Research Title: Objective Dynamic and 3D Knee Assessment Medical Device to Improve Recovery and Accelerate Return to Readiness in Service Members with Knee Pain

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WOMACK ARMY MEDICAL CENTER (WAMC)
CONSENT TO PARTICIPATE IN RESEARCH
Research Title: Objective Dynamic and 3D Knee Assessment Medical Device to Improve Recovery and Accelerate Return to Readiness in Service Members with Knee Pain
Principal Investigator: Don Goss, DPT, PhD, ATC

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. Participation is voluntary. 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 Womack Army Medical Center. 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.

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

1) KEY INFORMATION:

Purpose	The purpose of this study is to assess the effectiveness of using a 3D medical assessment device versus usual care to help guide clinical decisions about the management of patellofemoral pain
Duration	12 weeks
Procedures	• Physical Therapy treatments 2 times a week for 4 weeks • 3 3D Knee Kinesiography exams will be administered by the research team (15-20 minutes for each exam) at baseline, 4 weeks, and 12 weeks
Why might you want to participate in this research (benefits)?	If placed in the intervention group, you will have a personalized plan of care based on knee biomechanics. The success of this project will help with validating a clinical tool and program to improve therapy for knee injuries in active duty service members.
Why might you choose not to participate in this research (risk)?	There is little to no physical, psychological, legal, social, or economic risk as a result of participation in this study. Any time information is collected for a study there is a chance of breach of confidentiality. All data collected will be deidentified and secured in a lock-tight area to reduce any breach of confidentiality.

What are the alternatives to participating?	Choosing not to take part in this research study is an alternative option. You can opt to continue with regular Physical Therapy care.
What is the compensation for participating?	You will not be compensated for your participation in this study.

2) WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to evaluate the value of using an objective functional knee three-dimensional (3D) assessment medical device (KneeKG – an FDA cleared class II device) for individuals with knee patellofemoral pain within the Military Health System, by assessing its effectiveness compared to care rendered without the diagnostic assistance of this device.

Secondarily, this study will explore biomechanical markers linked to knee musculoskeletal injuries in military personnel and how results from the assessment helps improve clinical care and return to duty compared to usual assessment pathways.

All participants will be randomly assigned to one of two groups.

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 between the ages of 18 to 50 years old and have reported atraumatic anterior knee pain.

4) HOW LONG IS THE RESEARCH STUDY?

Each participants' enrollment in the study will last approximately 12 weeks, with 8 physical therapy sessions within the first 4 weeks of the study. Participation involves standard rehabilitative care Physical Therapy visits.

Each visit will be 45 minutes in addition to the regular scheduled therapy sessions.

There will be about 180 people taking part in the study at Womack Army Medical Center and Tripler Army Medical Center, over a period of 2 years.

5) WHAT IS THE SCREENING PROCESS TO BE IN THIS RESEARCH STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the study team can confirm if you qualify for the study. This is the "screening process." These tests may have been done or this information may have been collected as a part of your regular medical care and rehabilitative care.

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

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. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the groups. All participants will receive standard rehabilitative care and will receive 3 KneeKG exams throughout the duration of the study to assess knee biomechanics. The KneeKG system will be placed and secured around the knee that you are seeking treatment. During the KneeKG exam, you will walk for 5 minutes on a treadmill at your comfortable speed. Three-dimensional (3D) knee kinematics will be captured on each leg using the KneeKG system. There will be two 45-second trials to electronically capture the data which is immediately accessible through automatic reports. The entire exam will take approximately 15-20 minutes. This exam will occur during your first appointment, after 4 weeks, and again at 12 weeks of care.

The intervention group will receive standard rehabilitative care, with the therapist also utilizing the KneeKG analysis information to guide care.

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.

This research study is a single blind study, which means that you will not know whether you are receiving the KneeKG informed treatment. The research team will know if you are receiving the Knee KG informed treatment.

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 KneeKG exam. However, soreness would be expected during standard rehabilitative care, and typically resolves within 2-3 days. There is a small risk that participants may fall during treadmill walking.

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 your therapist will create targeted exercises based on your knee biomechanics, if you are placed in the intervention group.

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.

12) 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. Medical Technology Enterprise Consortium (MTEC) and the Military Operational Medicine Research Program (MOMRP) provided funding for this research study. As a sponsor of this research, the Department of Defense may also have access to your research data in accordance with DoD Instruction 3216.02.

13) IS THERE A SOURCE OF FUNDING?

Medical Technology Enterprise Consortium (MTEC) and the Military Operational Medicine Research Program (MOMRP).

14) WHAT IS THE LOCATION OF THE RESEARCH?

All research activities will take place at Womack Army Medical Center and Robinson Health Clinic.

15) ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

None of the investigators have 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.

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. You can locate and read the form online (https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf), or a copy of the form can be given to you upon request.

The research team will keep your research records. These records may be looked at by staff from the WAMC Human Research Protections Program, the Defense Health Agency, 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 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 maintained by the Geneva Foundation. 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. 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 the Geneva Foundation.

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, DoD ID, or other protected identifier. All records will be maintained in a secured cabinet in a secured room at WAMC.

Information about the master key will be kept in a secure location and access limited to authorized WAMC research study personnel during the course of the study. Approved study personnel 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. With the exception of the dates on which you provide research data (to include any adverse events), personnel outside of DoD (MTEC, MOMRP) will only have access to your de-identified data. This means they can receive research data, but nothing that is linked to private information. Members of the research team within the DoD will have access to your de-identified data. Your de-identified data will go into the data repository of the study sponsor so that they can also use it in completely anonymous form for any future analyses.

The WAMC study team 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.

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 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. Your research records may be disclosed outside of the hospital, but in this case, you will be identified only by a unique code number.

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.

17) WILL YOUR INFORMATION OR SPECIMENS BE USED IN THE FUTURE?

The investigator has requested to save de-identified data collected from your participation in this research study for possible use in future research. De-identified data means that all information that could directly link your identity to the data, such as your name or other identifying details, will be permanently removed before the data is stored.

This de-identified data may be used for future research studies in areas related to this study, such as running biomechanics or gait retraining, or for other types of research studies. For example, the data from this study may be combined with data from other studies conducted at Womack Army Medical Center that you may have consented to previously that have longer term follow-up.

By agreeing to participate in this study, you are consenting to the use of your de-identified data for future research. If you do not wish for your de-identified data to be used in future research, you should not sign this consent form.

The research team at Womack Army Medical Center (WAMC) will securely destroy the master key (used to link your identity to your data) and any other paper-based research data at the end of this study. However, this consent form and HIPAA authorization will be securely maintained for six years following the study's completion.

Your de-identified data will be securely stored alongside other de-identified research data in REDCap and the Emovi system. This data will be kept indefinitely or as long as it is practical to maintain, and it may be used in future research studies or shared with other approved researchers for such purposes.

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 participating in research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

18) WHAT HAPPENS IF THE RESEARCHERS SEE AN INCIDENTAL FINDING?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

There is a possibility that while reviewing your test results, the researchers may see something abnormal that they did not expect to see in this study. This is what is called an "incidental finding."

They will let you know if they see such an incidental finding. Depending on the type of incidental finding, they may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

The researchers will also give information about this incidental finding to your primary doctor or will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

Only incidental findings will be reported to the participants, no other clinical research information.

You can opt out of receiving results of incidental findings by notifying the Principal Investigator.

19) 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. If you do not want to continue taking part in the research study, you must notify the Principal Investigator. If you decide to no longer take part in this research study, the researcher will identify and remove your data that was part of this research study.

You will no longer be eligible for research-related treatment. You will continue to receive the prescribed physical therapy treatment for your knee pain as directed. Contact your personal doctor to discuss medical treatment for your condition.

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 Investigator.

The Principal Investigator 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.

20) 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: Donald Goss, PT, DPT, OCS, ATC
Phone: (910) 907-8531
Email: donald.l.goss.ctr@health.mil
Mailing Address: 2817 Rock Merritt Road
Fort Liberty, NC 28310

Clinical Research Coordinator: Caitlin Melton
Phone: (910)703-0568
Mailing Address: 2817 Rock Merritt Road
Fort Liberty, NC 28310

Womack Army Medical Center 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.

Caryn Duchesneau, CIP
Human Research Protection Program Office
Womack Army Medical Center
2817 Rock Merritt Road
Fort Liberty, North Carolina, 28310
Email: caryn.l.duchesneau.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 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 photocopy of this document will be given to you.

21) HIPAA AUTHORIZATION

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. A valid Authorization must include the core elements and required statements as contained below.

The consent above describes the purposes of the requested use and disclosure of your health information. 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. If you do not wish to give permission to use and disclose your health information, you may not be able to participate in the study.

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, 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, SSN, 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.

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 MHS Genesis. Information will be obtained at Womack Army Medical Center (WAMC) or an affiliated clinic.

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?

You do not have to sign this Authorization, but if you do not, you will not receive research-related treatment.

The MHS **will not** refuse treatment that is not part of this study, payment, enrollment, or eligibility for benefits based 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. However, your fully de-identified data collected from this study may be used in a completely anonymous form for any future analysis.

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: Dr. Donald Goss at donald.l.goss.ctr@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.

22) 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 as described in the HIPAA Authorization;
- 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 approved to administer consent)

_____
Printed Name of Administering Individual

_____ __ __ / __ __ __ / __ __ __ __
Signature of Administering Individual Date (DDMMMYYYY)