Does Self-efficacy Predict Outcomes Among U.S. Military Academy Cadets During Initial Entry Training?

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Baylor University-Keller Army Community Hospital Division 1 Sport Medicine Physical Therapy Fellowship
CONSENT TO PARTICIPATE IN RESEARCH
Research Title:
Does self-efficacy predict outcomes among U.S. Military Academy cadets during initial-entry training?
Principal Investigator: Brian Kreisel, DPT, OCS
Associate Investigator: Kelly Scott, DPT, SCS

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. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without any consequence.

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

NOTE: If you are providing consent as a legally authorized representative (LAR), "you" or "your" refers to the research participant.

1. KEY INFORMATION:

Voluntary Participation	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 Keller Army Community Hospital. 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.
Purpose	The purpose of this study is to learn about relationships between self-efficacy, injury and physical/tactical performance.
Duration	Throughout cadet basic training and for 9 additional weeks during the summer of 2022.
Procedures	During study visits, you will: • Complete a cadet demographics and self-efficacy questionnaire • Participate in all cadet basic training events • Complete a questionnaire before and after the ACFT • Complete a questionnaire after cadet basic training

IRB Office Use Only
Protocol Version: 1.1
EIRB Reference Number: 950973

Why might you want to participate in this research (benefits)?	The possible benefits to others include improving injury risk screening protocols, developing holistic injury prevention programs or organizing training events to maximally enhance performance.
Why might you choose not to participate in this research (risk)?	There is a small risk that someone else could access your health information, but no more risk than what occurs at medical treatment facilities.
What are the alternatives to participating?	Your alternative is not to participate in this research.
What is the compensation for participating?	No, you will not receive any compensation for participating in this study.

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this study is to learn about relationships between self-efficacy, injury and physical/tactical performance. Self-efficacy is similar to self-confidence, but only applies to one specific task. For example, you will be asked to rate your confidence to complete a 250-meter swim. If you are certain you can perform this task, then your self-efficacy would be high for this task.

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

You are being asked to take part in this research study along with the rest of the U.S. Military Academy Class of '26. Military leaders and trainers strive to ensure the best quality training with minimal risk. Information on your experiences in cadet basic training will help improve training quality. Maximal participation will ensure the most accurate information.

4. HOW LONG IS THE RESEARCH STUDY?

The study will take no additional time outside of the cadet basic training schedule with the exception of one 5-minute electronic questionnaire completed afterwards.

There will be about 1,200 cadets taking part in the study at the United States Military Academy conducted over a period of about three months.

At the end of this research study, the clinical results- including research results about you- will be available to you by request. To request results, contact the principal investigator on this form.

5. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

There is no screening process to participate in this study. Your acceptance into the USMA Class of 2026 fully qualifies you to participate.

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

You will complete several questionnaires throughout the study- one at the start of cadet basic training, one before the Army Combat Fitness Test (ACFT), one after the ACFT, and one at the conclusion of cadet basic training. These questionnaires will gather information about you and your injury history (if any).

A portion of the study is looking at the effects of different education about lower back injuries and the possible effects on maximum deadlift performance during the ACFT. These types of education have not been well studied before. This means the education is considered experimental for performance on the maximum deadlift.

Before the day of the ACFT, your Company will be randomly assigned to receiving a particular type of education to be provided before the start of the test. Your entire Company will be in the same research group, will receive the same education, and will remain together throughout the test. The education will take place shortly before the start of the ACFT and will take no longer than 10 minutes.

This part of the study is double blind, which means neither you nor your graders will know if you are receiving the experimental instructions or control instructions. Only the research team will know if you are receiving the experimental or control instructions.

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

Although efforts are made to protect your research 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.

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

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from this research. The possible benefits to others are improving injury risk screening protocols and developing holistic injury prevention programs or organize training events in such a way to maximally enhance performance.

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

Choosing not to take part in this research study is also an option.

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

No, you will not receive any compensation for participating in this study.

11. ARE THERE COSTS FOR TAKING PART IN THIS RESEARCH?

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

12. WHO IS THE STUDY SPONSOR?

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoD Instruction 3216.02.

13. IS THERE A SOURCE OF FUNDING?

No funding is required for this study.

14. WHAT IS THE LOCATION OF THE RESEARCH?

U.S. Military Academy, West Point, New York

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. A copy of DD Form 2005 can be given to you upon request, or you can read online 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 staff from Keller Army Community Hospital and the DoD. 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: The investigators have a reviewed and approved plan to safeguard your personal information, which is the same as the standard in medical treatment facilities. Your personal health information will be limited to firewall-protected department of defense computers which require common access card (CAC) and pin number plus an additional username and password key for access. All paper documents will be locked inside a filing cabinet in a secure medical treatment facility.

Researchers will make every effort to protect your privacy and confidentiality. However, there are 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. For this study, the researchers will not share your medical information and will direct all medical inquiries to the appropriate medical provider.

The researchers 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.

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.

17. WILL YOUR INFORMATION BE USED IN THE FUTURE?

Following the completion of this study, you will have the option to allow, or not allow the researchers to keep your data and use it in the future. At the end of this form you will choose to give us permission, or not, to use your protected health information and study data (non-protected health information) for future research studies. Following study completion, we will remove anything that might identify you from the information. If you choose so, the remaining de-identified information may then be used for future research studies or given to another investigator without getting additional permission from you. If we do want to use the information or give the information to another investigator for future research, a review board will decide whether this is allowed.

This future research may be in the same area as the original study, or it may be for a different kind of study or distributed to another investigator for future research studies. The specifics of these research studies are unknown at this time, but these studies will be in the area of self-efficacy, physical performance and musculoskeletal injury. For example, in future studies, we may want to merge the outcomes of this study with studies at the Keller Army Community Hospital you may have consented to previously that have a longer-term follow-up. Any information utilized will be done in a way to protect your privacy and confidentiality. You have a number of options with regard to this request. At the bottom of this form you may choose to allow (or not) any further use of your protected health information, and/or any further use of your non-protected health information to be used in future studies.

HIPAA AUTHORIZATION

I. Purpose

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.

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.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

In the U.S. Army, musculoskeletal injuries (MSKIs) are the leading cause of nondeployability, lost duty days, medical encounters, military discharge, and disability. Ironically, the leading causes of MSKIs are same activities that leaders deliberately choose to develop physical readiness. Self-efficacy, or one's confidence to be able to complete a specific task, has also been shown to predict injury and performance and is modifiable through non-physical means. Before we can explore the potential impact of self-efficacy development will have on preventing injury, we must first see if there is a correlation between self-efficacy and MSKI in the cadet basic training population. To explore this relationship, we will be assessing cadets' self-efficacy through a questionnaire and then collecting their MSKI information to see if there is a relationship.

A. What health information will be used or disclosed?

We will be monitoring the Cadet Injury and Illness Tracking System (CIITS) and the Armed Forces Health Longitudinal Technology Application (AHLTA) for only musculoskeletal injuries that occur during cadet basic training. We are not gathering any other medical information (illness, psychological, etc.) This information is documented during routine medical visits; no other information will be gathered.

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

All medical facilities within the West Point/ Keller Army Community Hospital system routinely collect all necessary information for this study during cadet basic training and up to nine weeks after cadet basic training. The information is no different than what is normally collected at these during medical visits.

C. Who may receive your health information?

Principal Investigator: Brian Kreisel

Principal Investigator: Kelly Scott

Co-Investigator: Timothy Benedict

Associate Investigator: Erin Miller

Human Protection Administrator: Lori Cartwright

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

The MHS **will not** refuse treatment that is not part of this study, payment, enrollment, or eligibility for benefits 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.

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:

Brian Kreisel at brian.r.kreisel.mil@mail.mil (OR)

Kelly Scott at kelly.m.scott6.mil@mail.mil

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.

18. 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. **Your status as a cadet will not be adversely affected**. If you do not want to continue taking part in the research study, you must email one the principal researchers as brian.r.kreisel.mil@mail.mil or kelly.m.scott6.mil@mail.mil.

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 Investigators as discussed above.

The Principal Investigators 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.

19. 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: Brian Kreisel
Phone: (845)938-8340
Mailing Address: Arvin Cadet Physical Development Center, West Point, 10996

Associate Investigator: Kelly Scott
Phone: (845)938-3929
Mailing Address: Arvin Cadet Physical Development Center, West Point, 10996

Keller Army Community Hospital Human Research Protection Program (HRPP) Office
The Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director: Lori Cartwright
Phone: (845)938-2680
Email: lori.d.cartwright.civ@mail.mil

Humans Protections Director: Karen Peck
Phone: (845)938-7385
Email: Karen.peck@westpoint.edu

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@mail.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 copy of this document will be given to you.

20. FUTURE USE OF INFORMATION AND/OR SPECIMENS:

The researchers would like to use your de-identified information collected as part of this research for future research studies. Once information is de-identified, it cannot be traced back to you in any way. Please choose below if you would like to refuse or allow the researchers to keep your de-identified data and use it for future research. Whatever option you choose will not affect your participation in this research study.

Please initial the sentences that reflect your choices:

Your health information will not be used for future research studies unless you give your permission by initialing your choices below:

_____ I *do not* give permission to use my protected health information for future research studies.

_____ I give permission to use my protected health information for future research studies.

_____ I *do not* authorize the storage of data (non-protected health information) collected as a part of this study for future use in research studies.

_____ I authorize the storage of data (non-protected health information) collected as a part of this study for future use in research studies.

21. 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;
- 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 has 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 ADMINSTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

Printed Name of Administering Individual

Signature of Administering Individual | Date (DDMMMYYYY)

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