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TITLE: Brief Cognitive Behavioral Therapy (BCBT) Replication Trial

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CONTRACTING ORGANIZATION: The 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 credentialling 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 thosewho 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 amongmilitary 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
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 9/30/203.
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 experienced multiple obstacles to resuming enrollment during the past year including the resignation of research therapists, inability to recruit replacement therapists, and suspension of our project coordinator's medical record access. In light of these challenges, we met with the scientific officer and decided to end enrollment at Camp Lejeune, open new recruitment sites at The Ohio State University and Medical University of South Carolina, and broaden the inclusion criteria from active duty Marines only to all military personnel and veterans. These changes were approved by the contracting officer and put into place in December 2022. We also received a one-year no-cost extension.

We have received IRB approval from the OSU and MUSC IRBs and OHRO approval to begin enrollment at both sites. We have made adjustments to our databases and procedures accordingly and initiated staff training in June 2023. We anticipate resuming enrollment at both sites in the first quarter of the no-cost extension year. Follow-up assessments continue for the participants enrolled to date at Camp Lejeune. We submitted the continuing review report to the NMCP IRB in June 2023 to continue these follow-up assessments and are awaiting final approval.

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 will resume and follow-up assessments will continue.

4. Impact

What was the impact on the development of the principal discipline(s) of theproject?

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 the past year, our study therapist unexpectedly resigned the week that enrollment was scheduled to resume. Within a few months, NMCCL suspended our project coordinator's access to medical records. Due to the challenges of recruiting qualified staff in Jacksonville, NC, who meet NMCCL credentialing requirements, we determined that continuing the study at Camp Lejeune was not feasible. At the direction of our scientific officer, we identified two alternate sites to continue the project: The Ohio State University and the Medical University of South Carolina. Both sites have existing infrastructure, staffing, and access to military personnel and veterans for recruitment purposes. We therefore requested and received approval from the contracting officer to change the study sites and the eligibility criteria to enroll all military personnel and veterans with suicidal ideation or a recent suicide attempt. We also received approval for a one-year no-cost extension. We have subsequently received regulatory approval for these changes and initiated staff training to resume enrollment during the no-cost extension year.

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 overseen the training and supervising study personnel, completed administrative tasks, and ensured continuing regulatory approval.
Funding Support:	National Institute of Mental Health, Department of Defense, The Boeing Company, Navy SEAL Foundation, USAA Foundation, American Foundation for Suicide Prevention
Name:	Brian Baucom, Ph.D.
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-0263-3763
Nearest personmonth worked:	0.6
Contribution to Project:	Dr. Baucom has assisted with administrative tasks.
Funding Support:	Department of Defense
Name:	Lauren Khazem, Ph.D.
Project Role:	Project Coordinator
Researche r Identifier (e.g. ORCID ID):	0000-0002-0787-2368
Nearest person month worked:	12
Contribution toProject:	Dr. Khazem has maintained the study database, supervised study personnel, and assisted with document preparation.
Funding Support:	American Foundation for Suicide Prevention, Department of Defense, National Institute of Mental Health
Name:	Johnnie Young
Project Role:	On-Site Project Coordinator

Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	10
Contribution toProject:	Mr. Young has assisted with maintaining regulatory approval and conducting follow-up assessments
Funding Support:	N/A
Name:	AnnaBelle Bryan, MS
Project Role:	Research Manager
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.6
Contribution toProject:	Ms. Bryan has assisted with management of study personnel and overseen purchasing of study equipment and materials
Funding Support:	N/A
Name	Justin Gibson, LCSW
Project Role	Study Clinician
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Mr. Gibson conducted assessments and administered study treatments to participants.
	Justin Baker, PhD
Project Role	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.4

Contribution to Project:	Dr. Baker supervised study personnel, coordinated with military collaborators, and assisted with document preparation
Name:	Sean Williams, LCSW
Project Role	Study Assessor
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Mr. Williams conducted follow-up assessments.

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

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

Project Title: Web-based provider training for Brief Cognitive Behavior Therapy (BCBT) for suicide prevention
Time Commitment: 5% Role: Co-I
Supporting Agency: DOD
Performance Period: 09/01/2023-08/31/2027
Level of Funding:
Project Goals: Specific Aim 1 - Develop a web-based training program for improved dissemination of BCBT x Specific Aim 2 - Assess practitioner reaction/satisfaction and learning/knowledge gain. x Specific Aim 3 - Compare reaction/satisfaction, learning, and subsequent behavior of providers who complete BCBTweb to a control group of providers who attend a live workshop (in-person or virtual) using the same training materials.
Overlap: None

Project Title: Piloting a brief cognitive-behavioral therapy (BCBT) group intervention for suicidal behavior among active duty military personnel
Time Commitment: 1% Role: Co-I
Supporting Agency: DOD
Performance Period: 08/01/2022 – 09/30/2023
Level of Funding:
Project Goals: (1) to demonstrate that group BCBT is not inferior to dialectical behavior therapy (DBT) group skills training, an established group-based treatment with reputable efficacy for preventing suicidal behavior, and (2) to explore three possible mechanisms of therapeutic change: coping self-efficacy beliefs, behavioral inhibition, and emotion regulation.
Overlap: None

During the current reporting period, Dr. Baker began receiving active other support for the

following projects:

Project Title: Web-based provider training for Brief Cognitive Behavior Therapy (BCBT) for suicide prevention
Time Commitment: 20% Role: PI
Supporting Agency: DOD
Performance Period: 09/01/2023-08/31/2027
Level of Funding:
Project Goals: Specific Aim 1 - Develop a web-based training program for improved dissemination of BCBT x Specific Aim 2 - Assess practitioner reaction/satisfaction and learning/knowledge gain. x Specific Aim 3 - Compare reaction/satisfaction, learning, and subsequent behavior of providers who complete BCBTweb to a control group of providers who attend a live workshop (in-person or virtual) using the same training materials.
Overlap: None

Project Title: Piloting a brief cognitive-behavioral therapy (BCBT) group intervention for suicidal behavior among active duty military personnel
Time Commitment: 20% Role: PI
Supporting Agency: DOD
Performance Period: 08/01/2022 – 09/30/2023
Level of Funding:
Project Goals: (1) to demonstrate that group BCBT is not inferior to dialectical behavior therapy (DBT) group skills training, an established group-based treatment with reputable efficacy for preventing suicidal behavior, and (2) to explore three possible mechanisms of therapeutic change: coping self-efficacy beliefs, behavioral inhibition, and emotion regulation.
Overlap: None

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

Title: Couples Healthy Aging, Rhythms and Sleep (CHARMS)
Time Commitment: 5%; Co-I
Supporting Agency: NIH
Performance Period: 12/01/2022 – 11/31/2026
Level of Funding:
Major Goals: The goal of this R01 is to test associations between sleep, biosocial rhythms, and cognitive functioning in older adults who are showing early signs of cognitive decline.

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

Title: Analgesic and Opioid Sparing Brain Mechanisms of Mindfulness-Oriented Recovery Enhancement for Chronic Low Back Pain
Time Commitment: 15%; PI
Supporting Agency: NCCIH
Performance Period: 09/2022 – 05/2027
Level of Funding:
Major Goals: The major goal of this proposed R01 is to identify neural mechanisms supporting the reduction of chronic low back pain (cLBP) by Mindfulness-Oriented Recovery Enhancement (MORE) and the neural mechanisms supporting MORE's opioid sparing effects.

Title: Motivational Interviewing and Mindfulness-Oriented Recovery Enhancement for Tobacco Dependence and Other Drug use in Methadone Treatment
Time Commitment: 9.4%; Co-PI
Supporting Agency: NCCIH
Performance Period: 9/30/2022 to 9/29/2025
Level of Funding:
Major Goals: The major goal of this proposal is to conduct a Hybrid Type 2 implementation- effectiveness study of mindfulness-oriented recovery enhancement and motivational interviewing as an adjunct to methadone treatment for tobacco and other drug use.

Title: Implementation and Effectiveness of Mindfulness Oriented Recovery Enhancement as an Adjunct to Methadone Treatment for Opioid Use Disorder
Time Commitment: 9.4%; Co-PI
Supporting Agency: NIDA
Performance Period: 9/2022 to 7/2027
Level of Funding:
Major Goals: The major goal of this proposal is to conduct a Hybrid Type 2 implementation- effectiveness study of MORE as an adjunct to methadone treatment for opioid use disorder.

Title: Physical Therapy Integrated with Mindfulness for Patients with Chronic Musculoskeletal Pain and Long-Term Opioid Treatment
Time Commitment: 7.5%; Co-I
Supporting Agency: NCCIH
Performance Period: 12/2022 – 11/2025
Level of Funding:
Major Goals: The major goals of this project are to evaluate the feasibility conducting a cluster randomized clinical trial to evaluate the integration of mindfulness principles with evidence- based physical therapy in patients with chronic musculoskeletal pain and long-term opioid treatment.

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