

AWARD NUMBER: W81XWH-18-2-0022

TITLE: Brief Cognitive Behavioral Therapy (BCBT) Replication Trial

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

CONTRACTING ORGANIZATION: The Ohio State University

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TYPE OF REPORT: Annual

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

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# REPORT DOCUMENTATION PAGE

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|   |                    |                     |                                 |                                   |   |   |
|---|--------------------|---------------------|---------------------------------|-----------------------------------|---|---|
| <b>1. REPORT DATE</b><br>July 2020  |                    |                     | <b>2. REPORT TYPE</b><br>Annual |                                   | <b>3. DATES COVERED</b><br>07/01/2019 -06/30/2020 |   |
| <b>4. TITLE AND SUBTITLE</b><br>Brief Cognitive Behavioral Therapy (BCBT) Replication Trial   |                    |                     |                                 |                                   | <b>5a. CONTRACT NUMBER</b>                        |   |
|   |                    |                     |                                 |                                   | <b>5b. GRANT NUMBER</b><br>W81XWH-18-2-0022       |   |
|   |                    |                     |                                 |                                   | <b>5c. PROGRAM ELEMENT NUMBER</b>                 |   |
| <b>6. AUTHOR(S)</b><br>Craig J. Bryan Psy.D., ABPP<br>Lauren R. Khazem, Ph.D.<br><br>E-Mail: lauren.khazem@osumc.edu; craig.bryan@osumc.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><br><br>The Ohio State University<br>Wexner Medical Center<br>410 W 10th Ave, Columbus, OH<br>43210  |                    |                     |                                 |                                   | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>   |   |
| <b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b><br><br>U.S. Army Medical Research and Development Command<br>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><br><br>Approved for Public Release; Distribution Unlimited   |                    |                     |                                 |                                   |   |   |
| <b>13. SUPPLEMENTARY NOTES</b>  |                    |                     |                                 |                                   |   |   |
| <b>14. ABSTRACT</b><br>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. Ten Marines have been enrolled in the protocol. All study activities are currently halted due to implementing COVID-19 precautions. Recruitment and enrollment are anticipated to start again in August 2020. |                    |                     |                                 |                                   |   |   |
| <b>15. SUBJECT TERMS</b><br>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> | <b>18. NUMBER OF PAGES</b>                        | <b>19a. NAME OF RESPONSIBLE PERSONNEL</b> |
| <b>a. REPORT</b>  | <b>b. ABSTRACT</b> | <b>c. THIS PAGE</b> | USAMRMC                         |                                   |   |   |
| Unclassified  | Unclassified       | Unclassified        | Unclassified                    | 9                                 | <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:

#### o 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). 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). 5% 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). 1% complete, expected completion by 9/30/2023.
12. Complete data analyses (Target: 6/30/2023). 0% complete, expected completion by 6/30/2021.

#### o What was accomplished under these goals?

The objectives for this year were to complete initial training of all study personnel begin recruitment and enrollment of participants into the protocol and begin follow-up assessments for participants who have completed treatment. All study personnel completed initial training on 8/23/2019. Enrollment in the study began on 1/22/2020, and follow-up assessments began on 4/22/2020.

Effective July 15, 2020, the project PI (Bryan) changed institutions from the University of Utah to the Ohio State University. Dr. Bryan will remain the overall PI for the project after the change in institutions. The budget and statement of work were updated to reflect this change and has been approved by the sponsor. The University of Utah and The Ohio State University are currently in the process of enacting the changes approved by the sponsor. This change will not slow or interfere with the project timeline.

- **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.

## 1. 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

## 2. 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**  
On 3/25/2020, the Study PI received notification from Naval Medical Center Camp Lejeune that all on-site study activities must be halted due to COVID-19 precautions. All on site study activities, including recruitment and enrollment, are currently halted and are anticipated to recommence in August 2020.
- **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

## 3. 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

#### 4. 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, 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, 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 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:           | 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   |

**o 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:

|                            |                     |               |
|----------------------------|---------------------|---------------|
| R01AT010627-01 (Goldstein) | 8/15/2019-6/30/2024 | 0.51 calendar |
| NIH-NCCIH                  | \$457,004           |               |

Neuroimaging response inhibition and salience attribution changes during mindfulness-based treatment of human heroin addiction

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

|                       |                    |              |
|-----------------------|--------------------|--------------|
| R01 MH119084 (Butner) | 9/1/2019-8/31/2023 | 1.2 calendar |
| NIH (prime sponsor)   | \$1,134,679        |              |

Predicting binge and purge episodes from passive and active Apple Watch data using a dynamical systems approach

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

**5. Special Reporting Requirements**

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

**6. 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: The Ohio State University

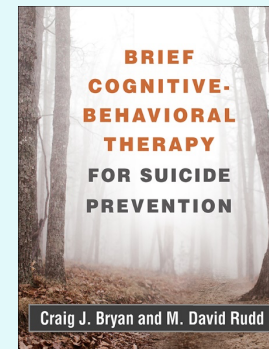
Award Amount: \$4,854,657.00

## 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:** Follow-up assessments have begun for Marines enrolled in the study before suspension of in-person study activities.

## 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

- In person study activities were suspended on 3/25/2020 due to COVID-19 and remain suspended until August 2020.

## Budget Expenditure to Date

Projected Expenditure: \$1,941,863

Actual Expenditure: \$1,165,296

Updated: 7/30/2020