NAVAL MEDICAL CENTER PORTSMOUTH
CONSENT TO PARTICIPATE IN RESEARCH
Research Title: Group Risk Reduction Intervention Therapy (GRRIT)
Principal Investigator: CDR Shawna G. Grover PhD, ANP-BC, ACNS-BC, AOCNS

You may have been recently contacted by our research staff and provided information about your potential involvement in this study outlined below.

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions that you have. You may also wish to talk to others (for example, your friends, family, or your personal doctor) about your potential participation in this research study. Participation is voluntary. You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study. Your decision will not affect your current or future care at Naval Medical Center Portsmouth. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

1) KEY INFORMATION:

Purpose	The purpose of the study is to compare two group therapies. We are interested in outcomes for patient mental health and suicide.
Duration	Depending on which therapy group you are assigned into, the study may last 12 weeks (3 months) or 24 weeks (6 months). Each comes with a 3-month and 6-month survey follow-ups by web-based link.
Procedures	During study visits, you will: • Read this consent document and decide if you consent to the final screening for eligibility to participate in the study. • If you are eligible, you will complete questionnaires and a short interview at the initial visit. • You will be randomly placed into one of the two treatments based on a pre-screening questionnaire. You will complete additional questionnaires after each therapy session. • At 3- and 6-month follow-up, you will complete questionnaires and interviews.

Why might you want to participate in this research (benefits)?	The direct benefit of participating in this study is the likely therapeutic benefit from two treatments that are known to improve suicide thoughts and behaviors, and related health concerns. The indirect benefit is your contribution to the development of better therapies for military service members who have similar experiences as you.
Why might you choose not to participate in this research (risk)?	You may experience short-term emotional distress, including thoughts of suicidal and/or attempts. Less than 5% of suicide attempts result in death. This risk exists regardless of your participation in the study. The procedures in this study are expected to decrease this risk. There is a small risk that your research records could be lost or otherwise compromised. To reduce this risk, all research staff members have been trained in data protection and confidentiality. Access to data will be limited to only approved members of the research team.
What are the alternatives to participating?	Choosing not to take part in this study is also an option. You will then receive standard medical treatment that may or may not include any one of the procedure(s) or treatment(s) that are part of the planned study.
What is the compensation for participating?	You will receive a $50 Amazon e-gift card for each follow-up assessment that you complete. Because there is a total of two follow-up assessments, you could potentially receive up to $100 total in Amazon e-gift cards during the course of this study. E-gift cards will only be provided to participants who complete follow-up assessment surveys.

2) WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this study is to compare how effective two different group therapies for suicidal thoughts in an active duty military community. The two group therapies are Group Brief Cognitive Behavioral Therapy (GBCBT) and Dialectical Behavioral Therapy (DBT). GBCBT (12 sessions) focuses on teaching you skills to better regulate your emotions and improve perspective taking during distressing events. DBT (24 sessions) prioritizes skills and coping strategies to help regulate your distress. Both treatments are considered effective care. We will compare their overall effectiveness.

3) WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this study because you have qualified for the study's intended participant sample, including (1) being an active duty service member; (2) being 18 years-of-age or older; (3) seeking mental health and/or substance abuse treatments; (4) having recent suicidal thoughts with intent to die and/or a suicide attempt within the past month.

4) HOW LONG IS THE RESEARCH STUDY?

This initial visit(s) will be around 1 to 2 hours total, which consist of this informed consent process, eligibility screening, and baseline questionnaires and interview if you become eligible.

If you are assigned to the group that completes Group Brief Cognitive Behavioral Therapy (GBCBT), there will be 1 individual session and 12 group sessions with a study clinician. Each session will last approximately 90 minutes. The sessions will be held over a period of about 13 weeks. You will return weekly to Naval Medical Center Portsmouth for these sessions.

If you are assigned to the group that completes Dialectical Behavioral Therapy (DBT), there will be 1 individual session and 24 group session with a study clinician. Each session will last approximately 90 minutes. These sessions will be held over a period of about 25 weeks. You will return weekly to Naval Medical Center Portsmouth for these sessions.

We will then complete follow ups at 3 months and 6 months from the end of treatment, for a total participation time of 9 months to 1 year depending which treatment you are randomized to.

There will be about 136 people taking part in the study at Naval Medical Center Portsmouth over a period of about three years.

This study is looking to evaluate the effectiveness of delivering evidence-based treatments for individuals suffering from suicidal thoughts and/or behaviors when delivered in a group format.

- DBT is a known evidence based treatment often delivered in group format for high-risk individuals.
- Individually delivered BCBT is an evidence-based treatment that is being adapted to a group format in this study assessing effective group treatments for active duty military personnel.

At the end of this study, the clinical results, including research results about you will not be shared with you.

5) WHAT IS THE SCREENING PROCESS TO BE IN THIS RESEARCH STUDY?

Before you can take part in this study, you will need to fill out surveys and provide some information so that the research team can confirm that you qualify for the study. This is called the “Screening Process”. These measures may have been done or this information may have been collected as a part of your regular medical care. If you fall into any of these categories, you will not be eligible to take part in this study:

- You have psychiatric or medical condition that affects your ability to provide informed consent or participation in outpatient treatment.
- You are retired from military service.
- You are family/beneficiaries of active duty service members.

6) WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you choose to participate, a computer code will assign you to one of the two group therapies: GBCBT or DBT.

GBCBT has two steps. Step 1 (Session 0) is a single 90-minute session focused on understanding your own suicide-related concerns and safety planning. Step 2 includes 12 additional weekly group sessions teaching you a variety of coping skills. Each session is 90 minutes.

DBT has two steps. Step 1 (Session 0) is an individual session focused on orientation to group treatment, expectations for treatment, and an opportunity for questions and answers. Step 2 includes 24 weekly group therapy sessions, including an orientation to remaining in the present moment. You will receive additional skills training such as how to regulate your emotions, manage difficult situations, and maintain healthy relationships. Each session is 90 minutes.

Individual and group sessions will be audio-recorded to ensure treatment fidelity.

Regardless of which group therapy you take part in, you will be asked to complete the same survey after each treatment session. This task is completed by clicking a web link and takes about 20 minutes per session. After you complete therapy, you will be contacted two more times via email and/or phone by research staff: three and six months after the day you complete therapy. You will be asked to individually complete a similar survey via an embedded link at these follow-up points.

Measure	Before Any Treatment	During Each Treatment Session	After All Treatment Complete	3 Months After Treatment Complete	6 Months After Treatment Complete
Surveys/Questionnaires	X	X	X	X	X

7) WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH STUDY?

The following are risks and side effects related to the treatments we are studying. These risks and side effects are part of regular medical care that exist even if you do not join the study:

Likely:

- Short-term psychological distress: Answering survey questions about difficult experiences in life and talking about these events during treatment might increase some of your short- term symptoms or emotional discomfort. This increase is usually not severe, however, and does not last long.
- Suicide attempts: Prior research has shown that suicidal ideation can be associated with making a suicide attempt. Also, having a history of a suicide attempt is associated with making another attempt. We therefore anticipate that a number of participants enrolled in this study could attempt suicide during the 6-month follow-up assessment period, although the procedures in this study are expected to decrease this risk. Monitoring of

suicide attempts will occur by tracking hospitalization records, reviewing your medical records, discussion with therapists, and survey information.

Rare

- Death: A small number (less than 5%) of suicide attempts result in death. This risk is no more than when one receives standard care. The procedures in this study are expected to decrease this risk.

The following are potential risks and side effects that you may experience while participating in the study. You should discuss them with the research staff member and your regular healthcare provider. Other treatments (e.g., individual therapy, medications, hospitalization) may be given to make the risks less serious and make you more comfortable. Although we expect these risks to decline soon after the start of treatment, in some cases these risks can last for long periods of time.

The following are risks that are part of the study that exist if you join the study:

Rare

- Breach of Confidentiality: Although efforts are made to protect your study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- Disclosure of illegal activities: Disclosure of a violation of military regulation or laws that involves risk to life or mission may need to be reported to Commanding Officers, which may affect participants' military careers.

There may also be other risks of taking part in this study that we do not yet know about.

For more information about risks and side effects, ask the investigator.

Principal Investigator: CDR Shawna Grover
Phone: 757-953-0605
Mailing Address: Naval Medical Center Portsmouth, 620 John Paul Jones Circle,
ATTN: Building 3, Nursing Research and Consultation Services/DPE. Portsmouth, VA 23708

8) ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

One possible direct benefit of participating in this study is the likely therapeutic effects from the two treatments that are known to reduce suicide thoughts and attempts. However, generally, there is no guarantee that you will benefit from being in this research.

The indirect benefit is your contribution to the development of psychological treatment for military service members who have similar experiences. Others may benefit in the future from the information learned.

9) WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH STUDY?

You may choose to not participate. You will then receive standard medical treatment that may or may not include any one of the procedure(s) or treatment(s) that are part of the planned study.

You may seek alternative treatments and/or procedures that may be available to you such as medications, psychotherapy (individual, group, marriage and family), in outpatient and inpatient settings. You should talk with your personal physicians about these options.

10) WILL YOU GET PAID FOR TAKING PART IN THIS RESEARCH STUDY?

Yes. You will receive a $50 Amazon e-gift card for each follow-up assessment that you complete. Because there is a total of two follow-up assessments, you could potentially receive up to $100 total in Amazon e-gift cards during the course of this study. E-gift cards will only be provided to participants who complete follow-up assessment surveys. DoD policy requires you to be off-duty in order to receive these incentives. Off-duty refers to days and times during which you are not scheduled for work or expected to be engaged in work or job duties. All treatments related to this study will be provided in accordance with applicable regulations.

11) ARE THERE COSTS FOR TAKING PART IN THIS RESEARCH STUDY?

No, there are no costs to you for taking part in this research study.

12) WHO IS THE STUDY SPONSOR?

The study sponsor is the organization or people who oversee the study. They may also be responsible for analyzing any research study information.

The Department of Defense, Naval Medical Center Portsmouth, University of North Carolina-Charlotte (UNCC), and The Ohio State University (OSU) are overseeing and analyzing the study.
As the sponsor of this research, the Department of Defense may also have access to your research data in accordance with DoD Instruction 3216.02.

13) IS THERE A SOURCE OF FUNDING?

This study is funded through the Department of Defense.

14) WHAT IS THE LOCATION OF THE RESEARCH STUDY?

The study is being conducted at Naval Medical Center Portsmouth (NCMP), Portsmouth, Virginia. in cooperation with the University of North Carolina at Charlotte (UNCC) and The Ohio State University (OSU).

15) ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

The research study team has no financial interests or commercial relationships related to this research study.

16) WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Your records related to this research study may only be shared in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act

Statement for the records. You can locate and read the form online (https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf), or a copy of the form can be given to you upon request.

The research team will keep your research records. These records may be looked at by staff from the NMCP Nursing Research and Adult Mental Health departments, the research team at University of North Carolina Charlotte, the research team at the Ohio State University, the Defense Health Agency, and the DoD Higher Level Review. The committee responsible for protecting research participants, called the Institutional Review Board (IRB), may also look at your records as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: All information we collect will be de-identified using a unique study ID number. Surveys will be completed by you via secure link and will not request any identifying information (e.g., name, DOB, medical record number, zip code). As such, your data will be stored separately and securely from any way of identifying you. Data are stored electronically on password-protected devices and on a secure, password-protected cloud.
Researchers will make every effort to protect your privacy and confidentiality. However, there are risks of breach of information security and information loss. The researchers agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

For participants in the G-BCBT or DBT skills group: We also ask that each of you respect the privacy of everyone participating in either group treatment and not share or repeat what is said during groups in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

If you agree to participate in this study, your interviews and therapy sessions will be audio recorded using a digital recorder. Recordings will be stored on the digital recorder and transferred electronically to a password protected computer. The recordings will be de-identified and sent to research staff at UNCC where they will be stored on secured and encrypted servers that can only be accessed by approved members of the research team so they can be reviewed by researchers on a weekly basis. These researchers will provide feedback to the interviewers and therapists to ensure they continue conducting interviews and providing treatments correctly.

After the audio recording has been transferred, the research team members will delete the audio file from their computer and the audio recorder. As mentioned above, the audio recordings will be de-identified and stored for three years after completion of the study. Files will be stored on secured and encrypted servers at UNCC.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be

personally identified when your information is shared in these ways; all information will de-identified and reported in group format.

If applicable, a description of this clinical trial will be available online at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

Complete confidentiality cannot be promised for military personnel because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

17) WHAT KIND OF SPECIMENS WILL YOU PROVIDE AND HOW WILL THEY BE USED?

No biological specimens will be used in this research study.

18) WILL YOUR INFORMATION OR SPECIMENS BE USED IN THE FUTURE?

The investigator has requested to save information collected from your participation in this research study for possible use in future research. De-identified information may be used in secondary analyses. This future research may be in the same area as the original study, or it may be for a different kind of study.

19) WHAT HAPPENS IF THE RESEARCHERS SEE AN INCIDENTAL FINDING?

This study does not involve collection of any type of data or information that may lead to an incidental finding.

20) WHAT HAPPENS IF YOU WITHDRAW FROM THIS RESEARCH?

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled. If you do not want to continue taking part in the research study, you must notify a member of the research team or to ensure an orderly termination process and return any study material issued. If you decide to no longer participate in this study, the researcher will still include your data that was part of this study.
If you are receiving treatment as part of this study, you will no longer be eligible for such research-related treatment. Contact your personal doctor to discuss medical treatment for your condition.
Please note that taking back your consent to take part in this research does not take back your HIPAA Authorization to use or reveal your protected health information. To take back your authorization, please send a letter to the Principal Investigator (CDR Grover).

The Principal Investigator of this research study may stop you from taking part in this research study at any time if the investigator thinks it is in your best interest, if you can't complete the research study procedures, or if you no longer qualify to take part.

21) WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator (CDR Grover) as soon as possible using the contact information in the section below.

If you are injured because you took part in this research study and you are a DoD healthcare beneficiary, you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

22) WHO DO YOU CONTACT IF YOU HAVE QUESTIONS?

Principal Investigator (PI)
The Principal Investigator or a member of the research study team will be available to answer any questions throughout this study.

Principal Investigator: CDR Shawna Grover
Phone: 757-953-0605
Mailing Address: Naval Medical Center Portsmouth, 620 John Paul Jones Circle,
ATTN: Building 3, Nursing Research and Consultation Services/DPE. Portsmouth, VA 23708

Clinical Research Coordinator: Cherita Washington
Phone: 757-953-2172
Mailing Address: Naval Medical Center Portsmouth, 620 John Paul Jones Circle, ATTN: Building 3, Nursing Research, Portsmouth, VA 23708

NMCP Human Research Protection Program (HRPP) Office
The Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director: Kersten Wheeler, MS
Phone: 757-953-5939

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, you can contact the office of the committee responsible for ensuring research participant protection, the Institutional Review Board (IRB).

Naval Medical Center Portsmouth
620 John Paul Jones Circle
ATTN: CID
Portsmouth, VA 23708
(757) 953-5939
usn.hampton-roads.navhospporsva.list.nmcp-irboffice@health.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE RESEARCHER BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL DOCTOR OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated photocopy of this document will be given to you.

23) HIPAA AUTHORIZATION

An Authorization is your signed permission to use or reveal your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or reveal your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained below.

The consent above describes the purposes of the requested use and disclosure of your health information. Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information. If you do not wish to give permission to use and disclose your health information, you may not be able to participate in the study.

a. What health information will be used or disclosed?

The following health information will be used: responses to surveys and interviews. Some of this information may be obtained from your medical record with your authorization. All information used will be de-identified, used for study purposes only and your protected health information will not be disclosed.

b. Who will be authorized to use or disclose (release) your health information?

Study team members from the local facility where you are participating in the study will be authorized to use your health information. Only de-identified health information about you will be disclosed to study team members at other sites.

c. Who may receive your health information?

- Naval Medical Center Portsmouth Research Staff
- Naval Medical Center Portsmouth Institutional Review Board (IRB)
- University of North Carolina at Charlotte
- The Ohio State University

d. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not receive research-related treatment.

The MHS **will not** refuse treatment that is not part of this study, payment, enrollment, or eligibility for benefits based on whether you sign this Authorization.

e. Is your health information requested for future research studies?

No, your health information is not requested for future research studies, as we will not contact you with additional questions. However, deidentified data from this current research study may be utilized in secondary analyses.

f. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

g. Can you take back this authorization?

- You may change your mind and take back your Authorization at any time. However, if you take back this Authorization, any person listed above may still use or share any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you take back this Authorization, you may no longer be allowed to take part in this research study.
- If you want to take back your Authorization, you must write to: If you want to take back your Authorization, you must write to: CDR Shawna Grover, 620 John Paul Jones Circle, Naval Medical Center Portsmouth, Building 3, NURSING RESEARCH AND CONSULTATION SERVICES/DPE. Portsmouth, VA 23708.

h. Does this Authorization expire?

Yes, it expires at the end of the research study.

i. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all the information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or shared for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

24) SIGNATURES

SIGNATURE OF PARTICIPANT

Your signature below indicates that:

- You authorize the Military Health System to use and reveal your health information for the research purposes stated above as described in the HIPAA Authorization;
- You have read (or someone has read to you) the information in this consent including the HIPAA Authorization;
- You agree that you have been provided time to read the information describing the research study in the consent form. The content and meaning of this information have been explained to you. You have been provided with the opportunity to ask questions.
- You voluntarily consent to take part in this research study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ __ __ / __ __ __ / __ __ __ __
Signature of Participant Date (DDMMMYYYY)

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator approved to administer consent)

_____
Printed Name of Administering Individual

_____ __ __ / __ __ __ / __ __ __ __
Signature of Administering Individual Date (DDMMMYYYY)