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Uniformed Services University of the Health Sciences (USUHS)

CONSENT TO PARTICIPATE IN RESEARCH

Title: Better Together: A Relationship Enrichment Program Targeting Transdiagnostic Interpersonal Emotion Regulation Among Military Couples

Principal Investigator: Dr. Sarah Carter, Ph.D.

Thank you for your interest in the Get Better Together study. This form gives you important information about the study.

Please take time to carefully review the following information about the study. You are encouraged to talk to the researchers and ask them any questions you have. You may also wish to talk to others (for example, friends or family) about your potential participation in this research study. Participation in this study is voluntary. You do not have to take part in the study and you may leave the study at any time without penalty.

1. KEY INFORMATION

The purpose of this study is to identify the effects of the Get Better Together program on your relationship functioning, mental health, and military readiness. We will do this by comparing military couples who attend a Get Better Together retreat to those that do not.

If you choose to participate, you and your partner will:

- Complete online questionnaires over the next six months
- Select a weekend retreat to attend, although only half of couples will be assigned to go
- Optional: You can choose to give researchers limited access to your DoD records to better understand potential long-term impacts.

Potential benefits include learning skills to strengthen your relationship and manage stress, while helping improve programs for other military couples. Risks are expected to be minimal but may include discomfort from personal questions. Participation is voluntary.

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.

2. What is the purpose of this research and who will take part?

The purpose of this study is to examine whether Get Better Together, a relationship enrichment program, improves relationship functioning, mental health, and military readiness. This program has not been tested in a randomized controlled trial before and is considered experimental for this purpose. A total of about 500 military couples are expected to enroll in the study.

3. What will happen if you decide to participate?

You will be part of this study for approximately six months, although it may be longer depending on the weekend retreat you select. Below is a list of study activities and the estimated off-duty time each one may take.

1. **Complete Online Questionnaires:** You will be asked to complete questionnaires about your relationship and mental wellbeing before selecting your retreat date, and again 2, 4, and 6 months after your scheduled retreat. Each questionnaire takes up to 45 minutes to complete. You can take breaks and come back to the survey. You may skip any questions that you do not want to answer.

2. **Schedule a Weekend Retreat:** You and your partner will identify a retreat weekend that you anticipate being able to attend. You will have a 50% chance of being selected (randomized) to attend this retreat.

Please note, Service Members that are E6 or below are required to secure supervisor endorsement to attend a retreat.

3. **Randomized to Attend or Not Attend a Get Better Together Retreat:** You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either attend or not attend Get Better Together retreat. No matter which group you are randomized to, all participants will have access to relationship enrichment programming at no cost.

Group 1: Attend the Get Better Together Retreat

About 50% of participants will be randomly assigned to attend the Get Better Together retreat. Retreats are held Friday evening through Sunday afternoon and will include about 10 hours of retreat sessions consisting of group activities and discussions, brief lectures, videos, and skills practice. Lodging and meals are provided; however, you are responsible for transportation to and from the retreat.

Group 2: Do Not Attend the Get Better Together Retreat

About 50% of participants will be randomly assigned to not attend the Get Better Together retreat. We also ask that you do not attend any other relationship enrichment retreats or workshops for six months. You are welcome to continue any mental health or relationship support you're already receiving, or to seek out additional help if you feel it would be useful. This could include behavioral health treatment, counseling, books, or other resources that support your wellbeing and relationship. At the end of six months, you will be given no-cost access to ePREP, an online relationship enrichment program.

Optional: Permission for Limited Access to Your DoD Administrative and Medical Records

In addition to the activities described above, we ask you to allow the research team to access information from your DoD records. We are interested in understanding the longer-term effects that Get Better Together may have on your relationship, wellbeing, and military readiness. With your consent, information would be obtained from records related to your relationship (such as marriage, divorce, birth of a child, substantiated domestic violence), records relating to military readiness (such as promotions, training completion, disciplinary actions, discharge), and complete medical records, which includes information on your physical and mental health.

The DoD already has all of this information, so this does not create any risk for you. However, we need your permission to collect these records and combine them with the information you provide in this study. These records will be handled with strict confidentiality and will not be shared outside the research team in any form that could identify you.

In order to link your study responses to your DoD data, we will also request your DoD ID or DEERS ID. Identifying information will always be stored separately from your DoD records and questionnaire responses. If you choose not to allow us to access your DoD files, you may still participate in this study; however, it will limit what we can learn about the longer-term benefits of Get Better Together.

3. What are the possible risks or discomforts from being in this study?

This study involves only minimal risk. However, some activities, such as answering personal questions, may cause emotional discomfort. Please remember that you do not have to answer any questions you do not want to answer, you can fill out assessments at your own pace to include taking breaks as needed, and you can leave the study at any time. If experiencing significant distress, please call the telephone number(s) on the Resources handout that will be provided to you, or go to your local behavioral health clinic.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information researchers are collecting from you.

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

4. What are the possible benefits of being in this study?

No benefits of participation can be guaranteed. However, you and your partner will have access to relationship enrichment programming which may help you learn new skills to strengthen your romantic relationship, help manage stress, and overcome challenges.

5. What are the alternatives to taking part in this study?

You do not need to take part in this study to attend relationship enrichment programming. Other options may include, but are not limited to: retreats or workshops being offered at your installation, online, or in your local community.

6. Is there compensation for your participation in this study?

You and your partner can each earn up to \$100 for completing questionnaires: \$20 for the Baseline Questionnaire, \$20 for the 2-Month Follow-Up Questionnaire, \$30 for the 4-Month Follow-Up Questionnaire, and \$30 for the 6-Month Follow-Up Questionnaire. Service Members must complete questionnaires during off-duty hours to be eligible for compensation.

Compensation will be provided through an online platform called Mural Link. You can select to receive your payment through Venmo, PayPal, check, direct deposit, physical debit card, or virtual debit card. The research team will register you in Mural Link using your legal name, address, date of birth, phone number, and email. This information is only shared with necessary parties to process your payment. If you want to stop sharing your information with Mural Link, notify research staff at any time. For further information on Mural Link's privacy policy, please visit: muralhealth.com/privacy-policy.

7. Are there costs for participating in this study?

If you attend the Get Better Together retreat, meals and lodging during the retreat will be covered at no cost to you. For Saturday dinner, each couple will receive \$80 to cover the cost of an off-site meal. A child care stipend of \$300 per couple is also available upon request. Please note that you may still incur other costs, such as transportation or taking time off work.

8. Who is responsible for this study?

This study is being conducted at Uniformed Services University of the Health Sciences (USUHS) and the Henry M. Jackson Foundation for the Advancement of Military Medicine.

The Principal Investigator for this study is Dr. Sarah Carter. She is a Research Assistant Professor at USUHS and a Research Scientist at the Henry M. Jackson Foundation. Dr. Carter is responsible for overseeing all scientific and technical aspects of the study.

9. Are there any financial interests?

The Principal Investigator, Dr. Sarah Carter, received a one-time payment for licensing Get Better Together to PREP, Inc. to support broad, long-term implementation for military couples. She has waived any right to future income from this license and has no current financial interests related to the study outcome.

10. Who funds this study?

This study is funded through Congressionally Directed Medical Research Programs, Award #HT9425241084. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

11. Who will see my information and how will it be protected?

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss. Steps we will take to protect the confidentiality of your data include, but are not limited to:

- A. Your name and other identifying information will be stored separately from your questionnaires and records. Instead of your name, we will use a unique study number to label your responses.
- B. We will not allow anyone outside the research team to access identifying data. However, in some cases, limited information may be shared for logistical reasons (e.g., arranging your retreat lodging) or due to safety concerns (see below).
- C. Identifying data will be stored using secure, access-controlled systems.

Records from this study may also be looked at by authorized staff from the USUHS Institutional Review Board (IRB) and the Department of Defense Higher Level Review as part of their duties. These duties include making sure that the rights of participants are protected.

Privacy Laws and Federal Protections

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, which you can read on-line at:

<https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf>

To help us protect your privacy, this study has obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate does not stop reporting that federal, state or local laws require. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research.

When We Are Required to Share Information

Every attempt will be made to strictly maintain the confidentiality of all information collected in this study. However, in some cases, we are legally required to report certain information. This includes any credible threat of harm to yourself or others, as well as suspected abuse of children, elders, or vulnerable adults. If you are at imminent risk of harming yourself or others, we will take appropriate action, including reporting to outside personnel. Our first priority will be protecting the safety of anyone who might be in danger. If this were to happen, our research team will make every effort to fully discuss the situation with you before taking any action. Here is a brief summary for your review:

1. If a member of our research team believes that you are an imminent danger to yourself or to someone else, then we will attempt to ensure the physical safety of those involved, even if this means breaking confidentiality.
2. If you give a member of our research team information pertaining to the abuse or neglect of a child, or an elderly or vulnerable person, and the victim is identified to us, we are required to report this information to the local authorities, even without your permission.

We are required to report even a suspicion of such abuse to the local authorities.

Additionally, 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. This kind of reporting is rare and would only occur if specific concerns related to mission readiness or safety were identified.

How your information may be used in research

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This web site 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.

Information gained from your participation in this research study may be published in research articles, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; any identifying details will be removed.

12. What will happen to my information after the study ends?

Identifying information will be retained for the minimum period necessary to meet institutional and regulatory requirements, typically at least six years following the conclusion of the study. After this time period, all identifying details will be permanently destroyed.

Information collected during the study, with any potentially identifying information removed, will be stored to support future research aimed at better understanding and supporting military service members and their families. It may also be shared with other qualified researchers for the same purpose. Any future use will be reviewed by the Principal Investigator to ensure your information is handled safely and responsibly. The same confidentiality safeguards described in this form will continue to apply.

13. What if you do not want to join this study?

Your participation in this research is completely voluntary. You do not have to take part if you do not want to. If you choose not to participate in this study, there are no penalties or loss of any benefits to which you are otherwise entitled. However, please note that both you and your partner will need to join the study in order to participate.

14. What if you want to stop participating in this study?

You can choose to stop participating at any time. If you decide to withdraw from the study, please inform study personnel at GetBetterTogether@usuhs.edu.

If you give permission for the research team to access your DoD medical and administrative records, please note that withdrawing from the study does not automatically cancel your HIPAA authorization. To fully revoke that authorization, you must clearly state this in your request.

The Principal Investigator of this research study may terminate your participation in this research study at any time if they determine 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.

15. Who can you contact if you have questions?

If you have questions at any point during the study, you may contact the study team at GetBetterTogether@usuhs.edu or (301) 400-5675. You may also contact the Principal Investigator, Dr. Sarah Carter, at Sarah.Carter.ctr@usuhs.edu or (301) 295-0087. If you have questions about your rights as a research participant or concerns about the study, you may contact the USUHS Institutional Review Board (IRB) Office at IRB1@usuhs.edu or (301) 295-0819.

Permission to Access Records

Please indicate whether or not you agree for the research team to access your DoD administrative records and complete medical record data. If you choose not to allow us to access your DoD data, you may still participate in this study.

- ☐ I am willing to allow the research team to access my DoD records
- ☐ I am not willing to allow the research team to access my DoD records

Signature

By signing this consent form, I freely agree to take part in the research it describes.

Signature of Participant

Date