

AWARD NUMBER: W81XWH-18-2-0022

TITLE: Brief Cognitive Behavioral Therapy (BCBT) Replication Trial

PRINCIPAL INVESTIGATOR: Craig J. Bryan Psy.D., ABPP

CONTRACTING ORGANIZATION: University of Utah  
Salt Lake City, UT 84112

REPORT DATE: July 2019

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
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# REPORT DOCUMENTATION PAGE

Form Approved  
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<b>1. REPORT DATE</b> July 2019		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 1 Jul 2018 - 30 Jun 2019	
<b>4. TITLE AND SUBTITLE</b> Brief Psychological Treatment to Reduce Suicidal Behavior				<b>5a. CONTRACT NUMBER</b>	
				<b>5b. GRANT NUMBER</b> W81XWH-18-2-0022	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Craig J. Bryan Psy.D., ABPP  Lauren R. Khazem, Ph.D.  E-Mail: lauren.khazem@utah.edu				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b>	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  University of Utah 201 Presidents Cir, Salt Lake City, UT 84112				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> Brief Cognitive Behavioral Therapy (BCBT) has been indicated as an efficacious treatment to decrease suicide risk in military personnel but has yet to be empirically examined as a treatment to reduce suicide attempts in Active Duty US Marines. In the current study, 210 Active Duty Marines with past-month suicide ideation and/or attempt(s) will be enrolled in BCBT or Present Centered Therapy (PCT) an active control condition, and assessed every 3 months for 2 years following treatment completion. Main outcomes examined in the study include suicide attempts and suicide ideation. All IRB and HRPO approvals have been obtained for the original protocol. Enrollment in the study is anticipated to begin in September 2019. Supplementary funding for the project has been awarded to examine the temporal dynamics between sleep disorders and suicidal behavior in a subset of Active Duty Marines enrolled in the original protocol. This addition to the original study is currently under IRB review at Naval Medical Center Camp Lejeune.					
<b>15. SUBJECT TERMS</b> Suicide, suicide ambivalence, cognitive behavioral therapy, psychotherapy, crisis, Crisis Response Plan (CRP), Brief Cognitive-Behavioral Therapy (BCBT)					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  7	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC
<b>a. REPORT</b>  Unclassified	<b>b. ABSTRACT</b>  Unclassified	<b>c. THIS PAGE</b>  Unclassified			<b>19b. TELEPHONE NUMBER (include area code)</b>

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1. **INTRODUCTION:** Suicides in the U.S. Marine Corp (USMC) have remained increased, despite a relative decline in 2014. Furthermore, 33% of Marines who die by suicide access outpatient behavioral health services in the month preceding their death, while 55% of those who make a nonfatal suicide attempt access these services in the month before their attempt. As Brief Cognitive Behavioral Therapy (BCBT) has been indicated as an efficacious treatment to decrease suicide risk in Army soldiers, additional research is needed to determine whether its efficacy is generalizable to the USMC. The current, longitudinal randomized controlled trial (RCT) will compare the efficacy of BCBT against Present Centered Therapy (PCT), an active control condition, in 210 treatment-seeking Marine with past-month suicide ideation (SI) or attempts (SA).
2. **KEYWORDS:** Suicide, suicide ambivalence, suicidal ideation, reasons for living, reasons for dying, military, clinical trial, cognitive behavioral therapy, psychotherapy, crisis, Crisis Response Plan (CRP), Brief, Cognitive-Behavioral Therapy (BCBT)
3. **ACCOMPLISHMENTS:**
  - **What were the major goals of the project?**

#### Major Goals

1. To replicate previous findings supporting the efficacy of BCBT for the prevention of SA among military personnel;
2. To identify cognitive-affective mediators of BCBT's effects on risk for SA.

#### Project Milestones

1. Obtain DOD IRB approval (Target: 4/30/2019). 100% complete
2. University IAIR approvals (Target: 4/30/2019). 100% complete for University of Utah.
3. CRADA approvals (Target: 4/30/2019). 100% complete.
4. HRPO approvals (Target: 6/30/2019). 100% complete.
5. Project coordinator trained (Target: 1/30/2019). 100% complete.
6. Research therapists and evaluator trained (Target: 6/30/2019). 0% complete, expected completion by 8/30/2019.
7. Complete database build (Target: 6/30/2019). 100% complete
8. Begin enrollment (Target: 6/30/2019). 0% complete, expected completion by 9/30/2019.
9. Complete enrollment (Target: 6/30/2021). 0% complete, expected completion by 9/30/2021.
10. Begin interim data analyses (Target: 6/30/2021). 0% complete, expected completion by 09/30/2021.
11. Complete follow-up assessments (Target: 9/30/2023). 0% complete, expected completion by 9/30/2023.
12. Complete data analyses (Target: 6/30/2023). 0% complete, expected completion by 6/30/2021.
  - **What was accomplished under these goals?**
    - The objectives for this year were to obtain IRB and HRPO approvals, hire and train study personnel, and create study databases. Conditional IRB approval was obtained from the Naval Medical Center Camp Lejeune (NMCCL) IRB in October 2018, pending execution of the IAIR, which occurred on 2/5/2019. Approval for the study was obtained from HRPO on 3/22/2019. All study personnel have been hired, and training for all study

personnel will occur from 8/12/2019 – 8/23/2019. The study databases have also been created.

- **What opportunities for training and professional development has the project provided?**
  - Nothing to Report
- **How were the results disseminated to communities of interest?**
  - Nothing to Report
- **What do you plan to do during the next reporting period to accomplish the goals?**
  - During the next reporting period, training of study personnel will be completed and enrollment in the study will begin.

#### 4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**
  - Nothing to Report
- **What was the impact on other disciplines?**
  - Nothing to Report
- **What was the impact on technology transfer?**
  - Nothing to Report
- **What was the impact on society beyond science and technology?**
  - Nothing to Report

#### 5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**
  - Supplemental funding has been obtained from the Military Suicide Research Consortium to examine the temporal dynamics between sleep disorders and suicidal behavior in a subset of Active Duty Marines enrolled in the current study. This addition to the original study is currently under IRB review at Naval Medical Center Camp Lejeune.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - Nothing to Report
- **Changes that had a significant impact on expenditures**
  - Nothing to Report
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  - Nothing to Report
- **Significant changes in use or care of human subjects**
  - Nothing to Report

- **Significant changes in use or care of vertebrate animals.**
  - Nothing to Report
- **Significant changes in use of biohazards and/or select agents**
  - Nothing to Report

## 6. PRODUCTS:

- **Publications, conference papers, and presentations**  
*Report only the major publication(s) resulting from the work under this award.*
  - **Journal publications.** Nothing to Report
  - **Books or other non-periodical, one-time publications.** Nothing to Report
  - **Other publications, conference papers, and presentations.** Nothing to Report
- **Website(s) or other Internet site(s)**  
Nothing to Report
- **Technologies or techniques**  
Nothing to Report
- **Inventions, patent applications, and/or licenses**  
Nothing to Report
- **Other Products**  
Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Craig J. Bryan, Psy.D., ABPP
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-9714-0733
Nearest person month worked:	2.4
Contribution to Project:	Dr. Bryan has performed work in the areas of recruiting and hiring study personnel, responding to IRB requests, coordinating IAIR approval for the University of Utah, and overseeing database construction.
Funding Support:	U.S. Army Medical Research Acquisition Activity, Military Suicide Research Consortium, National Institute of Mental Health, Department of Defense, The Boeing Company, Pass-Through Entity Denver Research Institute, U.S. Air Force, VA Tele-Hub IPA
Name:	Eric Garland, Ph.D.
Project Role:	Co-Investigator

Researcher Identifier (e.g. ORCID ID):	0000-0003-2891-857X
Nearest person month worked:	0.6
Contribution to Project:	Dr. Garland has performed work in the areas of assisting with database construction for psychophysiological assessment methods.
Funding Support:	National Institute on Drug Abuse - Behavioral and Integrative Treatment Program, Department of Defense, National Institute of Health - National Center for Complementary and Integrative Health, Patient Centered Outcomes Research Institute
Name:	Brian Baucom, Ph.D.
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-0263-3763
Nearest person month worked:	0.6
Contribution to Project:	Dr. Baucom has performed work in the areas of assisting with database construction for psychophysiological assessment methods.
Funding Support:	National Institute of Health, Department of Defense, Military Suicide Research Consortium, AAA Foundation
Name:	David Rozek, Ph.D.
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-5441-7388
Nearest person month worked:	1.2
Contribution to Project:	Dr. Rozek has performed work in the areas of document and fidelity checklist preparation, and staff training.
Funding Support:	N/A

Name:	Lauren Khazem, Ph.D.
Project Role:	Project Coordinator

Researcher Identifier (e.g. ORCID ID):	0000-0002-0787-2368
Nearest person month worked:	12
Contribution to Project:	Dr. Khazem has performed work in the areas of database construction, hiring and training of study personnel, communication with study personnel, and document preparation.
Funding Support:	N/A
Name:	Johnnie Young
Project Role:	On-Site Project Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	9
Contribution to Project:	Mr. Young has performed work in the areas of assisting with IRB approvals and database construction.
Funding Support:	N/A
Name:	AnnaBelle Bryan, MS
Project Role:	Research Associate
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.6
Contribution to Project:	Ms. Bryan has performed work in the areas of management of study personnel and acquisition of study equipment and materials
Funding Support:	N/A

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

During the current reporting period, Dr. Bryan began receiving active other support for the following projects:

1 R01 MH117600-01 (Bryan) National Institute of Mental Health \$1,072,141 Identifying suicidal subtypes and dynamic indicators of increasing and decreasing suicide risk	1/1/2019 – 12/31/2021
W81XWH-18-2-0064 (Bryan) U.S. Army Medical Research Acquisition Activity \$2,560,669 Congressionally Directed Medical Research Programs Peer to Peer Programs for Military Suicide Prevention	9/30/2018 – 9/29/2021
University of Pennsylvania (Prime sponsor: MSRC) Suicide Risk and Sleep in Treatment: An Intensive Daily Sampling Study \$165,676	1/1/2019-12/31/2020
IPABRYAN VA Tele-Hub IPA \$15,650	9/1/2018-08/31/2019

During the current reporting period, Dr. Garland began receiving active other support for the following projects:

R01DA048094 (Garland) National Institute on Drug Abuse - Behavioral and Integrative Treatment Program Neural Mechanisms Mediating Appetitive Regulation in Smoking and Nicotine Addiction \$2,277,413.	2019 – 2024
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R61AT010134 (Finam) National Center for Complementary and Integrative Health Separate and Combined Effects of Mindfulness Meditation and Savoring on Pain-Related Corticostriatal Function \$1,005,568	2019 - 2021
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R21AT010109 (Cooperman) National Center for Complementary and Integrative Health Mindfulness Oriented Recovery Enhancement as an Adjunct to Methadone Treatment for Opioid Use and Chronic Pain Management \$1,819,967	2019 - 2021
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Patient Centered Outcomes Research Institute (PCORI) – Optimized Multidisciplinary Treatment Programs for Nonspecific Chronic Low Back Pain (Fritz) \$9,689,014	2018- 2025
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During the current reporting period, Dr. Baucom began receiving active other support for the following projects:

1R34MH113681 D. Baucom, Bulik (Multi-PIs) NIH / NIMH Targeting Relationship Domains in Community-based Treatment of Binge-eating Disorder and Bulimia Nervosa	2018-2021
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Role: Co-Investigator

PT170195  
 Bryan (PI) 2018-2023  
 Department of Defense  
 Peer to Peer Programs for Military Suicide Prevention  
 Role: Co-Investigator

R01 HL137606  
 Uchino (PI) 2018-2021  
 NIH / NHLBI  
 Understanding Relationship Ambivalence and its Links to Cardiovascular Health  
 Role: Co-Investigator

W81XWH1820022  
 Bryan (PI) 2018-2022  
 Department of Defense  
 Replication trial of Brief Cognitive Behavioral Therapy to prevent suicide  
 Role: Co-Investigator

MSRC-FY18-04  
 May, Bryan (Multi-PI) 2018-2021  
 Department of Defense / Military Suicide Research Consortium  
 Couples Crisis Response Planning to Reduce Post-Discharge Suicide Risk  
 Role: Co-Investigator

R03MH116455  
 Fischer, D. Baucom (Multi-PI) 2018-2020  
 NIH / NIMH  
 Social Processes in RDoC: Function and Dysfunction of Interpersonal Emotion Regulation in  
 Depression and Anxiety  
 Role: Consultant

AAA  
 Strayer, Cooper (Multi-PI) 2019-2020  
 A Research Program to Assess Advanced Vehicle Technologies on Younger and Older Drivers'  
 Workload and Performance  
 Role: Co-Investigator

- **What other organizations were involved as partners?**
  - Nothing to report

#### 8. SPECIAL REPORTING REQUIREMENTS

- **COLLABORATIVE AWARDS:** *Nothing to Report*
- **QUAD CHARTS:** See attached

#### 9. APPENDICES: N/A

# Brief Cognitive Behavioral Therapy (BCBT) Replication Trial

160433 / Broad Agency Announcement for Extramural Medical Research

W81XWH-18-2-0022



PI: Craig J. Bryan, Psy.D., ABPP

Org: University of Utah

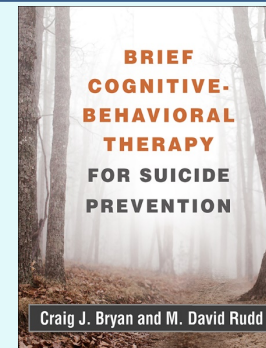
Award Amount: \$4,854,657.00

## Study/Product Aim(s)

- To replicate previous findings supporting the efficacy of Brief Cognitive Behavioral Therapy (BCBT) for decreasing suicidal ideation and preventing suicide attempts among military personnel
- To identify cognitive-effective mediators of BCBT's effects on the risk for suicide attempts

## Approach

The aims of the current study will be accomplished by: a) testing BCBT in a sample of Marines compared to Present Centered therapy (PCT) and b) examining *how* or *why* BCBT is effective for reducing the risk of suicide attempt as compared to existing mental health care services already available to Marines.



*BCBT is a 12-session treatment that has demonstrated promise as an effective treatment for reducing suicidal thoughts and behaviors in military personnel. The current randomized controlled trial will examine its efficacy in a sample of treatment-seeking Marines.*

**Major accomplishments during this reporting period:** The IAIR between the University of Utah and DON HRPP had been fully executed, and DON IRB approval has been obtained. HRPO approval has been obtained.

## Timeline and Cost

Activities	FY	18	19	20	21	22
Training study personnel						
Participant recruitment						
Baseline assessment						
Follow-up assessment						
Data analysis and dissemination of results						
<b>Estimated Budget (\$K)</b>		<b>\$780</b>	<b>\$978</b>	<b>\$1006</b>	<b>\$1035</b>	<b>\$1054</b>

## Goals/Milestones

**CY18 Goals** – Initial approval and development

- ✓ Obtain IRB and HRPO approval

**CY19 Goals** – Implementation

- Begin baseline and follow-up assessment

**CY20 Goal** – Implementation

- Continue baseline and follow-up assessment

**CY21 Goals** – Initial analyses

- Continue baseline and follow-up assessment

- Begin data cleaning and analyses

**CY22 Goal** – Final baseline assessments

- Complete final baseline assessments

**CY23 Goals** – Analysis and dissemination

- Complete all follow-up assessments
- Complete data analyses and disseminate results

## Comments/Challenges/Issues/Concerns

- None to report

## Budget Expenditure to Date

Projected Expenditure: \$970,931.40

Actual Expenditure: \$292,542.03

Updated: 7/30/2019