UNIFORMED SERVICES UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Adjustment disorders in the US military:
Addressing gaps in knowledge and practice
Principal Investigator: Jouhayna Bajjani-Gebara, PhD, RN

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 you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

Your decision will not affect your future care at your local Military Treatment Facility (MTF) or within the Military Health System (MHS). If you decide to take part in this research study, you will be asked to verbally confirm that to the researcher communicating with you on the phone, who will notate your understanding and acceptance to participate. Before you decide, 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:

Faculty at the Uniformed Services University of the Health Sciences are conducting this study to learn about adjustment disorders in military populations. It is the most frequently diagnosed mental health problem in military populations, but little research has been conducted on it. There are also challenges associated with diagnosing and assessing adjustment disorders, and we aim to help provide insight on the diagnosis and assessment processes.

You are being asked to take part in this research study because you are either a credentialed health care provider who actively treats active duty military service members or a researcher who studies mental health disorders in the US Military.
If you decide to take part in this study, you will be asked to participate in either a focus group or an interview. The focus group/interview will ask questions about your attitudes and behaviors as a provider with regards to diagnosing Adjustment Disorders in the Military population. The focus group/interview will be audio recorded for data analysis purposes. Focus groups will consist of up to 7 participants. Approximately 45 providers will participate in this research. This study will run for 3 years.
Your participation in this study is voluntary. The primary risk associated with participation in this study is the potential for you to be uncomfortable, embarrassed, or distressed while answering questions in the focus group/interview. You will have the option to skip any questions you are uncomfortable answering.
The Study Team will take all appropriate measures to ensure your data remains secure. You will be provided with a Study ID that you will use in place of your name when completing the surveys. This will ensure your responses are not directly linked to your name. Only approved members of the Study Team will have access to the document linking your name with your Study ID. There is always a risk of a breach of data security.
There is no cost to you to participate in this study. Your participation in this study is voluntary, and you can decide to withdraw at any time. Any information you provide up to the point of withdrawal may be used for analysis.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

The purpose of this research study is to learn about adjustment disorders in military populations. It is the most frequently diagnosed mental health problem in military populations, but little research has been conducted on it. There are also challenges associated with diagnosing and assessing adjustment disorders and we aim to help provide insight on the diagnosis and assessment processes. A total of 45 health care providers who treat active duty service members with adjustment disorder diagnosis will take part in this study. The study will run for 3 years.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will take part in focus groups/interviews to learn about your thoughts on assessment and diagnosis of adjustment disorders in the active duty military

population. The interview/focus group will take approximately 60-90 minutes to complete. Focus groups will consist of up to 7 participants. The interview/focus group will be recorded for data analysis purposes only.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

There are risks, discomforts, and inconveniences associated with any research study. You should speak with the study investigator if you have any questions.

Potential risks may include discomfort with some of the questions. You may find some of the survey questions make you feel anxious or stressed. You may experience mild embarrassment if you reveal something deemed socially undesirable. However, you will have the option to skip/abstain from questions or to withdraw from the study with no penalty or loss of military benefit to which you are entitled.

Researchers will make every effort to protect your privacy and confidentiality; however, there are always risks of breach of information security and information loss. Please see section 15, below.

5. IS THERE A POSSIBILITY OF INCIDENTAL FINDINGS?

Because the focus groups/interviews will not ask you questions about your personal mental health, there is not possibility of incidental findings.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

Participation in this research study may include benefits from having the opportunity to share experiences to assist in the development of a tool to use in active duty military populations. The knowledge gained from the information you provided, will help to provide the necessary foundation for informing the very limited information on diagnosing, assessing, and screening for AD in military populations, and informing the development of an assessment tool and comprehensive training framework. However, there is no guarantee that you will benefit from being in this research.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

You may choose not to participate in this research study

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

There is no compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

There are no costs to you for participating in this research.

10. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

A research injury is any physical or mental injury or illness caused by being in the study. While there are no anticipated injuries as this study is only asking questions and not conducting any form of treatment, if you have a research injury related to being in this study, the principal investigator can help you determine the appropriate place to get treatment. If you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), 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. If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you will not be reimbursed for medical expenses if you obtain care for research-related injuries. For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

11. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

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Daniel K. Inouye Graduate School of Nursing
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Uniformed Services University of the Health Sciences
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12. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

This study is sponsored by the Uniformed Services University of the Health Sciences, Daniel K. Inouye Graduate School of Nursing.

13. SOURCE OF FUNDING:

Funding is through the Congressionally Directed Medical Research Programs (CDMRP) funding mechanism - Psychological Health and Traumatic Brain Injury Research Program, Prevention Research to Reduce Sexual Assault and/or Understand Adjustment Disorders Investigator-Initiated Focused Research Award.

14. LOCATION OF THE RESEARCH:

The study will take place online by a research team at USUHS.

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

Records of your participation in this research study may only be disclosed 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. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by research team members from the USU Graduate School of Nursing, the F. Edward Herbert School of Medicine, the USUHS Institutional Review Board (IRB), and the DoD Higher Level Review 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.

Representatives of CDMRP may have access to study data for audit purposes.

Procedures will be taken to protect the confidentiality of the data in this study. A research study coordinator will contact you by phone to review the informed consent. After ensuring you have read and understand the information in the informed consent, the study coordinator will ask for your verbal consent. The research coordinator will document your verbal consent for the study files. Upon providing informed consent, you will be assigned a study ID. The study ID will be used to mask your personal information such as name and other identifiable information in research records. A Master List linking your real name with your study ID will be kept in a locked office and file cabinet or in an electronic database located behind a secure firewall. A firewall is a protection or barrier within a computer to protect the information from being viewed by unauthorized people. Only approved study personnel will have access to information that could be used to distinguish or trace an individual's identity. If you do not want them to have access to your personal email address, you may create and provide an email address other than your personal email address. Study collaborators will not share this email address or use it to contact you outside of automatic emails generated by the portal for study participation. Before the interviews/focus groups are conducted and recorded, you will be reminded by the researchers to not use your names. Any names will be deleted off the recordings at the end of each focus group/interview.

Researchers will make every effort to protect your privacy and confidentiality; however, there are always risks of breach of information security and information loss.

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.

The Department of Defense (DoD) is supporting the study and may have access to research records as a part of its human subjects protection oversight activities. De-identified data collected during this study will be stored indefinitely following completion of the study. By providing your verbal consent, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data. If you wish to withdraw from this study at any time, you may contact the principal investigator. However, please note that after all data has been collected, any documentation linking your identity to your data will be destroyed and at that time, it will not be possible to remove your data from analysis.

16. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are not any financial interests and/or other personal arrangements to disclose

17. LONG TERM USE OF DATA

Selected data collected during this study will be saved and stored for possible use in future research. This data will not contain information that could be used to identify you.

No identifiable information will accompany your data and all identifiable information will be removed. Your data will be coded with a randomly generated code. The data will be stored indefinitely. Your data may be shared with other collaborators and investigators and used for a variety of research purposes that we may not be able to specify at this time. All information that can identify you will be removed before sharing with any investigator or collaboration.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

You will be given the opportunity to opt out of long-term use of data at the end of this form.

18. VOLUNTARY PARTICIPATION

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.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify the study principal investigator in writing.

Data collected up until the point of withdrawal may be used in data analysis.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

20. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator will be available to answer any questions throughout this study.

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Uniformed Services University Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Hours of Operation: Monday through Friday, 8:00 a.m. to 4:30 p.m.
Office Hours: Tuesdays and Thursdays, 1:30 pm - 3:00 pm
Main Office Phone Number: 301-319-4730 (direct)

Uniformed Services University 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, please contact the IRB Office at:

Uniformed Services University Institutional Review Board (IRB) Office 4301 Jones Bridge Road
Room A2051 Bethesda, MD 20814
301-319-4730

I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I have not given up any of my legal rights as a research participant.

Do you agree to voluntarily participate in this study?

Yes
No

_____
Printed Name of Participant

_____
Printed Name of Administering Individual Obtaining Verbal Consent

_____ _____ _____
Signature of Administering Individual Obtaining Verbal Consent Date Time

Long-Term Use of Data

Please indicate if you do or do not give permission to have your de-identified data from this study used for future research
[ ] I give permission to have my di-identified data used in future research

[ ] I do not give permission to have my di-identified data used in future research

_____
Printed Name of Administering Official Obtaining Permission to use Data in Future Research

_____
Signature of Administering Official Obtaining Permission to use Data in Future Research _____Date: Time: