CONSENT FORM COVER PAGE

STUDY TITLE:
Evaluation of a Group-based, Skills Training for Increasing Mental Toughness

NCT Identification Number: NCT07050238

Date of Document: 02/12//2026

UNIFORMED SERVICES UNIVERSITY

CONSENT TO PARTICIPATE IN RESEARCH

Title: Life Force Study

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Uniformed Services University of the Health Sciences (USUHS), Department of Psychiatry, which includes the off-site
Center for the Study of Traumatic Stress (CSTS)

You may be eligible to take part in this research study and receive specialized training geared towards enhancing mental toughness. 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. 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.

1. KEY INFORMATION:

The Life Force program is a group skills training designed to boost mental toughness—the ability to maintain peak performance under pressure or adversity, recover from setbacks, cope effectively with challenges, maintain a positive attitude, and persevere towards goals. The training sessions are led by skilled Life Force trainers from the study team, focused on the "Five Cs" of mental toughness: Control, Commitment, Challenge, Confidence, and Connection. This research will be the first to study the Life Force program in active-duty Soldiers.

If you choose to participate, you will complete a 15-20 minute baseline survey today. However, study eligibility isn't guaranteed and will be determined by an AI machine learning algorithm built from existing DoD administrative records to predict who may benefit most from this training. Your consent is needed to combine this existing data with your survey responses to evaluate the program's effectiveness. Only a minority of Soldiers will be invited to participate in this program. If you are not initially eligible to participate in the training, you may become eligible at a later date, at which time the study team may contact you to ask if you are still interested in participating. Those not selected will not be contacted to inform them that they were not selected.

Eligible participants will be randomly assigned to either the Life Force training or a control group. The training group sessions for currently eligible participants will be scheduled to start within the next two weeks. Both training and control groups will complete 15-20 minute follow-up surveys at 6 and 12 months, assessing military service, personal history, relationships, social networks, and personality. Training group data will be compared to the control group (who will only complete the surveys) to track progress.

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

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The training program includes five 75-minute sessions (one per day for five days), plus two 15-20 minute follow-up surveys at 6 and 12 months. Approximately 2400 Soldiers at Fort Hood will be enrolled over 52 weeks, with 1200 assigned to the training and 1200 to the control group (surveys only). Although participation in this research study is completely voluntary, if you choose to enroll, you are expected to attend all scheduled group sessions as part of your commitment to the program. To ensure accountability for your whereabouts, much like any other scheduled duty or training, your unit command will be made aware of your attendance of scheduled training sessions. In the event of an unapproved absence from a scheduled training, the team will attempt to contact you via email or phone. If the team is unable to reach you in the 24 hours following an absence, unit command will be informed. Again, you are free to withdraw from the study at any time by notifying the study team, in which case you must return to your regularly scheduled duty.

3. WHAT WILL THE TRAINING PROGRAM INCLUDE?

Life Force participants will create a Mental Toughness Action Plan using what they learn throughout the training by participating in group discussions and exercises to build and enhance psychological skills. The curriculum uses evidence-informed strategies to enhance mental toughness, overcome challenges, foster confidence, consistency, and commitment, utilize support networks, manage setbacks, and encourage openness. By the program's end, participants will have an action plan for continued skill development. Training sessions will be recorded for research purposes only and recordings will not be shared with anyone outside of the research team.

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

Participation in this study involves minimal risk. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. The study team is obligated to report any threats of harm to self to Ft Hood Department of Behavioral Health and any cases of harm to others, including child or elder abuse/neglect, to the proper authorities, which could affect service eligibility.

Increased self-awareness of limitations and stressors may cause temporary emotional discomfort. While the program integrates techniques for managing difficult emotions, some exercises may be mentally and emotionally challenging. You can modify or stop any exercise causing significant discomfort. Group sessions involve the risk of sensitive information disclosure; although participants will review expectations for privacy and confidentiality during the first group session, it cannot be fully guaranteed. There may be unknown risks.

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

The possible benefits to those who participate in the training program are learning skills for 1) improving mental toughness, 2) overcoming challenges, 3) maintaining confidence, consistency, and commitment, 4) leveraging support networks, 5) learning to better manage setbacks/failure, and 6) developing openness to new experiences. While those in the control group will not receive this training, this study may help us better understand how these skills could improve the mental health and well-being of service members. This information may be used to inform the development of skills training programs to help service members. However, there is no guarantee that you will benefit from being in this research.

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6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH? Your alternative is not to participate in this research.

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

Yes, participants will receive $15 for completing the 6 month follow up survey and another $15 for completing the 12 month follow up survey. Compensation will be provided electronically (via Mural Health) upon completion of each follow up survey. Surveys must be completed while off-duty in order to receive compensation.
In order to provide compensation to you as part of your trial participation, the following information is required and will be collected by your Study Coordinator or research team member.

- First & Last Name
- Address (Street/City/State/Postal Code)
- Date of Birth
- Phone Number
- E-Mail Address
- SSN
- Trial Participant ID

You can select your payment method by downloading the Mural Health App on your phone. Your payment choices include:

- Venmo
- PayPal
- Check
- Direct Deposit
- Physical Debit Card
- Virtual Debit Card

Your study coordinator or research team member will collect your address, date of birth, phone number and email address to register you in Mural Health so that you can receive payment for participation in the study. This information will be shared only with the necessary parties to facilitate the payment processes. If at any time you no longer wish to have your information shared with Mural Link, you can notify your study coordinator accordingly. For further information regarding Mural Link's privacy policy, please visit: muralhealth.com/privacy policy.

In order to receive payment for your participation in this study, you may be asked to provide your social security number and home address on a W-9 form, if you will receive a total of $1,700 or more in payment. The W-9 form will be sent to the Accounts Payable office at the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF). If you receive $2,000 or more for taking part in a combination of research studies in one tax year, you will be sent a 1099 form from HJF for tax purposes.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

9. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

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The study is overseen by the USUHS Institutional Review Board (IRB), the Principal Investigator, and study staff. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

10. SOURCE OF FUNDING:

The study is funded by the U.S. Department of Defense (DoD).

11. LOCATION OF THE RESEARCH:

Study activities will take place on site at Ft. Hood and remotely.

12. 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

For the duration of this study, confidentiality of participant records will be protected as much as possible under law. Research records will be secured but may be accessed by authorized personnel from the research team (USUHS, HJF, University of Michigan & Harvard Medical School), the USUHS IRB, DoD Higher Level Review, and other government agencies as part of their duties to ensure participant protection. The investigators will keep your research records secured. All study personnel will safeguard your information according to this consent and applicable laws.

Confidentiality will be protected by using coded IDs for participant data. All electronic data will be stored in password-protected and encrypted files on a secure server. Data will be analyzed after complete collection, not in real time. Study results will be published in military health research literature, but participants will not be identified in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

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 Web site will include a summary of results. You can search this Web site at any time.

13. USE OF INFORMATION

If you consent to participate, the survey data collected from you in this study (regardless of eligibility for the training) will be stored for use in future military health research and/or secondary analysis, and may be stored for an indefinite period of time, as costs allow, and as long as they may be of value to the healthcare of Service members, veterans, or until exhausted.

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However, you retain the right to request the destruction of your data at any time by emailing the study team at life-force-study-ggg@usuhs.edu. If your data will be used in a future study, anything that might identify you will be removed from the data prior to being used for future research studies or given to another investigator for future research.

14. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary. You may leave the research study at any time without penalty or loss of benefits to which you are otherwise entitled. You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, please notify a study team member. Your withdrawal is effective upon stating your intent to withdraw. Unless you request otherwise, data collected until your withdrawal will be used. You may also request deletion of your survey data, which will initiate its removal from our servers and analysis datasets, and you will not be contacted for further surveys.
Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if the principal investigator 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.

16. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (**HIPAA**) includes a Privacy Rule that gives special safeguards to Protected Health Information (**PHI**) that is identifiable, in other words, can be directly linked to you (for example, by your name, DoD ID, birthdate, etc.). We are required to advise you how your PHI will be used. This authorization is effective until this study is closed.

A. What health information will be used or disclosed about you?

All health information from your EHR from the past 5 years and data entered over the duration of the study will be made available for Life Force research, but only the minimum necessary information from your record will be used for the study. Only a few authorized individuals from the data management and analysis team will have access to this data. The study team members that you interact with throughout this study (e.g. recruiters and trainers) will not be authorized to access your health record data.

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

Any DoD health plan or DoD health care provider who has treated you or provided service

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during the past 5 years of your military service and over the duration of the study.

C. Who may receive your health information?

Only a few authorized individuals from the Life Force study team may receive your health information. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

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

The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization. If you choose not to sign this authorization, you will not be eligible to participate in the training program.

E. Is your health information requested for <u>future</u> research studies?

No, your health information is not requested for future research studies.

F. Can you access your health information during the study?
Yes.

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

Life Force Study Team, life-force-study-ggg@usuhs.edu

H. Does this Authorization expire?

No.

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 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 disclosed 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.

Your signature below acknowledges that:

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- You authorize the MHS to use and disclose your health information for the research purposes stated above, including all follow ups for the Life Force study.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

17. CONTACT INFORMATION:

Study Contact
The Clinical Supervisor or a member of the research staff will be available to answer any questions throughout this study.

Clinical Supervisor: Dr. Christopher Paine
Phone: (240) 595-0457
Email: life-force-study-ggg@usuhs.edu

Uniformed Services University Institutional Review Board (IRB) Office/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.

If you have questions about your rights as a study participant, or you want to make sure this is a valid study, you may contact the IRB. This is the Board that is responsible for overseeing the safety of human participants in this study. If you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input, you may contact the USUHS IRB Human Protections Administrator/HRPP POC at:
Phone: 301-295-0819
Email: IRB1@usuhs.edu

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:
Phone: 301-295-8239
Email: IRB1@usuhs.edu
Mailing Address:
4301 Jones Bridge Road, Rm A2051
Bethesda, Maryland 20814

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

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

SIGNATURE OF PARTICIPANT

By typing my name below, I agree that I have been provided time to read the information

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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 voluntarily consent to participate in this study.

By typing my name below, I have not given up any of my legal rights as a research participant.

ENTER NAME

_____
[Typed Name of Participant]

Effective [Today's Date]

[ ] I prefer not to provide consent at this time.

Enter your email address to receive a copy of this form for your personal records. ENTER EMAIL

_____
[Typed Email Address]

[ ] I prefer not to receive a copy at this time.

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