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TITLE: Piloting a Brief Cognitive Behavioral Therapy (BCBT) Group Intervention for Suicidal Behavior Among Active-Duty Military Personnel

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CONTRACTING ORGANIZATION: University of North Carolina at Charlotte, Charlotte, NC

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Approved for public release; distribution unlimited.

13. SUPPLEMENTARY NOTES
None

14. ABSTRACT

In this clinical trial we test a new therapeutic intervention for suicidal behavior among active duty service members: Group Brief Cognitive-Behavioral Therapy (G-BCBT). Adapted from a best practice individual therapy format of BCBT, G-BCBT comprises 12 90-minute sessions. Following an individualized crisis response plan, service members partake in weekly group therapy sessions to build coping skills in three areas: (1) emotion regulation, (2) cognitive flexibility, and (3) relapse prevention. The underlying framework showing how these areas reduce suicidal behavior is called the suicidal mode. In this clinical trial we examine the influence of three pre-existing characteristics as they may influence G-BCBT effectiveness: (1) coping self-efficacy, (2) behavioral inhibition, and (3) emotion regulation skills. Importantly, the current project phase was devoted completely to setting-up logistics for the clinical trial; no patients have been enrolled nor any data analyses conducted yet.

15. SUBJECT TERMS
Suicide, military, coping skills, emotion regulation, group therapy, crisis response plan

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TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

In this clinical trial we test a new therapeutic intervention for suicidal behavior among active duty service members: Group Brief Cognitive-Behavioral Therapy (G-BCBT). Adapted from a best practice individual therapy format of BCBT, G-BCBT comprises 12 90-minute sessions. Following an individualized crisis response plan, service members partake in weekly group therapy sessions to build coping skills in three areas: (1) emotion regulation, (2) cognitive flexibility, and (3) relapse prevention. The underlying framework showing how these areas reduce suicidal behavior is called the suicidal mode. In this clinical trial we examine the influence of three pre-existing characteristics as they may influence G-BCBT effectiveness: (1) coping self-efficacy, (2) behavioral inhibition, and (3) emotion regulation skills. Importantly, the current project phase was devoted completely to setting-up logistics for the clinical trial; no patients have been enrolled nor any data analyses conducted yet.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Suicide, military, coping skills, emotion regulation, group therapy, crisis response plan

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Goals:

1. To pilot a group format of BCBT (G-BCBT) for its impact on suicidal behavior among active duty military service members.

2. To assess the relationship between G-BCBT and self-regulatory factors (i.e., coping self-efficacy, behavioral inhibition, and emotion regulation skills).

Planning Phase Project Milestones (1 Aug 2022 to 31 Jan 2023):

1.1. Obtain human subjects regulatory approvals

- Refine inclusion/exclusion criteria and recruitment procedures (if necessary) (Target date: 9/1/2022; 100% complete).
- Submit and revise Naval Medical Center Portsmouth (NMCP) single IRB (sIRB) application for approval (Target date: 11/01/2022; 100% complete).
- Submit University of North Carolina at Charlotte (UNCC) and Ohio State University (OSU) secondary IRB reliance agreement acknowledgments (Target date: 12/01/2022; 100% complete).
- Submit and revise Office of Human Research Oversight master submission (Target date: 01/31/2023; 100% complete); OHRO approval received 12/06/2022.

1.2. Hire NMCP stationed study coordinator (SC) and clinicians (CL), UNCC post-doctoral associate, and OSU post-doctoral associate (PD)

- Coordinate hiring process with UNCC Human Resources and NMCP (Target date: 09/01/2022; 100% complete).
- Draft position announcements for SC, CLs, and PDs (Target date: 09/01/2022; 100% complete).
- Advertise and interview candidates (Target date: 12/01/2022; 100% complete).

- Complete UNCC hiring paperwork (Target date: 01/01/2023; 100% complete).
- Complete internal Ohio State University hiring paperwork for post-doc hire (target date: 01/01/2023; 100% complete)

1.3. Orient and train all study staff
- Draft standard operating procedures (SOP) manual (Target date: 01/31/2023; 100% complete).
- Complete required CITI training and add new staff to IRBs (Target date: 1/01/2023; 100% complete).
- Complete data collection staff crisis response planning (CRP) training (Target date: 1/01/2023; 100% complete).
- Compose G-BCBT and DBT fidelity materials (Target date: 01/31/2023; 100% complete).
- Set G-BCBT and DBT training schedules for beginning of clinical trial phase (Target date: 01/31/2023; 100% complete).
- Orient new hires to facility-specific policies and procedures (Target date: 01/31/2023; 100% complete).
- Train SC and CLs in recruitment and screening procedures (Target date: 01/31/2023; 100% complete).
- Train SC and UNCC PD in data security procedures (Target date: 01/31/2023; 100% complete).

1.4. Prepare data collection, storage and access infrastructure
- Create and validate databases and survey links (Target date: 01/31/2023; 100% complete).
- Work with UNCC OneIT to obtain sponsored UNCC accounts (Target date: 01/31/2023; 100% complete).

1.5. Reporting
- Submit quarterly and final reports to CDMRP (Target date: 01/31/2023; 100% complete).

Clinical Trial Phase Project Milestones (1 Feb 2023 to 31 July, 2026):

Major Task 1: Fidelity Assessment Preparation and Training
1.1. Train clinicians in G-BCBT and DBT
-Conduct G-BCBT educational and interactive training (target date: 04/30/2023; 100% complete)
-Conduct DBT educational and interactive training (target date: 04/30/2023; 100% complete)

Major Task 2: Reporting
2.1. Submit all required reports
-Submit quarterly reports to CDMRP (target date: quarterly; 8% complete)
-Submit annual reports to the IRBs & obtain renewal (target date: annually; 0% complete)
-Submit annual reports to the CDMRP (target date: annually; 33% complete)
-Submit annual reports to OHRO (target date: no longer required; 100% complete)
-Submit final report to IRBs (target date: 07/31/2026; 0% complete)
-Submit final report to CDMRP (target date: 07/31/2026; 0% complete)
-Submit final report to OHRO (target date: 07/31/2026; 0% complete)

Major Task 3: Clinical Trial Implementation
Subtask 3.1: Data recruitment and collection
-Hold weekly team meetings (target date: 07/31/2026; 12% complete)
-Hold bi-weekly leadership team meetings (target date: 07/31/2026; 12% complete)
-Conduct NMCP site visits (target date: Semi-annually; 12% complete)
-Implement subject recruitment and randomization procedures for G-BCBT and DBT groups (target date: 07/31/2025; 3% complete)
-Complete informed consent and baseline data collection (target date: 12/31/2025; 2% complete)
-Complete G-BCBT and DBT interventions (target date: 12/31/2025; 0% complete)
-Complete G-BCBT and DBT session-by-session and post-treatment data collection (target date: 12/31/2025; 0% complete)

-Complete G-BCBT and DBT 3-month follow-up data collection (target date: 07/31/2026; 0% complete)
-Complete G-BCBT and DBT 6-month follow-up data collection (target date: 07/31/2026; 0% complete)
-Conduct monthly data quality checks (target date: 07/31/2026; 0% complete)

Subtask 3.2: Fidelity monitoring
-Hold weekly on-site NMCP clinical supervision & consultation (target date: 12/31/2025; 12% complete)
-Conduct weekly G-BCBT fidelity checks (target date: 12/31/2025; 0% complete)
-Conduct weekly DBT fidelity checks (target date: 12/31/2025; 0% complete)

Subtask 3.3: Data processing, analysis, and dissemination
-Conduct data cleaning (target date: 07/31/2026; 0% complete)
-Conduct data analyses (target date: 07/31/2026; 0% complete)
-Complete year 1 dissemination: GBCBT protocol (target date: 02/28/2023; 100% complete)
-Complete year 1 dissemination: study protocol journal article (target date: 03/31/2023; 80% complete)
-Complete year 1 dissemination: professional conference abstract (target date: 07/31/2023; 100% complete)
-Complete year 2 dissemination: professional conference abstract (target date: 07/31/2024; 0% complete)
-Complete year 3 dissemination: train-the-trainer materials (target date: 07/31/2025; 0% complete)
-Complete year 3 dissemination: professional conference abstract (target date: 07/31/2025; 0% complete)
-Complete year 4 dissemination: technical report (target date: 07/31/2026; 0% complete)
-Complete year 4 dissemination: professional conference abstract (target date: 07/31/2026; 0% complete)
-Complete year 4 dissemination: journal article (target date: 07/31/2026; 0% complete)
-Complete year 4 dissemination: infographic abstract (target date: 07/31/2026; 0% complete)
-Complete year 4 dissemination: military suicide prevention white paper (target date: 07/31/2026; 0% complete)
-Complete year 4 dissemination: op-ed (target date: 07/31/2026; 0% complete)
-Complete year 4 dissemination: revised fidelity assessment protocol (target date: 07/31/2026; 0% complete)
-Compete year 4 dissemination: NMCP grand rounds (target date: 07/31/2026; 0% complete)

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Planning phase: The first 6 project months consisted of a planning phase with the overall goal of setting up clinical trial logistics, including obtaining human subjects regulatory approvals, hiring new staff, orienting and training new staff, and preparing data collection, storage and access infrastructure. We met all milestones within the 6-month time frame. Importantly, the planning phase was devoted completely to setting-up logistics for the clinical trial; as such, no patients were enrolled nor any data analyses conducted yet. Specific work in each milestone category was conducted as follows.

1.1. Obtain human subjects regulatory approvals.

We finalized project inclusion/exclusion criteria and recruitment procedures. Inclusion/exclusion criteria did not change from those proposed in the grant proposal. University and NMCP team members worked together to refine referral streams and initial contact procedures. This content is now part of the Standardized Operations Procedures (SOP) manual.

NCMP and university team members drafted and submitted the initial sIRB application on 06/02/2022. We received initial sIRB stipulations on 07/18/2022, and we responded to these on

08/31/2022. We received another round of sIRB stipulations on 09/22/2022, and we responded to these on 10/14/2022. We received sIRB approval on 10/31/2022. NMCP and UNCC affirmed an IRB reliance agreement. The UNCC and OSU teams submitted the sIRB application and approval for secondary acknowledgments with their respective IRBs. University and NMCP team members composed and submitted the OHRO application on 11/05/2022; OHRO approved the application on 12/06/2022. Although not a specifically stated objective, UNCC, OSU, and NMCP also completed a Cooperative Research and Development Agreement (CRADA), which was signed on 10/13/2022.

1.2. Hire NMCP stationed study coordinator (SC) and clinicians (CL), UNCC post-doctoral associate, and OSU post-doctoral associate (PD).

PI Cramer worked with UNCC human resources to identify hiring processes, draft, and advertise the positions. Members from UNCC, OSU, and NMCP took part in two rounds of hiring interviews for each position (UNCC PD, and NMCP SC and CLs). We successfully hired the UNCC PD, SC, and CLs. Hiring paperwork was completed for all new employees by 10/31/2022. OSU hired their PD from an internal hire by 8/31/2022.

1.3. Orient and train all study staff.

UNCC and OSU staff composed a full SOP. The SOP included sections on inclusion/exclusion criteria, recruitment procedures, initial contact guidelines, informed consent procedure and script, baseline assessment, randomization procedures, survey measures, Qualtrics survey administration, storage of session transcripts, electronic health record documentation, interventions (DBT and G-BCBT subsections), follow-up evaluation survey procedures, and a G-BCBT eligibility checklist. SOP details are designed to ensure the study protocol as outlined in the sIRB is adhered to by all research staff. The SOP was used in training all new study personnel. New PD, CL, and SC personnel completed CITI training required to participate in NMCP research. Other team members already completed CITI training.

The UNCC PD and SC underwent UNCC-related onboarding and training for institutional policies and procedures, such as accessing secure files, data security and institutional review board materials. The training schedule for clinical/data collection staff occurred as follows. Training in the delivery of DBT for both CLs was completed from 12/13/2022 to 12/16/2022. Training in the delivery of G-BCBT for both CLs was completed from 01/26/2023 to 01/27/2023. Training in evidence-based crisis response planning (CRP) for all clinical/data collection staff occurred 01/18/2023. OSU team members drafted the G-BCBT and DBT fidelity materials by 01/01/2023. The updated G-BCBT manual was prepared by OSU staff by 01/01/2023. The DBT manuals and handouts have been purchased for CLs and transported on site to NMCP by PI Cramer (delivered 12/06/2022).

Staff training and orientation was advanced in part through a site visit which took place between 12/08/2022 to 12/09/2022. PI Cramer and co-PI Baker visited NMCP with the following main accomplishments: (1) orienting new staff to NMCP location, policies and procedures; (2) briefing NMCP hospital leadership and referral clinics on the study logistics, timeline and referral procedures; (3) reviewing regulatory, SOP and other documents with the full NMCP study team; and (4) engaging with other NMCP stakeholders (e.g., credentialing office staff; IRB staff) to facilitate enhanced inter-organizational collaborative relationships.

1.4. Prepare data collection, storage and access infrastructure.

UNCC Information Technology (IT; “OneIT”) provided UNCC and OSU team members with REDCap access. REDCap training was provided on 10/10/2022 for the study PI (Cramer), co-PI (Baker), UNCC PD, statistician (Dr. Gunn), SC, and OSU support staff. UNCC PD and OSU staff met and built survey databases in REDCap. For reasons summarized in the section 5 regarding problems and solutions below, we needed to shift to Qualtrics. UNCC OneIT staff provided UNCC and OSU team members a training on multi time-point data collection in Qualtrics on 12/2/2022. The UNCC PD and OSU staff built Qualtrics surveys and provided pilot links to PI Cramer and Dr. Gunn on 12/13/2022. Feedback was provided by Drs. Cramer and Gunn to the UNCC PD and OSU on 12/18/2022. Revised survey links were completed by the UNCC PD and OSU staff on 01/03/2023. Final review and validation of survey links and

databases were approved on 01/09/2023.

All NMCP, OSU and UNCC team members provided required information to receive secure sponsored accounts through UNCC IT. UNCC IT created a secure project folder managed by PI Cramer and the UNCC PD. All project team member confirmed secure access to the project folder. This set of tasks was completed by 09/30/2022.

1.5. Reporting.

Submission of the required planning phase quarterly report occurred 11/05/2022, and the required planning phase close out report on 01/10/2023.

Clinical trial phase: We held the following weekly meetings: (1) full team, (2) UNCC evaluation team, (3) clinical team meetings. We held the following bi-weekly meetings: (1) leadership team, (2) NMCP site team. PI Cramer also conducted a site visit at NMCP 26-27 June, 2023. We conducted the following activities under each major project milestone during the first six months of the clinical trial phase.

Major Task 1: Fidelity Assessment Preparation and Training

1.1. Train clinicians in G-BCBT and DBT

We completed the credentialing process for both study clinicians (Charles and Rikli), as well as military background check approvals for both clinicians and the new clinical research coordinator (Washington). Under supervision of NMCP AI Grover, both clinicians and the coordinator further received their CACs, and completed required Naval Medical Center Portsmouth (NMCP) onsite training (e.g., electronic health record documentation). These steps were necessary prior to training clinicians. Onsite trainings for clinicians included, but were not limited to, interview training for research, Genesis Electronic Health Record (EHR) system trainings (two), and study specific protocol training (including informed consent process). Both clinicians completed a two-day BCBT training and two-day DBT training. They further received and reviewed the BCBT and DBT manuals. Both clinicians and the study coordinator completed a full day training in crisis response planning (CRP). Clinicians attend weekly clinical consultation and supervision meetings with OSU team leads (Baker, Khazem) in preparation for clinical trial implementation. Consultation meetings will primarily be used for recruitment updates, participant tracking, and fidelity monitoring. Currently, the time is being used to review mock sessions as described below in Subtask 3.2.

Major Task 2: Reporting

2.1. Submit all required reports

Led by staff from all sites (Grover, Cramer, Schnecke, Baker), we submitted an sIRB application amendment on 04/21/2023, and was approved 05/16/2023. The amendment added approved study personnel now onsite at NMCP (clinicians) and team members completing required trainings since the planning phase (e.g., OSU staff). The amendment also contained minor study updates, such as an updated informed consent form (per new Defense Health Agency format), transition from REDCap to Qualtrics for data collection, and details of the stepwise subject randomization process. Led by staff at NMCP and UNCC (Washington, Bennette, Cramer, Grover), we submitted another sIRB amendment on 07/07/2023, which was approved on 07/20/2023. The amendment added new approved UNCC study personnel (Washington, Cain), and removed personnel who departed the project (Le). Other minor content updates included editing suicide-related evaluation measures for updated de-stigmatizing phrasing, dropping primary care clinics from recruitment (to maintain focus on just mental health related referral sources), clarifying wording regarding consenting and crisis management protocols, and revised initial contact phone scripts to increase participant confidentiality when leaving a voicemail message. Regarding reports, we submitted required CDMRP quarterly and annual reports (including this one).

Major Task 3: Clinical Trial Implementation

Subtask 3.1: Data recruitment and collection

We held weekly full team (i.e., NMCP, UNC Charlotte, and OSU), UNCC team (Cramer,

Washington, Rikli, Charles, Cain, Gunn), and bi-weekly leadership team (i.e., Cramer, Baker, Grover). Across meetings and site visits, we devoted considerable effort to (a) ensuring all study staff have mastered respective roles and responsibilities, and (b) educating NMCP leadership, clinics, and providers about the clinical trial.

We conducted the following additional activities supporting data recruitment and collection. First, the statistician (Gunn) designed and provided a training in the stepwise subject randomization procedure. Trainees included the study PI (Cramer), coordinator (Washington), clinicians (Charles, Rikli), and NMCP support staff (Bennette). Second, the study coordinator and post-doc designed comprehensive (i.e., from initial contact to 6-month survey follow-up) internal participant tracking systems. Third, the study coordinator and clinicians were also trained in data collection administration processes. Administrative processes were followed by the coordinator further practicing survey administration to collect and audit mock data with the statistician and PI. The SOP was updated to reflect finalized procedures. Fourth, we onboarded the new project PD, Dr. Shannon Cain, who will support data collection and other activities. Dr. Cain completed her complete onboarding requirements, such as necessary NMCP training (e.g., CITI training) and UNCC hiring procedures (e.g., data security awareness training). Fifth, NMCP and UNCC study staff (Grover, Washington, Bennette, Charles, Rikli, Cramer) held collaborative remote sessions to practice the recruitment and data collection procedures. Under the supervision of CDR Grover, the coordinator (Washington), support staff (Bennette), and clinicians (Rikli, Charles) all practiced the following steps from beginning to end: informed consent, eligibility screening, baseline data collection, and participant tracking. Finally, clinicians prepared a project referral summary for NMCP referring clinics.

Several site visits occurred during this time period as well. First, the study clinicians and coordinator completed a two-day site visit to UNC Charlotte. The purposes of this site visit were to enhance team cohesion for remote UNC Charlotte employees, and to complete many project related tasks summarized in this report (e.g., participant randomization training). Second, PI Cramer conducted a site visit at NMCP from 26-27 June. Much of the effort of this site visit focused on data recruitment and collection. For instance, PI Cramer gave two briefings to NMCP/Division leadership (e.g., Commanding Officer) reviewing the study and clinical services. PI Cramer and UNCC onsite research study staff (Washington, Charles, Rikli) held educational drop-in sessions for referring clinicians. Supported by clinician (Rikli, Charles) creation of a clinical service study summary document, PI Cramer and study team leadership (e.g., CAPT Franks, CDR Grover) met with clinic leaders (e.g., attending physician of inpatient unit) to review the study clinical services and referral procedure. This site visit also included review and updating of administrative and sIRB details summarized elsewhere.

Collectively, preparatory tasks and site visits set us up for successful project launch. Consistent with our approved Scope of Work, we began accepting referrals for clinical trial enrollment on 07/20/2023. As of the end of this reporting period have screened 9 total referrals. Three patients have been enrolled, with numerous prospective participants from inpatient and outpatient referrals streams being scheduled. We will soon add the third referral stream, the NMCP Substance Abuse Rehabilitation Program.

<u>Subtask 3.2: Fidelity monitoring</u>

The OSU clinical team (Baker, Khazem, Williams, Ammendola) held weekly clinical team meetings with clinicians (Charles, Rikli). These meetings entail training clinicians in session recording, storage, and fidelity check procedures. OSU clinical team members (Khazem and Ammendola) completed advanced training in standardized DBT fidelity review. Fidelity ratings for GBCBT were adapted for this study from existing individual BCBT fidelity rating forms and tailored for the group delivery format. They also completed advanced review of session-by-session G-BCBT and DBT protocols in the context of fidelity check procedures. Clinicians organized and conducted 4 mock sessions (2 G-BCBT and 2 DBT) with volunteers to begin mastery in delivering both clinical protocols. Taped sessions were reviewed and assessed through fidelity ratings to support Charles and Rikli in incorporating new skills in future sessions by the OSU clinical team. The focus of the mock sessions was to allow the clinicians to hone their delivery of the two modalities, manage patient responses, and to strengthen their therapeutic alliance as a group therapy team. The clinical consultation team (Baker, Khazem, Ammendola, Williams) then completed

fidelity assessment review and provided feedback on mock sessions to clinicians.

Subtask 3.3: Data processing, analysis, and dissemination

The UNC Charlotte team (Washington, Cramer, Gunn, Charles, Rikli) conducted two rounds of mock data collection and auditing. Final Qualtrics surveys were prepared for eligibility, baseline, session-specific, 3- and 6-month follow-up. This includes recent updates to suicide-related questions to foster de-stigmatizing language. The OSU team (Baker, Bryan, Khazem, Williams, and Ammendola) finalized the G-BCBT protocol in preparation for training clinicians and implementing the clinical trial. We drafted the study protocol journal article which is currently in final review followed by routing for approval with NMCP public affairs. Finally, we submitted a protocol paper conference abstract to the 2023 Military Health System Research Symposium (MHSRS). The abstract was accepted.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

The following training activities occurred:

1. All OSU and UNCC team members received training in the use of Qualtrics software for multi time-point data collection.
2. Study CLs underwent a four-day training in Dialectical Behavior Therapy (DBT) clinical skills.
3. Study CLs and UNCC post-doc underwent a two-day training in Brief Cognitive-Behavioral Therapy (BCBT) for suicide.
4. Study CLs and data collection staff received a one-day training in crisis response planning.
5. Study CLs completed virtual training "Military Cultural Competence: Providing Effective Assessment and Treatment" provided by the American Insurance Trust
6. Study CLs completed virtual training "Military Culture: Enhancing Clinical Competence" provided by the Center for Deployment Psychology
7. Study CLs and coordinator underwent Informed Consent training provided by senior NMCP staff.
8. Study CLs and coordinator received two days training in Genesis, the military electronic health record system.
9. Study CLs and coordinator received half day research regulatory (e.g., Research Compliance Program) hosted by NMCP IRB staff.
10. Study CLs and coordinator underwent HIPAA and Privacy Act training provided by NMCP.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Planning phase goals are now completed.

For the clinical trial phase, as outlined in the approved SOW, in the next quarter we will:
1. Build CL skills through continued interactive DBT and G-BCBT training and fidelity monitoring.
2. Hold weekly full team, UNCC team, clinical team, and bi-weekly leadership team meetings.
3. Continue participant enrollment, consenting, eligibility, baseline data collection, and randomization procedures.
4. Conduct randomization auditing.
5. Implement initial individual sessions to determine participant fit for group therapy sessions
6. Implement initial group therapy sessions, as well as session-by-session data collection, as participant enrollment facilitates requisite participant numbers.
7. Conduct quality checks of any baseline or session data collected during this time period.
8. Conduct clinical fidelity monitoring.
9. Submit the study protocol journal article.
10. Complete new UNCC PD training (e.g., randomization checks)
11. Attend and present the protocol conference paper at MHSRS conference.
12. Submit IRB amendments and continuing review as needed.

4. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*

- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:
- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

We encountered the following problems in the first project year.
1. CDR Grover was assigned for a 3-month deployment (09/20/2022 to 12/22/2022). We agilely managed this challenge through early notification and strong team communication. CDR Grover completed several major tasks early prior to her departure. Also, CAPT Franks and supporting NMCP research staff stepped in to assume CDR Grover's project leadership tasks for the time being.
2. Staff shortages in key UNCC departments (e.g., human resources) posed challenges at times through the early project phase. We overcame this potential barrier by beginning key processes early. PI Cramer is in consistent communication with key campus leadership to ensure timely completion of project tasks. There have been no hiring or staffing delays.
3. We encountered staff turnover; specifically, Dr. Le (post-doctoral associate) moved on to a new position. Because she provided adequate notice, we temporarily reassigned her duties through June 2023 to the PI, statistician, and research coordinator. We also successfully hired and onboarded a new post-doctoral associate, Dr. Shannon Cain, started in July 2023.
4. We encountered a problem centered on functionality of UNCC's REDCap account. Because Redcap is infrequently used at the university, UNCC's REDCap cloud had limited functionality and access to supporting online resources. Also, UNCC's OneIT expertise in Redcap was limited because personnel do not need to support the software very frequently. In consultation with OneIT and Dr. Gunn, we elected to shift to Qualtrics, a platform the team has experience with and OneIT has ample capacity to support.
5. All Defense Health Agency hospitals are transitioning to MHS Genesis (electronic health record).

The MHS Genesis roll out has been slow and at times unclear at NMCP. Available trainings for clinicians and other study staff are sporadic. Because MHS Genesis is involved in recruitment/referral, clinical documentation, and other processes, the slow roll out has contributed to minor delays in launching referrals and recruitment. However, at the time of this report, all necessary study team members (clinicians, study coordinator) have received Genesis training.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Study clinicians and the study coordinator started on 12/1/2022, whereas the budget accounted for a more flexible, earlier start date. Also, we experienced two-month gap in having a UNCC postdoctoral research associate on staff. As such, salary and fringe savings occurred during the first year. We were able to flexibly use these funds to support equipment (laptops, mobile hotspots, and audio recorders), and additional training opportunities, for UNCC staff stationed at NMCP.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

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:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Baker, J.C., Franks, M.J., Grover, S., Troncoso, M., Gunn, L.H., Khazem, L.R., Rikli, H., Charles, C., Williams, S., Ammendola, E., Le, N., Bennette, M., Starkey, A., Schnecke, K., Washington, C., Bryan, C.J., & Cramer, R.J. (August, 2023). Group Brief Cognitive Behavioral Therapy for Suicidal Servicemembers: Preliminary Roll-out. Oral presentation accepted at the 2023 Military Health System Research Symposium (MHSRS) (Kissimmee, FL).

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that

makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*

Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name: Robert J. Cramer, Ph.D.
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0001-9105-5565
Nearest person month worked: 4 academic months
Contribution to Project: Dr. Cramer performed work in areas of leading weekly and other ad-hoc team meetings, facilitating CRADA completion, submitting OHRO application, supporting NMCP sIRB application composition and revision, overseeing all hiring and onboarding processes, coordinating creation of sponsored UNCC accounts, registering the clinical trial with clinicaltrials.gov, liaising with UNCC IT to establish secure folders and data security procedures, supervising staff (e.g., postdoctoral associate), composing all required reports, overseeing protocol manuscript background composition, conducting periodic site visits for NMCP, co-supervising UNC Charlotte remote team members (clinicians, coordinator), supporting data collection and auditing, co-authoring dissemination outputs (e.g., conference

abstract), and presenting and meeting with NMCP leadership and clinic staff.
Funding Support: The UNCC Belk Endowment funds some of Dr. Cramer's time for research activities.

Name: Justin C. Baker, Ph.D., ABPP
Project Role: Co-Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0001-7010-5009
Nearest person month worked: 3.6 calendar months
Contribution to Project: Dr. Baker performed work in areas of co-leading weekly and ad-hoc team meetings, supervising establishment and revision of the SOP, co-writing the NMCP IRB application, leading HRPO application composition, leading drafting intervention fidelity materials, working with clinicians on the NMCP credentialing process, supervising all OSU staff, supporting other key project tasks (e.g., hiring), leading clinical consultation team meetings, co-leading project dissemination products (e.g., MHSRS conference paper), leading protocol paper, and providing crisis response planning and BCBT training for team staff.
Funding Support: Department of Defense, USAA, Care Innovation and Community Improvement Program

Name: CDR Shawna Grover, Ph.D., ANP-BC, ANCS-BC
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.2 calendar months
Contribution to Project: CDR Grover performed work in areas of leading the NMCP IRB application, collaborating on the SOP, participating in interviews for all new project staff, co-writing the HRPO application, supervising NMCP staff, liaising with NMCP IRB, legal and other personnel (e.g., in establishing CRADA), leading IRB amendment submission, co-authoring dissemination outputs (e.g., protocol paper), and co-supervising UNC Charlotte team on site at NMCP (clinicians, coordinator).
Funding Support: NMCP is funding CDR Grover's effort for this project.

Name: CAPT Michael Franks, PsyD, MP, ABPP
Project Role: Site Principal Investigator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1 calendar month
Contribution to Project: CAPT Franks performed work in areas of participating in weekly and ad-hoc team meetings, pursuing necessary NMCP approval processes, reviewing clinician and coordinator applicant credentials, advising on NMCP clinical credentialing and IRB procedures, providing NMCP site-specific content for the SOP, and arranging project logistics (e.g., referral streams, group therapy space).
Funding Support: NMCP is funding CAPT Franks' effort for this project.

Name: Anh Thu "Nancy" Le, Ph.D.
Project Role: Former UNCC Post-Doctoral Research Associate
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 7 calendar months
Contribution to Project: Dr. Le performed work in areas of attending weekly and ad-hoc team meetings, co-writing the SOP, completing CITI and other training, reviewing grant application and procedures materials, creating electronic data collection surveys, editing and validating survey links, and supporting other project tasks.

Name: Cherita Washington, BA

Project Role: UNCC Clinical Research Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 12 calendar months
Contribution to Project: Ms. Washington performed work in areas of coordinating weekly and ad-hoc team meetings, co-designing participant tracking systems, completing required onboarding (e.g., NMCP background check) and training (e.g., crisis response planning), co-authoring dissemination activity (e.g., conference abstract, protocol manuscript), practicing eligibility screening/informed consenting, coordinating site visit schedules, co-leading sIRB amendments, leading preparation of data collection and auditing, and setting-up referral procedures.

Name: Cindy Charles, MA, LMFT
Project Role: UNCC Licensed Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 12 calendar months
Contribution to Project: Ms. Charles performed work in areas of attending weekly and ad-hoc team meetings, engaging reviewing and practicing clinical protocols, completing required onboarding (e.g., NMCP credentialing) and training (e.g., clinical documentation system), co-authoring the protocol manuscript, co-authoring dissemination outputs (e.g., conference abstract, protocol paper), supporting recruitment and consenting efforts, and working with OSU team on fidelity review and clinical consultation.

Name: Heather Rikli, MSW, LCSW
Project Role: UNCC Licensed Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 12 calendar months
Contribution to Project: Ms. Rikli performed work in areas of attending weekly and ad-hoc team meetings, engaging reviewing and practicing clinical protocols, completing required onboarding (e.g., NMCP credentialing) and training (e.g., clinical documentation system), co-authoring the protocol manuscript, co-authoring dissemination outputs (e.g., conference abstract, protocol paper), supporting recruitment and consenting efforts, and working with OSU team on fidelity review and clinical consultation.

Name: Laura Gunn, PhD
Project Role: Co-Investigator & Statistician
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1 calendar month
Contribution to Project: Dr. Gunn performed work in areas of attending weekly and ad-hoc team meetings, designing and training the team in the subject randomization process, reviewing data for practice and auditing, attending Qualtrics training, supporting IRB amendment and reporting, co-supervising the UNCC coordinator and post-doctoral research associate, co-leading hiring and evaluation process for the UNCC postdocs, and co-authoring dissemination activity (e.g., conference abstract, protocol manuscript).

Name: Craig Bryan, PsyD, ABPP
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 0.12 calendar months
Contribution to Project: Dr. Bryan attended weekly clinical and full team meetings; he also assisted with development of the GBCBT therapy manual, fidelity checklists, and preparation of the protocol paper, co-authoring dissemination activity (e.g., protocol paper).

Name: Lauren Khazem, PhD
Project Role: DBT Clinical Supervisor
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.6 calendar month
Contribution to Project: Dr. Khazem attended weekly clinical and full team meetings; she also assisted with training therapists in DBT skills group, providing DBT skills group supervision for the therapists, co-authoring dissemination activity (e.g., conference abstract, protocol paper), and developing and reviewing of fidelity monitoring for the DBT skills group.

Name: Sean Williams, LCSW
Project Role: GBCBT Clinical Supervisor
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.6 calendar month
Contribution to Project: Mr. Williams attended weekly clinical and full team meetings; he also aided in the development of the treatment curriculum for adapting BCBT to a group format, assisted with training of the therapists in the BCBT model, co-authoring dissemination activity (e.g., conference abstract, protocol paper), and provided consultation of the onsite therapists.

Name: Ennio Ammendola, PhD
Project Role: DBT Clinical Supervisor
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.6 calendar month
Contribution to Project: Dr. Ammendola attended weekly clinical and full team meetings; he also assisted with training therapists in DBT skills group, providing DBT skills group supervision for the therapists, co-authoring dissemination activity (e.g., conference abstract, protocol paper), and development and review of fidelity monitoring for the DBT skills group.

Name: Austin Starkey, BS
Project Role: Former OSU Research Associate BH/1
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2 calendar months
Contribution to Project: Mr. Starkey performed work in areas of attending weekly and ad-hoc team meetings, co-writing the SOP, completing CITI and other training, reviewing grant application and procedures materials, creating electronic data collection surveys, co-designing participant tracking systems, assisting in the credentialing/onboarding process for clinicians and coordinator, and conducting test data collection and auditing.

Name: Kelly Schnecke, BA
Project Role: OSU Research Associate BH/1
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2 calendar months
Contribution to Project: Ms. Schnecke performed work in areas of attending weekly and ad-hoc team meetings, co-writing the SOP, completing CITI and other training, reviewing grant application and procedures materials, creating electronic data collection surveys, co-designing participant tracking systems, assisting in the credentialing/onboarding process for clinicians and coordinator, preparing materials for the sIRB amendments, co-authoring dissemination activity (e.g., conference abstract, protocol paper), and conducting test data collection and auditing.

Name: Marquita Bennette, BS
Project Role: NMCP Clinical Research Coordinator

Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2 calendar months
Contribution to Project: Ms. Bennette performed work in areas of attending weekly and ad-hoc team meetings, completing CITI and other training, leading on-site NMCP site visits, co-designing participant tracking systems, preparing materials for the sIRB amendment, conducting test data collection and auditing, co-authoring dissemination activity (e.g., conference abstract, protocol paper), and facilitating onboarding for UNCC team members onsite at NMCP.

Name: Shannon Cain, PhD
Project Role: Former UNCC Post-Doctoral Research Associate
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1 calendar month
Contribution to Project: Dr. Cain performed work in areas of attending weekly and ad-hoc team meetings, co-editing the SOP, completing CITI and other training, reviewing project evaluation tools and procedures, serving as second check on participant randomization, co-authoring administrative reports, co-authoring dissemination activity (e.g., conference abstract, protocol paper), and supporting other project tasks.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*

- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: Naval Medical Center Portsmouth
Location of Organization: Portsmouth, Virginia
Partner's contribution to the project: Facilities and collaboration

Organization Name: The Ohio State University Wexner Medical Center
Location of Organization: Columbus, Ohio
Partner's contribution to the project: Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: None

QUAD CHARTS: Not applicable at this time.

9. APPENDICES: None