NMCP IRB Approval
IRB NUMBER: RHC-A-19-035
IRB APPROVAL DATE: 07/25/2023

KELLER ARMY COMMUNITY HOSPITAL
CONSENT TO PARTICIPATE IN RESEARCH

Title: Evaluation of a Video Telehealth Gait Retraining Program Versus a Standard Exercise and Education Program for Patients with Running-Related Knee Pain

Principal Investigator: LTC Jamie B. Morris, PT, DSc

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 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 any consequence.

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

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 research study is to determine if Active Duty Soldiers and USMA Cadets with running-related knee pain benefit from video telehealth gait retraining.
Duration	The duration of your participation in this study is approximately 3 months.
Procedures	During study visits participants will: • Visit the Biomechanics Laboratory on three separate occasions for instrumented treadmill testing. • Follow up with your Physical Therapist as appropriate (approximately every 2-3 weeks). • If you are assigned to the intervention group, you will provide recorded video of yourself running to your clinician via the OnForm app from a mobile device at least once a week for the first four weeks, and then once during weeks 6 and 8.

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Why might you want to participate in this research (benefits)?	The most likely benefit from your participation in this study is that you will learn more about your running form.
Why might you choose not to participate in this research (risk)?	The greatest risk in participating in this study is a stress injury. Muscle soreness may also occur.
What are the alternatives to participating?	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.

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research is to determine if soldiers who receive running form training through video telehealth are able to return to running with less pain and improved function compared to soldiers who do not receive the running form training. This project will help determine whether soldiers with running-related knee pain benefit from running form feedback provided through a mobile device app.

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

You are being asked to take part in this research study because you are an Active Duty Soldier or Cadet between the ages of 18 to 60 years old, and have reported mild to moderate running related knee pain during or after running that was not due to an acute trauma.

4. HOW LONG IS THE RESEARCH STUDY?

We will schedule three separate visits to the Biomechanics Laboratory with you that will last no longer than 30 minutes each. These visits will take place at the beginning and end of a10-week period, and 1-month after the end the 10-week period.

We estimate having 180 people enrolled in the study. We expect the duration of open enrollment for this research project to last 2 years.

5. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, we will ask you to perform some movement tests and provide some information in order to determine if you qualify to participate in this study. Most of this information is collected as a part of your standard rehabilitative care. Also, we will ask you to perform 20 single-leg heel raises and run on a treadmill for 5 minutes.

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

After the screening process, you will first be asked to answer survey questions regarding your background information, knee function, and knee pain. Then you will be randomly assigned to either the control group, or the intervention group. All participants will receive standard rehabilitative care, which includes a return to run program with a home exercise program and

activity log. You will be encouraged to track details about your run progression and exercise progress on the activity log. The intervention group will also receive standard rehabilitative care, along with regular feedback on running form via telehealth. Participants in the intervention group will receive additional instruction on how to download and use the 'OnForm' app on their personal mobile device.

During the return to run program, you will follow up with your Physical Therapist as appropriate (approximately every 2-3 weeks). If you are in the intervention group, you will provide video of yourself running to your clinician via the OnForm app once a week for 4 weeks, and then once during weeks 6 and 8.

We will schedule three separate visits to the Biomechanics Laboratory with you that will last no longer than 30 minutes each. These visits will take place at the beginning and end of a10-week period, and 1-month after the end the 10-week period. During each visit, you will run at your own running speed on a treadmill for 5 minutes. During your run, information about your running and movement patterns will be collected with special cameras that only record reflective images. So, you will have small reflective spheres attached to your legs and shoes using double-sided tape. During your run, you will also be videotaped from the shoulders down with a regular video camera.

Finally, the study team is requesting that they can access your medical record so that they can track other characteristics related to your knee injury. The study team will collect information on relevant medical/treatment history related to your current knee symptoms as well as pain medications prescribed to you for your knee pain. This aspect of the study is completed entirely by the study team and requires no additional effort or time from you.

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

The physical risks associated with participating in this study are minimal. If you choose to take part in this study, there is minimal risk of muscle soreness as you complete the return to run progression. However, soreness would be expected during standard rehabilitative care, and typically resolves within 2-3 days. Additionally, there is a rare risk (<1% chance) of a stress injury or swelling, especially in the feet. However, you will be closely monitored for this throughout the return to run program. Finally, there is a small risk that you may fall during treadmill running. To minimize this risk, you will have time to adjust to walking and running on the treadmill and the treadmill's safety features will be used.

While every effort will be made to protect your identity and health information, there is a small risk of loss of privacy. Confidentiality of your health information is of priority and every effort will be made to protect your information.

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

There is no guarantee that you will benefit from participating in this study. A possible benefit to you as a participant in this study is that you may have the opportunity to learn about your

running form. Additional potential benefits include learning mobility and strengthening exercises for your core and lower extremities.

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

Your alternative is not to participate in this research. If you choose not to participate in this research, you will receive standard rehabilitative care from a medical provider (physical therapist or athletic trainer).

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.

WHO IS THE STUDY SPONSOR?

The study sponsor is the organization or people who oversee the study. They may also be responsible for analyzing any research study information.

The Collaboratory for Musculoskeletal Injury Rehabilitation Research (CMIRR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from the CMIRR and the USU will have access to your coded de-identified research data.

The Department of Defense (DoD) Defense Health Agency (DHA) provided funding for this research study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. IS THERE A SOURCE OF FUNDING?

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

13. WHAT IS THE LOCATION OF THE RESEARCH?

All research activities will take place at West Point, NY. Locations in NY will include the Keller Army Community Hospital, Arvin Cadet Physical Development Center, Mologne Health Clinic Laboratory and Mahan Hall Treadmill Lab.

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14. ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

None of the investigators has any financial interests or other personal arrangements that the institution, the research team members, or their immediate family members might have with this study, sponsors, or funding sources.

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 coded electronic research data for this study will be stored in Research Electronic Data Capture (REDCap), an encrypted, access controlled, password protected electronic data capture and management system housed on a Department of Defense (DoD) server and maintained by the Uniformed Services University Information Technology (USU IT). No Personally Identifiable Information (PII) will be entered into REDCap.

This coded electronic research data will only be accessible by research staff designated and authorized by the Principal Investigator and authorized staff from the Collaboratory for Musculoskeletal Injury Rehabilitation Research (CMIRR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University in Bethesda, MD, and is serving as the data coordinating center for this research study. Staff from the CMIRR/USU will not have access to identifiable research data. Access to the coded research data will be governed strictly on an individual-by-individual basis within REDCap. Individual data access as well as privileges will be clearly delegated, audited, and monitored by CMIRR/USU.

Your records may be looked at by staff from the Keller Army Community Hospital Department of Clinical Investigation, the Regional Health Command Atlantic (RHC-A) Institutional Review Board (IRB) (a committee responsible for protecting research participants), Clinical and Translational Research Program Office US Army Medical Command (CTRPO), and other government agencies as part of their duties. These duties include making sure that the research participants are protected.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Every effort will be taken to protect your identity as a participant in this study. You will be assigned a unique study number. The information that you provide will be stored with your study number, not with your name. All records will be maintained in a secured cabinet in a secured room. Only the investigators and their associates conducting or auditing this study will have access to the records from this study.

Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on 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. Your research records may be disclosed outside of the hospital, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

Investigators on the study 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. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss. Procedures to protect the confidentiality of the data in this study include but are not limited to: coded data, removal of personal information, computer password protection and locking of drawers and offices.

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.

16. WILL YOUR INFORMATION BE USED IN THE FUTURE?

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. 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 frequently be in the area of running biomechanics or gait retraining. For example, in future studies we may want to merge the outcomes of this study with other studies at the Keller Army Community Hospital you may have consented to previously that have longer term follow-up.
You have a number of options with regard to this request. If the stored data has an identifying link you can request to be contacted and sign a separate consent form to allow the use or available of this data in another study. You may also choose to allow use of only de-identified data or give consent now for the use of your identifiable data to be used in future studies. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

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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.

The research team in the Arvin Physical Therapy Clinic will keep the research data for up to six years following the end of this study. The master code will also be kept for up to six years following the end of the study and will be destroyed at the end of that 6 year period. This consent form and HIPAA authorization will be maintained for a period of six years after the study is completed.

Your de-identified research data, meaning that all of your personal identifiers have been removed, will be securely sent to the Collaboratory for Musculoskeletal Injury Rehabilitation Research (CMIRR) and stored at the Uniformed Services University (USU) alongside other deidentified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for future research studies or given to others for future approved research studies. If you do not want you de-identified data collected as part of this research study to be kept for use in future research studies, you should not sign this consent form.

In the future, a new research study may be developed based off of information gathered from this study. If you agree below, your identifiable data collected as part of this research may be kept for future research studies or given to others for future approved research studies. You have the opportunity below to choose whether you wish to allow your identifiable data to be kept and used in future research. This means that because you participated in this study, you may be contacted to participate in a future research study.

HIPAA AUTHORIZATION

I. Purpose

An Authorization is your signed permission to use or disclose 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 disclose 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. A valid Authorization must include the core elements and required statements as contained in this document. **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:

The purpose of this randomized clinical trial is to determine if runners who receive video telehealth running form training are able to return to running with less pain and improved function compared to

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runners who do not receive the training. Runners who use a forefoot strike running pattern experience less impact and joint stress at the knee when compared to runners who use a rearfoot strike pattern.

Return to run programs that include telehealth feedback to alter foot strike pattern may improve strength, running-related pain, loading and landing patterns while running after a knee injury. To date, running form has largely been studied in laboratory settings with the use of expensive and complicated equipment. Recently, wearable technologies have improved substantially in quality and cost, providing the means of moving running analysis out of the lab and into the clinic. Additionally, telehealth and mobile monitoring technologies have also improved.

A. What health information will be used or disclosed?

If you choose to participate in this study the following health information will be collected; self-reported pain, demographic information (age, gender, height/weight, ethnicity), shoe type/age, past medical history related to previous injuries, prescribed pain medication, and contact information. This information will be protected. If you decide to participate in this study, you will be assigned a unique identifier upon entrance into the study and subsequently given consent forms and data collection forms with the corresponding number. A master spreadsheet document linking subject names and their subject numbers will be kept secure on a government computer assigned to the PI. The computer is password and CAC-card protected, and the system is firewall protected. This document will not be shown to anyone except for the investigators in this study or governmental agencies only in accordance with federal law.

Any data submitted to an approved agency for review will be linked only to your study number and not your personal identity (i.e., protected health information such as name, address, phone number, etc.). If the data are used in scholarly presentations or journal articles, the investigators will protect the anonymity of individual patients and will report only aggregate data (e.g. group means) where appropriate. Subjects will not be specifically identified in any publication or presentation of research results.

No identifiable information will be obtained during this study such as social security number or home address.

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

The Military Health System (MHS) will use or disclose the participant's health information, including the Armed Forces Health Longitudinal Technology Application (AHLTA), MHS Genesis, and Cadet Injury and Illness Tracking system (CIITS). Information will be obtained at Keller Army Community Hospital (KACH) Physical Therapy department, Arvin Gym Physical Therapy Clinic, and/or Mahan Hall.

C. Who may receive your health information

Only researchers involved in this specific study will have access to your health information.

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?

Yes, your health information is requested for future research studies as specified below:

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In the future, a new research study may be developed based off of information gathered from this study. If you agree, your identifiable data collected as part of this research may be kept for future research studies or given to others for future approved research studies. You have the opportunity to choose whether you wish to allow your identifiable data to be kept and used in future research. This means that because you participated in this study, you may be contacted to participate in a future research study.

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: LTC Jamie B. Morris, PT, DSc at jamie.b.morris.mil@health.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.

17. WHAT HAPPENS IF YOU 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. You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should contact the principal investigator as soon as possible. By leaving this study at any time, you in no way risk losing your right to medical care and there will be no penalty to you, and you will not lose any of your benefits to which you are otherwise entitled.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your referring physical therapist to discuss medical treatment for your condition. 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 he 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.

18. 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: LTC Jamie Morris, PT DSc
Phone: (845) 938-3067
Email: jamie.b.morris.mil@health.mil

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 Administrator: Lori Cartwright
Phone: 845-938-2680
Email: lori.d.cartwright.civ@health.mil

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@health.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.

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19. FUTURE USE OF INFORMATION:

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 choice below:

_____I *do not* give permission to use my health information for future research studies.

_____I give permission to use my health information for future research studies.

_____I *do not* authorize the storage of data collected as a part of this study for future use in research studies.

_____I authorize the storage of data collected as a part of this study for future use in research studies.

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20. 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 ADMINISTERING 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)