SAFEGUARD Phase 2 Pathfinding Study

NCT07404787

April 16, 2026

UNIFORMED SERVICES UNIVERSITY
**CONSENT TO PARTICIPATE IN RESEARCH**

**Title:** Pathfinding Study

**Principal Investigator:** James A. Naifeh, Ph.D., Department of Psychiatry, Uniformed Services University of the Health Sciences (USUHS);

**This consent form is valid only if it contains the IRB stamped date**

**1. KEY INFORMATION:**

You are invited to participate in this research study because you are an active-duty Soldier recently discharged from inpatient behavioral health care, which is a time of heightened stress and suicide risk. Several studies have found that intensive case management programs reduce suicidal behavior following hospital discharge. This study aims to determine whether a newly developed case management program called Pathfinding can prevent suicidal behaviors among Soldiers transitioning out of the hospital. This study, which is funded by the Department of War, will help us evaluate whether the Pathfinding program is helping Soldiers as intended, and which Soldiers will benefit most from Pathfinding.

The study will evaluate the effectiveness of the Pathfinding program by comparing outcomes among Soldiers who receive the standard of care in the U.S. Army, which we call treatment as usual (TAU), to Soldiers who participate in Pathfinding plus TAU. Importantly, Pathfinding is delivered in addition to, not in place of, the standard care that Soldiers receive following discharge from inpatient behavioral health care.

Your participation in the study would last approximately 12 months, including a 30-minute baseline assessment and two 15-minute follow-up assessments 6 and 12 months after baseline. If you are randomly assigned to the Pathfinding program, you will have weekly or bi-weekly virtual sessions with a Pathfinding Guide for the first 6 months. The initial 4 sessions are 45 minutes, and 15–30 minutes thereafter. All participants will be asked for permission to access and link their DoW and VA administrative data to their assessment data.

Participation in this study is completely voluntary. Your decision to participate or not participate will not affect the health care you receive in the future from the Military Health System. If you decide to take part in this program, you will be asked to provide verbal consent over the phone and also to type your name on an electronic version of this consent form.

Your safety is our top priority—above all aspects of the research process. If research team members are concerned about your safety at any point during the study, they are required to help connect you to the Military & Veterans Crisis line or Military OneSource, and to notify your behavioral health provider.

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

This study will aim to enroll 1,500 active duty Regular Army soldiers recently discharged from inpatient behavioral health care. Study recruitment is expected to take 18–24 months. Your participation in the study would last approximately 12 months, including a baseline assessment and two follow-up assessments 6 and 12 months after baseline. If you are assigned to the Pathfinding program, you will have weekly or bi-weekly virtual sessions with your Pathfinding Guide for the first 6 months.

**3. WHAT WILL THE STUDY INCLUDE?**

**If you agree to participate, here's what to expect:**

**A. Screening Questions:**

- You will be asked several questions to assess your safety since leaving the hospital. Your answers may require a research team member to help connect you to the Military & Veterans Crisis line or Military OneSource, and to notify your behavioral health provider.
- These questions will also be used to determine your eligibility to continue in the study.

**B. Baseline Assessment:**

- You will complete a 30-minute assessment immediately after signing the consent form.
- A researcher will read assessment questions over the phone, and you will provide your responses.
- The assessment will cover topics such as your behavioral health, stressful experiences, suicidal thoughts and behaviors, and social support.
- You are free to skip any questions you prefer not to answer.
- We will also collect your contact information, which will be stored separately from your assessment responses.
- Your identifying information will be stripped from the assessments and replaced with a unique study ID.
- If you cannot complete the assessment immediately, we will schedule a time to complete it in the near future.
- **If you are unable to complete the assessment in a timely manner, you will be ineligible to participate in the study.**

**C. Randomization:**

- You will be randomly assigned to either the Pathfinding program or TAU, like a coin toss.
- Both groups will continue to receive standard Army care.

**D. Study Intervention Programs:**

- **Pathfinding:**
  - Pathfinding combines two evidence-based case management interventions found to decrease suicide risk and other negative outcomes during difficult transitions.
  - If assigned to Pathfinding, you will work with a Guide who is a masters-level, independently licensed mental health provider trained in the Pathfinding intervention.
  - The Guide will contact you within a few days of study enrollment to schedule your first session.
  - You will receive up to 26 weekly or biweekly telehealth (virtual) sessions over 6 months.
  - Sessions are initially longer and more frequent, becoming shorter and less frequent over time.
  - The first four sessions will be approximately 45 minutes each, with subsequent sessions lasting 15–30 minutes.
  - Sessions will be conducted using a secure virtual videoconferencing platform, such as Zoom for Government. Sessions will be recorded for quality assurance and to examine whether characteristics of the interaction can predict successful outcomes in the Pathfinding program.
  - If you choose, you can invite a significant person (friend, family member) to participate in some of the Pathfinding sessions for additional support.
  - Pathfinding does not replace your regular Army treatment.
- **Treatment as Usual (TAU):**
  - If assigned to TAU, you will continue your current treatment plan provided by the MTF and your current providers.

**E. Follow-up Assessments:**

- You will complete two 15-minute follow-up assessments 6 months and 12 months after your baseline assessment.
- These assessments will cover similar topics as the baseline assessment.
- You are free to skip any questions you prefer not to answer.
- You will receive an email link to complete these assessments online.
- If we do not receive your response, a researcher from the University of Michigan will call you to complete the assessment over the phone.

**F. Linkage to Your Health and Army Data:**

- We are asking for permission to access your electronic health records and Army administrative data (e.g., personnel records).
- We will use these data to track behavioral health outcomes during your 12-month participation in the study and for statistical analysis.
- Your name and other identifying information will be removed from these records prior to any analysis.
- Analyses will combine your deidentified health and administrative records with your deidentified assessment responses using your unique study ID.

**G. Notes in Your Electronic Health Record**

- Study staff will enter notes into your Electronic Health Record to inform your healthcare providers that you are participating in this study and which group you have been assigned to.
- If you are assigned to the Pathfinding program, study will document each session in your Electronic Health Record so that your healthcare providers are aware of your ongoing involvement in the program.

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

For some people, talking about stressful or challenging experiences can make them anxious or upset. Other people find it helpful to talk about these experiences. If you are upset at any time, you can tell a member of the study team that you want to take a break or discontinue the study activity. And you can skip anything you don't want to talk about.

Although the Pathfinding program combines interventions that have been found to improve behavioral health outcomes during difficult transitions, including hospital discharge, it is possible that participation in the Pathfinding intervention could lead to worsening of distress and suicide risk. If you are concerned that participation in the study is causing a worsening of distress, please call and report it to the Pathfinding team at 301-295-3409 or using the Pathfinding study email at pathfinding-study@usuhs.edu.

We will make significant efforts to protect your information using rigorous physical and electronic security procedures, but there is still a risk that someone could gain access to your medical or other personal data. Your study information will be kept confidential. However, complete confidentiality cannot be guaranteed, as the investigators are required to report threats of harm to yourself or others, and the abuse or neglect of children or elderly individuals. Depending on the nature of the information we receive, study staff may have to inform your primary care provider, which could ultimately impact service eligibility.

If your interactions with research team members or your assessment responses indicate that you may be at imminent risk of harming yourself, a study team member may connect you with helpful resources, such as the Military & Veterans Crisis Line, Military OneSource, or, in emergencies, 911.

There may also be unknown risks to participating in this study.

If new information arises during the study that could affect your decision to participate, we will inform you. You can choose to continue or withdraw. If you continue, you may need to sign an updated consent form. We may also withdraw you if it is in your best interest, and we will explain why.

Risks of the usual care you receive are not risks of this study, and therefore are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

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

You may or may not benefit from taking part in this study. If you are assigned to the Pathfinding program, working with a Guide may reduce your distress and suicide risk, and may also assist you in accessing other programs and services that may be helpful. The findings

from this study may help other Service Members discharged from inpatient behavioral health care.

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

The alternative to participating in this study is to not participate. This study is completely voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

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

You will receive $25 for completing the 6-month assessment and $25 for completing the 12-month assessment. Compensation will be provided electronically (via Mural Health) upon completion of each assessment. Please note that Soldiers must participate in all study activities while off-duty.

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 (only required if you earn $2,000 or more from research participation)
- 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. 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 $2000 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. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):**

James A. Naifeh, PhD, Center for the Study of Traumatic Stress, Department of Psychiatry, Uniformed Services University of the Health Sciences; Email: pathfinding-study@usuhs.edu; Phone: 301-295-3409

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

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 War may have access to your research data to ensure compliance with human subject research protections and ethics, in accordance with DoWI 3216.02.

**11. SOURCE OF FUNDING:**

The study is funded by the U.S. Department of War.

**12. LOCATION OF THE RESEARCH:**

Participants will be recruited over the telephone following discharge from MTFs across the U.S., and all study activities will take place remotely.

**13. 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 it online at:
https://www.esd.whs.mil/Portals/54/Documents/dd/forms/dd/dd2005.pdf

For the duration of this study, the investigators will keep your research records secured. Your records may be looked at by research staff from the USUHS, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF), the USUHS IRB, the DoW Higher Level Review, and other government agencies as part of their duties. These duties include making sure that the research participants are protected. Additional authorized staff/personnel affiliated with the research study at collaborating institutions will have access to your records and 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.

Confidentiality will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, as the investigators are required to report threats of harm to yourself or others, and the abuse or neglect of children or elderly individuals. Depending on the nature of the information we receive, study staff may have to inform your primary care provider, which could ultimately impact service eligibility. After the study is complete, the results will be published in the scientific literature and presented at professional meetings and may be posted on the Center for the Study of Traumatic Stress website. Your name will not appear in any published paper or presentation related to this study.

To protect your confidentiality, you will be assigned a unique study ID (e.g., 1001). Your study data will be deidentified and coded with your study ID. When an electronic assessment is completed, the data will be securely transferred to a secure HJF server. The data will be encrypted during transfer to and from the secured server and while residing on the secured server. Throughout electronic data transfer and storage, the data will always remain coded (non-identifiable) and password protected. Your deidentified data will be combined with the data from other participants and analyzed in groups.

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

**14. USE OF INFORMATION**

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

**15. VOLUNTARY PARTICIPATION**

Participation is voluntary. Refusal to participate will not affect your military health care or relationship with the Army. You can continue to receive standard Army treatment if you do not participate in this study.

**16. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?**

You can withdraw from the study at any time without penalty or loss of benefits. Data collected up until your withdrawal will be used unless you request otherwise. Withdrawal will not affect your military health care or relationship with the Army. You can continue to receive standard Army treatment without joining this study.

To withdraw, please communicate your request to a member of the research team. We may follow-up with you to discuss your reasons for withdrawal and facilitate your removal from the study.

The principal investigator may end your participation if it is in your best interest, you are unable to follow study procedures, or you do not respond to our attempts to contact you to complete study activities. We can also withdraw you for safety reasons, such as needing different treatment. You will be informed of such decisions

**17. 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, DoW ID, birth date, etc.). We are required to advise you how your PHI will be used. This authorization is effective until this study is closed. Withdrawal does not revoke your HIPAA authorization.

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

All health information from your EHR from the past 5 years of your military service and over the duration of the study will be made available to the Pathfinding research team. This includes your DoW/VA health information as well as your DoW administrative data from DEERS, DMDC, and DMSS, but only the minimum necessary information from your records will be used. Only a few authorized individuals from the data management and analysis team will have access to these data.

**B. Who will be authorized to use or disclose (release) your health information?** Any DoW health plan or DoW health care provider who has treated you or provided service during the past 5 years of your military service and over the duration of the study. No identifiable data will be disclosed externally.

**C. Who may receive your health information?**

Only a few authorized individuals from the Pathfinding 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 Pathfinding study.

**E. Is your health information requested for future research studies?**

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

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

Yes, you may have access to your health information at any time as long as the data includes identifiers.

**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: James Naifeh, PhD, pathfinding-study@usuhs.edu

**H. Does this Authorization expire?**
This authorization is effective until this study is closed.

**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:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- 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 your questions have been answered to your satisfaction.

**18. CONTACT INFORMATION:**

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

Principal Investigator: James Naifeh, PhD
Phone: 301-295-3409
Email: pathfinding-study@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: 301-295-8239
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:
4650 Taylor Road, Bldg.17B, 3rd Fl.
Bethesda, MD 20889

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.

You will have the option of receiving a signed and dated copy of this document.

**SIGNATURE OF PARTICIPANT**

By typing my name below, 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 have been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study. I understand that I have not given up any of my legal rights as a research participant.

ENTER YOUR NAME

_____

[Typed Name of Participant]

Effective: [Today's Date]

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

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

**ENTER YOUR EMAIL**

_____

[Typed Email Address]

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

**NAME OF STUDY TEAM MEMBER ADMINISTERING CONSENT**
(Can only be signed by an investigator or staff approved to administer consent)

_____

[Name of Administering Individual]

Date Administered: [Today's Date]

## Helpful Resources

Thank you for your participation in the Pathfinding study. If you have any questions or concerns, please feel free to contact the study team by phone at 301-295-3409 or by email at pathfinding-study@usuhs.edu

If you or someone you know needs help with their emotions or behavioral health, please use one of the resources below:

**Military & Veterans Crisis Line**
If you or someone you know is in emotional distress, please call the 24/7 Military & Veterans Crisis Line by dialing 9-8-8 then press 1, send a text message to 838-255, or visit https://www.veteranscrisisline.net/get-help/chat to chat online with a counselor.

**911**
If you or someone you know is ever at immediate risk or harm, please call 9-1-1.

**Military OneSource**
Additional resources, including confidential counseling, can be found at Military OneSource by calling 800-342-9647 or visiting https://www.militaryonesource.mil/benefits/confidential-counseling.

**Army Community Service**
For in-person assistance and family support, you can search for your local Army Community Service at https://www.armymwr.com/programs-and-services/personal-assistance/army-community-service.

**SAMHSA's National Helpline**
If you would like information about mental and/or substance use disorders, prevention, treatment, or recovery, please call SAMHSA's National Helpline at 1-800-622-HELP (4357).

**Thank you for your service to our country and for your help with this important research initiative.**