

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

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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. Forty-seven Marines have been enrolled in the protocol. All study activities resumed on 7/22/22 after a pause in study activities due to the departure of the previous study therapists and hiring and credentialing of a new study therapist.					
15. SUBJECT TERMS Suicide, suicide ambivalence, cognitive behavioral therapy, psychotherapy, crisis, Crisis Response Plan (CRP), Brief Cognitive-Behavioral Therapy (BCBT)					
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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

- 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). 22% complete, expected completion by 6/30/2023.
10. Begin interim data analyses (Target: 6/30/2021). 0% complete, expected completion by 9/30/2023.
11. Complete follow-up assessments (Target: 9/30/2022). 7% complete, expected completion by 6/30/2023
12. Complete data analyses (Target: 6/30/2023). 0% complete, expected completion by 6/30/2023.

What was accomplished under these goals?

We resumed enrollment during this reporting period. However, recruitment was paused again on 4/15/22 due to the departure of a study therapist and need to hire and credential a new therapist before treatment could resume. A new study therapist was hired, and recruitment and enrollment resumed on 7/22/22. Follow-up assessments have continued throughout these pauses in enrollment. The IRB of record was changed from NMCCCL to a centralized IRB at NMCP on 10/20/21. HRPO approved this change on 12/13/21.

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 resume. 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

During this past year, two study therapists departed, and one new therapist has been recently hired. During this transition, recruitment and enrollment was paused for four months until the hiring and credentialing process for the new study therapist was completed. Recruitment and enrollment resumed on 7/22/2022. Study enrollment is therefore behind by approximately one year. Since resuming the study, the enrollment pace is behind our original projections (approximately 2 subjects per month versus 8 subjects per month). Our team collaborated with NMCCL clinic leadership to arrange for Marines being discharged from the psychiatric inpatient unit to meet with a member of our team, who discusses the study, assess eligibility, and obtains consent to participate. This additional recruitment strategy has been approved by NMCCL leadership and NMCP IRB and is anticipated to result in a significantly increased rate of enrollment. To accommodate this anticipated increase in enrollment, we are currently hiring a second on-site project coordinator and a second study therapist. Due to the multiple delays we have experienced as a result of COVID, regulatory processes, staff turnover, and credentialing of new staff, we anticipate requesting a one-year No Cost Extension in order to carry out this project until 6/30/2024.

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.

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 personmonth 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

ID):	
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
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:	10
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:	5
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
Contribution to Project:	Dr. Baker has performed work in the areas of supervision of study personnel, document preparation, and coordination with military collaborators.
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 follow-up.
Name:	Justin Gibson, LCWS
Project Role	Study Therapist
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	1
Contribution to Project:	Mr. Gibson was recently hired after the departure of Dr. White. He has completed the majority of training and onboarding requirements at NMCCCL and is anticipated to begin providing treatment to Marines enrolled in the study beginning on 8/5/22.

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

Project Title: MTEC-21-05-CrossCutting-032; Protective environments: Military community engagement to prevent firearm-related violence

Time Commitment: 5% Role: PI

Supporting Agency: DOD

Contracting/Grants Officer: University of Colorado

Performance Period: 09/30/2021 - 07/25/2024

Level of Funding:

Project Goals: Objective: Our overarching objective is to facilitate implementation of acceptable, effective interventions for prevention of suicide and other non-fatal and fatal violence in military populations, with a focus on voluntary reductions in firearm access during at-risk periods as a way to decrease the risk of death. Goal: In this three-year project, our goal is use community engagement to adapt PSG and to then test it in a hybrid effectiveness-implementation trial.

Overlap: None

Project Title: Protective environments: Military community engagement to prevent firearm suicide - RESTORAL PROJECT

Time Commitment: 5% Role: PI

Supporting Agency: DHA

Contracting/Grants Officer: University of Colorado

Performance Period: 09/26/2021 - 09/26/2023

Level of Funding:

Project Goals: Our overarching goal is to facilitate implementation of acceptable and effective interventions for prevention of suicide and other non-fatal and fatal violence in military populations, with a particular focus on voluntary reductions in firearm access during at-risk periods to decrease the risk of death. In this two-year project, we will examine (1) preferred locking devices for personal weapons and (2) military spouse perspectives on intervention messaging. This will advance the scientific knowledge base and provide additional key information for the intervention adaptation and testing in the MTEC proposal, thereby enhancing impact.

Overlap: None

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

Title: Safety Messaging in the United State Military

Project Goals: The purpose of this study is to test a variety of methods for encouraging and supporting safe firearm storage in a national sample of military personnel.

Award Number: W81XWH-16-2-0004

Name of PD/PI: Anestis, Michael D.

Source of Support: Rutgers/DOD

Primary Place of Performance: Rutgers, The State University of New Jersey

Project Start and End Date: 09/01/2021-08/31/2022

Person Months per budget period:

Year	Person Months
1. 2022	1.2

Title: Real Time Assessment of Emotion Regulation and Suicidal Ideation among Individuals with First-Episode Psychosis

Project Goals: The purpose of this study is to clarify the mechanistic role of emotion regulation as a mechanism for suicidal thoughts in adults with first-episode psychosis (FEP).

Award Number: YIG-0-184-20

Name of PD/PI: Wastler, Heather

Source of Support: American Foundation for Suicide Prevention

Primary Place of Performance: The Ohio State University College of Medicine

Project Start and End Date: 12/1/2021-11/30/2023

Person Months per budget period:

Year	Person Months
1. 2022	0.24
2. 2023	0.24

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

Title: Targeting relationship domains in community-based treatment of binge-eating disorder and Bulimia Nervosa

Major Goals: The primary objective of this project is to test a couple-based cognitive behavioral psychotherapy for binge-eating disorder and Bulimia Nervosa in an out-patient psychotherapy clinic.

Status of Support: Active

Project Number: R34MH113681

Name of PD/PI: Bulik & D. Baucom (MPI)

Source of Support: NIH/NIMH

Primary Place of Performance: Univ. of North Carolina

Project/Proposal Start and End Date: 7/1/2018-6/30/2022

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY) Person Months (##.##)

1. 2018-2019 1.56

2. 2019-2020 1.8

3. 2020-2021 0.0

4. 2021-2022 0.0

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

Title: A Parent-Focused Approach

Major Goals: The major goals of this project are to conduct a randomized controlled trial comparing a web-based, multimedia, intervention that motivates and teaches parents how to communicate effectively with their sons about HIV-related topics and an active control condition

comprised of a documentary for parents who have a lesbian, gay, or bisexual child.

Status of Support: Active

Project Number: R01MH129169

Name of PD/PI: Huebner

Source of Support: NIH/NIAID

Primary Place of Performance: George Washington University
Project/Proposal Start and End Date: 9/1/2021-8/31/2026
Total Award Amount (including Indirect Costs): (Utah subaward only)
Person Months (Calendar/Academic/Summer) per budget period.
1. 2021-2022 1.2
2. 2022-2023 1.2
3. 2023-2024 1.2
4. 2024-2025 1.8
5. 2025-2026 1.8

Title: Repetitive Ritual Behaviors

Major Goals: The major goal of this project is to develop and test a smart ring to detect repetitive handwashing in individuals with obsessive compulsive disorder.

Status of Support: Pending

Project Number: Pending

Name of PD/PI: Asnaani

Source of Support: NIH/NIMH*Primary Place of Performance: University of Utah

Project/Proposal Start and End Date: 2/1/2022-1/31/2024

Total Award Amount (including Indirect Costs): (Utah subaward only)

Person Months (Calendar/Academic/Summer) per budget period.

1. 2022-2023 0.6
2. 2023-2024 1.2

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