trauma in suicidal states. Invited presentation at Aeschi West: Basic Principles in Working with Suicidal Adults, Vail, CO.

Brown, G., & **Ghahramanlou-Holloway, M.** (2013, May). Cognitive behavior therapy for suicidal patients. Invited workshop at Aeschi West: Basic Principles in Working with Suicidal Adults, Vail, CO.

Ghahramanlou-Holloway, M. (2013, January). Cognitive behavior therapy for depression and suicidality. Three day training workshop for mental health providers at the Baltimore Mental Health Systems, Baltimore, MD.

Ghahramanlou-Holloway, M. (2013, July). Cognitive behavior therapy for suicide prevention. Two day training workshop for military mental health providers at Camp Lejeune, NC.

❖ **Conference Presentations and Published Abstracts**

†Signifies Published Abstract

Neely, L. L., & **Ghahramanlou-Holloway, M.** (2012, August). Post admission cognitive therapy (PACT) for the prevention for suicide in military personnel with histories of trauma: Treatment development and case example. Breakout session presented at the Military Health System Research Symposium, Ft. Lauderdale, FL.

Ghahramanlou-Holloway, M., Jobes, D., Brown, G., Rudd, D., & Linehan, M. (2012, November). Evidence-based CBT approaches in inpatient care for suicide prevention. In K. Crowley (Chair), Cognitive and behavioral therapies for suicide: What do we know, and what makes them work? Symposium presented at the Annual Meeting of the Association of Behavioral and Cognitive Therapies, National Harbor, MD.

†MacIntyre, J., Perera, K., DeYoung, K., & **Ghahramanlou-Holloway, M.** (2013, April). Psychiatric inpatient trauma histories: An examination of documented trauma histories in military inpatients admitted for suicide ideation, suicide attempt, and non-suicide related events. Paper presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.

†Brown, G., K., **Ghahramanlou-Holloway, M.**, & Green, K. L. (2013, April). Cognitive therapy for the prevention of suicide among military personnel and Veterans: Ongoing research and clinical recommendations. Symposium presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.

†Neely, L., Carreno-Ponce, J. T., Irwin, K., Perera, K., Grammer, G., & **Ghahramanlou-Holloway, M.** (2013, May). Post Admission Cognitive Therapy (PACT) for the prevention of suicide in military personnel with histories of trauma: Treatment development and case example. Poster presented at Aeschi West: Basic Principles in Working with Suicidal Adults, Vail, CO.

†Neely, L. L., Irwin, K., Holloway, K., Perera, K., & Grammer, G., & **Ghahramanlou-Holloway, M.** (2013, August). Problem solving in suicidal service members: Clinical observations versus self-report. Breakout session presented at the Military Health System Research Symposium, Fort Lauderdale, FL.

†Carreno-Ponce, J. T., & **Ghahramanlou-Holloway, M.** (2013, August). Current intervention evaluations underway: The “SafeMil” and “PACT” randomized controlled trials at WRNMMC. Breakout session presented at the Military Health System Research Symposium, Fort Lauderdale, FL.

Research Funding Awarded Since Last Annual Report

2013-2015 **United States Navy Personnel Command – Suicide Prevention Program**

Military Interdepartmental Purchase Request

Title: Lessons Learned from United States Navy Service Members Following a Suicide Attempt

Conclusion

This research aims to deliver a brief and targeted intervention to military personnel and family members diagnosed with a trauma-related condition who are admitted for psychiatric care following a suicide attempt. If our designed intervention demonstrates to be clinically feasible, acceptable, and associated with preliminary evidence of improvement in symptoms relative to the control condition, its efficacy can be definitively determined by conducting a larger, randomized controlled trial. Evidence-based practices for the prevention of suicide among service members who have attempted suicide are desperately needed. Our work on the CDMRP funded study has served as the foundation for securing additional funding for an adequately powered multi-site trial over the course of the next five years.

Over the course of the study, our research staff have attended morning report five times per week to discuss the eligibility of newly admitted patients for the study and to maintain consistent communication with appropriate inpatient psychiatry key personnel. We offer services 7 days a week to make sure to accommodate the psychiatric unit and the study participants. We keep track of psychiatric admissions into the Psychiatric Inpatient Unit in order to make informed decisions about how to best problem-solve our recruitment difficulties. We have continued to further refine the components of Post Admission Cognitive Therapy and have outlined the stages of this intervention (as applied to a case of a military service member with a history of trauma and attempted suicide) in a peer-reviewed scholarly article that will be published in 2013 in *Clinical Case Studies*. We are currently working on finalizing the treatment guide and accompanying patient workbook.

After the receipt of all required regulatory approvals, study recruitment began on April 4, 2011. To date, 36 participants have been recruited. Please note that our study recruitment did not begin until after 21 months from the performance period start date. Therefore, the study experienced a late start given the significant delays encountered due to the IRB procedures, our study being the very 1st DoD reviewed randomized controlled trial for suicidal military service members, and the base realignment and closure-related (BRAC) transitional issues. As of August 30, 2013, a request was sent from HJF to the MOMRP contracting office in order to request a no cost extension of an additional 6 months. Please note that the study end date was proposed to be modified from August 27, 2013 to February 27, 2014. It was also requested that the study recruitment end at the current 36 out of 50 in order to allow any future patients to be recruited into the MOMRP funded well-powered RCT which is a continuation of this pilot study. The approval for an additional no cost extension for 6 months will allow us to complete the following: (1) 1, 2, and 3-month telephone follow-up assessments for existing participants; (2) Data analysis and interpretation; (3) Preparation of report for the sponsor; and (4) Preparation of at least one empirical manuscript in order to disseminate the findings associated with the study.

References

None.



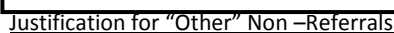
Justification for “Other” Non –Referrals

16 other reasons (justify)

- (4) Already enrolled in CDMRP, readmitted
- (3) Withdrew from study prior to randomization
- (4) Not actively recruiting, IRB Continuing Review Pending
- (5) No Coverage

¹ Justification for “other” non-referrals, and reasons for declined consent/ study withdrawal are listed immediately following the CONSORT diagram.

*Inclusion criteria was changed in March 2012 from SA w/ hx of Trauma, to SA w/ hx of Trauma OR SI w/ hx of SA + hx of Trauma. In February of 2013 Inclusion criteria no longer required a hx of SA.



*Inclusion criteria was changed in March 2012 from SA w/ hx of Trauma, to SA w/ hx of Trauma OR SI w/ hx of SA + hx of Trauma. In February of 2013 Inclusion criteria no longer required a hx of SA.

8 other reasons (justify)

- (3) Already enrolled in CDMRP, readmitted
- (2) Withdrew from study prior to randomization
- (3) No Coverage

¹ Justification for “other” non-referrals, and reasons for declined consent/ study withdrawal are listed immediately following the CONSORT diagram.

*Inclusion criteria was changed in March 2012 from SA w/ hx of Trauma, to SA w/ hx of Trauma OR SI w/ hx of SA + hx of Trauma. In February of 2013 Inclusion criteria no longer required a hx of SA.

Appendix C - Data Safety Monitoring Board Meeting #1

Time in Bethesda, MD / Philadelphia, PA
Sunday, April 14, 6:00pm-8:00pm

Time in Melbourne, Australia
Monday, April 15, 8:00am-10:00am

Conference Dial-in Number: (712) 775-7000
Participant Access Code: 853647#

Study 1: Pilot Trial of Inpatient Cognitive Therapy for the Prevention of Suicide in Military Personnel with Acute Stress Disorder or Post-Traumatic Stress Disorder

Principal Investigator: Marjan Holloway, Ph.D.

Sponsor: Congressionally Directed Medical Research Program (CDMRP)

Study 2: Inpatient Post Admission Cognitive Therapy (PACT) for the Prevention of Suicide Attempts: A Pilot Study

Principal Investigator: Marjan Holloway, Ph.D.

Sponsor: National Alliance for Research on Schizophrenia and Depression (NARSAD)

Study Representatives: Dr. Marjan Holloway (PI); Dr. Laura Neely (Clinical Coordinator)

DSMB Members: Dr. Sunil Bhar (Swinburne University of Technology); Dr. Jeff Goodie (Uniformed Services University of the Health Sciences); Dr. Walter Matweychuk (University of Pennsylvania)

Instructions to DSMB Members: Please review the documents provided.

Document Name	Description
2A_CDMRP_DSMB Report 2013	Report prepared for DSMB, Study 1 (CDMRP)
2B_CDMRP_Sponsor Report_Y5_Q2 2013	Report submitted to Sponsor, Study 1 (CDMRP)
3A_NARSAD_DSMB Report 2013	Report prepared for DSMB, Study 2 (NARSAD)
3B_NARSAD_Sponsor Report_Y4	Report submitted to Sponsor, Study 2 (NARSAD)

Meeting Agenda: The agenda for the DSMB meeting #1 is as follows:

1. Group Introductions
2. Brief Overview of CDMRP and NARSAD Studies
3. Discussion of Roles and Responsibilities of DSMB Members
4. Questions and/or Concerns about Human Participants' Protection
5. Vote for Continuation of Studies
6. DSMB Letter for Submission to IRB and Sponsor
7. Next Meeting