

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

REPORT DATE: July 2021

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE July 2021		2. REPORT TYPE Annual		3. DATES COVERED 7/1/2020 - 6/30/2021	
4. TITLE AND SUBTITLE Brief Cognitive Behavioral Therapy (BCBT) Replication Trial				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-18-2-0022	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Craig J. Bryan, Psy.D., ABPP Lauren R. Khazem, Ph.D. E-Mail: craig.bryan@osmc.edu ; lauren.khazem@osumc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Utah, 380 South 1530 East Room 502 Salt Lake City, UT 84102				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Brief Cognitive Behavioral Therapy (BCBT) has been indicated as an efficacious treatment 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. Thirty Marines have been enrolled in the protocol. All study activities have resumed after COVID-19 restrictions were lifted at Naval Medical Center Camp Lejeune.					
15. SUBJECT TERMS Suicide, suicide ambivalence, cognitive behavioral therapy, psychotherapy, crisis, Crisis Response Plan (CRP), Brief Cognitive-Behavioral Therapy (BCBT)					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
Unclassified	Unclassified	Unclassified	Unclassified	10	USAMRMC

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Accomplishments	1
4. Impact	2
5. Changes/Problems	2
6. Products	2
7. Participants & Other Collaborating Organizations	3
8. Special Reporting Requirements	7
9. Appendices	7

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

- To replicate previous findings supporting the efficacy of BCBT for the prevention of SA among military personnel;
- 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). 100% complete.
7. Complete database build (Target: 6/30/2019). 100% complete
8. Begin enrollment (Target: 6/30/2019). 100% complete.
9. Complete enrollment (Target: 6/30/2021). 14% complete, expected completion by 9/30/2022.
10. Begin interim data analyses (Target: 6/30/2021). 0% complete, expected completion by 9/30/2022.
11. Complete follow-up assessments (Target: 9/30/2022). 4% complete, expected completion by 9/30/2022
12. Complete data analyses (Target: 6/30/2023). 0% complete, expected completion by 6/30/2023.

What was accomplished under these goals?

The objectives for this year were to resume enrollment, treatment, and follow-up assessments and to begin interim data cleaning and analyses. All study activities were paused on 3/25/2020 due to COVID-19 protocols enacted by NMCCCL and resumed in March 2021.

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, enrollment in the study and follow-up assessments will continue. Data entry and cleaning 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

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

All on-site research activities at Naval Medical Center Camp Lejeune were temporarily halted due to COVID-19 precautions for one year. Study enrollment is therefore behind by approximately one year. Since resuming the study, the enrollment pace is slightly behind our original projections (approximately 5-6 subjects per month versus 8 subjects per month). We have been able to increase the amount of time that staff are working from the hospital, and have recently hired a new staff member to help accelerate recruitment during Year 4.

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

6. Products

Publications, conference papers, and presentations

Report only the major publication(s) resulting from the work under this award.

Journal publications.

Khazem, L. R., Rozek, D. C., Baker, J. C., & Bryan, C. J. (2021). The Marine Suicide Prevention and Intervention REsearch (M-SPIRE) study: A randomized clinical trial investigating potential treatment mechanisms for reducing suicidal behaviors among military personnel. *Contemporary clinical trials communications*, 21, 100731.

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 supervising study personnel, administrative tasks and responding to IRB requests,
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
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 Administrative tasks.
Funding Support:	National Institute of Health, Department of Defense, Military Suicide Research Consortium, AAA Foundation, U.S. Army Medical Research Acquisition Activity
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 maintenance, supervision of 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:	12
Contribution to Project:	Mr. Young has performed work in the areas of assisting with IRB approvals and modifications, recruitment, and enrollment of participants
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

worked:	
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
Name:	Abbey White, PhD
Project Role	Study Clinician
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	12
Contribution to Project:	Dr. White performed work in the areas of administering assessments and treatment to study participants.
Name	Stacy Schumpert, MS
Project Role	Study Clinician
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	12
Contribution to Project:	Ms. Shumpert performed work in the areas of administering assessments and treatment to study participants.
	Justin Baker, PhD
Project Role	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12
Name:	Sean Williams, LCSW
Project Role	Study Assessor
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12
Contribution to Project:	Mr. Williams performed work in the areas of assessing study participants at

on to Project:	follow-up.
-------------------	------------

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. Garland began receiving active other support for the following projects:

R44 DA053848-01 (Angelone) calendar NIH	3/1/2021 - 2/28/2025	1.2
		\$2,630,3
52 Digital Therapeutic Development of Virtual Cognitive-Affective Training for Opioid Use Disorder		

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

5R33AT010109 (Bioneau) calendar NIH-NCCIH	9/20/2018-8/31/2020	0.45
		\$1,067,8
60 Mindfulness-Oriented Recovery Enhancement as an Adjunct to Methadone Treatment for Opioid Use and Chronic Pain Management		

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

R61MH125759 (Bryan) calendar NIMH	09/21/2020-09/22/2022	2.4
		\$1,122,122
Title: Mechanisms underlying the association of firearm availability and vulnerability to suicide		

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

W81XWH-16-2-0003 (Anestis) calendar Department of Defense	2018-2020	1.2
		\$1,951,9
62 Title: Project Safe Guard		
W81XWH-16-1-0522 (Garland) calendar Department of Defense	2016-2021	1.2
		\$3,434,9
96 Targeting chronic pain and co-occurring disorders in the community with		

mindfulness-oriented recovery enhancement

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

