Virtual Exercise Rehabilitation In-home Therapy: A Randomized Study (VERITAS)

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Consent to Participate in a Research Study
VERITAS (**V**irtual **E**xercise **R**ehabilitation **I**n-home **T**herapy - **A** randomized **S**tudy)

Thank you for considering participation in the VERITAS research study. This study is being conducted by <<insert site PI>> and their research staff, in conjunction with Duke Clinical Research Institute (DCRI). Reflexion Health is funding this study. Dr <<insert site PI>> and their research staff will be compensated for conducting this study at <<insert Institution name>>.

You are being asked to take part in this research study because you have been identified as a candidate for total knee replacement (TKR) surgery. This study will involve up to 300 patients like you, enrolled from approximately 6 different sites across North Carolina. Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision. Ask your study doctor or study staff to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

WHY IS THIS STUDY BEING DONE?

This study will compare the cost and outcomes of a using a virtual rehabilitation (also called tele-rehab) platform compared with standard in-person rehabilitation to deliver physical therapy following total knee replacement (TKR) surgery. Successful post-operative tele-rehabilitation following TKR has been documented, and it is thought that the use of telemedicine may improve quality, increase access, and lower healthcare costs. However, availability of a physical therapist and the need for expensive hardware are seen as potential barriers to implementation. Virtual rehab platforms seek to address these problems but have not been widely evaluated.

WHAT WILL HAPPEN DURING MY CLINIC VISIT?

In order to participate you will have to complete the following activities before you leave today:

- If you agree to be in this study, you will be asked to sign this **Consent Form**. This form confirms that the procedures, risks and benefits have been explained to you, that you have been allowed to ask questions, and your questions have been answered to your satisfaction.
- You will also be asked to sign a **Medical Release Form**. This form gives study personnel and DCRI permission to collect copies of your medical records, if needed, throughout the course of the study. This provides information about your care and visits.
- You will be asked to complete a confidential **Patient Contact Form**. This form collects information such as your address and phone numbers, as well as contact information of family members or close friends whom you designate to respond in the event that you are unable to do so. This contact information will be available to <<insert site name>> and representatives of the DCRI so that we may contact you for follow-up interviews after hospital discharge. If you are assigned to the virtual system, this information will also be shared with Reflexion Health so they can schedule installation and removal of the system in your home.

- You will be **randomly assigned** (like the flip of a coin) to receive your pre- and post-surgery physical therapy through either traditional in-person visits, or through the virtual rehab platform installed in your home.
- You will complete several **basic assessments** about your knee function, including your gait speed (how quickly you can walk a short distance) and your level of pain.
- You will complete several **questionnaires** related to your knee feeling and function, your satisfaction with your physical function, and your perception about your overall health. You will be asked to select a personal recovery goal related to your knee function from a short list of options. You also will be asked about hospitalizations and falls in the previous 3 months, your living situation, and your comfort with using technology.
- You will be provided a **diary worksheet**, which you'll use after your surgery to keep track of any appointments with an in-person physical therapist. You will also be asked to track any visits or phone calls to a doctor, urgent care center, emergency room, or hospital. You will also use the diary to record your weekly progress on your personal recovery goal using a scale from 1 to 10.
- A member of your healthcare team will **review your medical record** after your visit to collect information about demographics, medical history, and basic vital signs like height and weight.

WHAT WILL HAPPEN AFTER MY CLINIC VISIT?

- **Before you are discharged** from the hospital following your surgery, a member of your healthcare team will measure your gait speed and level of pain, and also review your chart for information about any falls you had while hospitalized.
- You will **return to your surgeon's office** approximately 6 weeks after your surgery, so the surgeon's staff can see how you are doing. They will measure your level of pain, gait speed, and range of motion in the operated knee. This is standard care for all patients following TKR surgery.
- You will be contacted for the study via telephone by the DCRI Call Center about **6 weeks after your surgery** to complete an interview about falls, your level of pain, your knee feeling and function, and how closely you followed the physical therapy regimen you were prescribed. The Call Center also will collect information about your healthcare encounters and your weekly progress on your recovery goal from the diary you have been keeping. This phone call will last approximately 25 minutes.
- The DCRI Call Center will contact you again via telephone a**bout 12 weeks (3 months) after your surgery** to complete an interview about falls, your level of pain, your knee feeling and function, your satisfaction with your physical function, and your perception about your overall health. The Call Center also will collect information about your healthcare encounters and your weekly progress on your recovery goal from the diary you have been keeping. If you were assigned to receive virtual physical therapy, we will ask you your feelings about the virtual system. This phone call will last approximately 20 minutes.

HOW WILL MY PHYSICAL THERAPY OCCUR?

You will be prescribed a regular physical therapy regimen for patients undergoing TKR surgery, according to the standard of care. This study will randomly assign you to receive this therapy either using the virtual platform, or using traditional in-person visits.

- If you are randomized to the virtual platform, a representative of Reflexion Health will contact you to schedule installation of the system in your home prior to surgery. Your physical therapy will be delivered on the virtual system with oversight and guidance of a study physical therapist from Duke University's Department of Physical and Occupational Therapy (PT/OT). The study therapist will set a time convenient for both of you to conduct a virtual appointment to meet each other and ensure you are comfortable with the virtual platform. The study therapist will also use the virtual platform to prescribe exercises and monitor your progress before and after your surgery, as well as schedule virtual check-ins as needed.
- If you are randomized to traditional in-person therapy, your surgeon will provide a referral to a physical therapist as he/she would normally do, and your therapy will be completed via in-person visits with your local therapist. Your surgeon will decide if your physical therapy should begin before or after your surgery. The local therapist will prescribe exercises and monitor your progress.
- Regardless of your assignment, the therapist treating you will collaborate with your surgeon to determine how long you need to participate in therapy after your surgery. Usually this lasts about 6 weeks, but it may be shorter or longer for you, depending on how well you are recovering. Either your surgeon or your therapist will tell you when your therapy is complete. Once you have been told that you no longer need therapy, if you were randomized to the virtual platform, a representative from Reflexion Health will contact you to schedule pick-up of the system from your home.

HOW LONG WILL I BE IN THIS STUDY?

Today's portion of the study will take approximately 20-40 minutes. The DCRI study team will contact you by phone about 6 weeks after surgery, and again about 12 weeks after surgery. All other visits with your healthcare provider will occur as they normally would. Your participation will last until the time you have completed your last interview, which will be about 12 weeks (3 months) after surgery. You can choose to stop participating at any time, and it will not affect any rights or benefits to which you're otherwise entitled.

ARE THERE ANY RISKS TO ME?

Participating in this study will not change the care you receive for your knee. Your doctor will perform surgery, and present you with the same medications, activities, and other therapies, including physical therapy, as you would receive if you didn't participate.

Regardless of your randomization assignment, you would be instructed to complete certain exercises and activities at home as part of your physical therapy. The only difference will be in how the physical therapy instructions are delivered to you. This means that there are no extra physical risks associated with this study beyond those you would experience normally in the course of completing your physical therapy exercises and activities. You will be able to contact

your assigned therapist with questions. If you are assigned to the virtual system, you will receive immediate feedback if you are performing an exercise incorrectly at home, and this may make you feel more comfortable about your exercises.

Some of the survey questions we ask might make you feel uncomfortable or anxious. You can take a break, refuse to answer any of the questions, or stop your participation completely at any time during the study. If you mention having feelings about wanting to harm yourself, we'll make sure to refer you to a doctor who will talk to you about these feelings. There is a risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

WHAT ABOUT MY PRIVACY?

Federal Privacy Regulations govern the privacy, security, and authorized access of your private health information. If you agree to participate, your contact information will be shared with DCRI so they can reach you to complete the follow-up interviews. If you are randomized to the virtual system, your contact information will also be shared with Reflexion Health to schedule installation and removal of the virtual system from your home, and your date of birth will be entered into the virtual system in order to create your user profile. Additionally, your initials may be included on study records to help DCRI link all of your study data together for analysis. DCRI may use your address for calculations (for example, distance from the therapist's office) to analyze the relationship between location and healthcare delivery. After the data are linked and these calculations are complete, your date of birth, initials, and address will be removed from the database. You will not be identified in any analyses.

Except when required by law, no other personal identifiers from your study records will be shared outside of <<insert site name>> or the Duke Clinical Research Institute (VERITAS study coordinating and follow-up center). For records shared outside of <<insert site name>>, you'll be assigned a unique code number. The link between your identity and your study code will be stored electronically in a secure, password-protected database at DCRI. By agreeing to participate, you'll be giving permission for DCRI to access and share your health information for this research study. You don't have to give permission, but if you do not, then you won't be able to participate in the study

All information transferred to DCRI will be encrypted over a secure connection and only accessible by authorized DCRI personnel. The data that DCRI receives from study sites will be coded with a unique code number. Patient information will be entered by the <<Insert Institution name>> study team, and stored and maintained on a secure password-protected electronic data collection (EDC) system. Likewise, information you provide during the interviews will also be entered into a secure, password-protected data capture system. You will receive a copy of the signed informed consent.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the sponsor of this study (Dr. Bettger), the funding source (Reflexion Health), the DCRI study team, and <<*insert IRB name here*>> Institutional Review Board. If any of these groups review your research record, they may also need to review your entire

medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations. If disclosed by outside reviewers, the information is no longer covered by the federal privacy regulations. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WILL THIS COST ANYTHING?

There are no costs for participating in this study. Because you'll receive regular medical care for your condition, the costs of your regular care will be charged to you or your insurance, whether or not you choose to participate in this study.

WILL I BE COMPENSATED?

As a token of appreciation for your time and effort, you'll be compensated up to $150 by <<insert site name>> for participating in this study. Since your participation will occur over several weeks, this may be split into multiple payments totaling $150.

WHAT ELSE SHOULD I KNOW?

If you agree to participate, you're giving permission for access and sharing of your health information, but only for this research study. If you withdraw from the study, no new study information will be collected about you.

- **If I change my mind?** If you decide to withdraw your consent and authorization, please contact <<insert PI name>> in writing and let him/her know that you are taking back your permission. The mailing address is <<insert site address.
- **If I get injured?** If by chance you're injured as a result of participating in this study, immediate necessary medical care is available at <<insert site name here>>. However, there is no commitment by <<insert site name>> or any of the study sponsors to provide monetary compensation or free medical care to you if something happens.
- **If new information becomes available?** We'll tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor, <<insert site name>>, or regulatory agencies may stop your participation in this study if they feel it's in your best interest. If this occurs, you'll be notified and your study doctor will discuss other options with you.
- **If I have questions about the study?** For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, please contact <<insert PI name>>, or <<insert institution name>> study staff. The contact information is <<insert contact info, including a 24-hour number>>.
- **If I have questions about participating in this research?** For questions about your rights as a research participant; to discuss problems, concerns or suggestions related to the research; or to obtain information or offer input about the research, you may contact <<insert site IRB here>> at the following number <<insert IRB phone number/contact info>>.

STATEMENT OF CONSENT

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told who to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.

_____ _____ _____
Signature of Subject Date Time

_____
Printed name of Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed name of Person Obtaining Consent