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INTEGREVIEW IRB
JUNE 24, 2018

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

Lagniappe Physical Therapy

PROTOCOL NUMBER AND TITLE OF STUDY: 4357; "Traditional Home Health Physical Therapy Versus a Smartphone App for Patients Recovering from Total Knee Arthroplasty During the Home-bound Portion of Recovery: Study Protocol for a Randomized Controlled Trial"

NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (INVESTIGATOR): Dr. Eric M Rippetoe, PT, DPT

TELEPHONE NUMBER(S), DAYTIME & AFTER HOURS: 318-560-5726

INTRODUCTION

You are deciding if you would like to volunteer for a medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

The investigator is the sponsor, and is paying for this study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

PURPOSE OF THE STUDY

This study is an investigational treatment via smartphone application to provide physical therapy prescriptive exercise and other important information during the home-bound portion of rehabilitation following total knee replacement surgery.

"Investigational" means the smartphone app being tested is not approved by the Louisiana Department of Health or the US Food and Drug Administration. The purpose of this study is to determine if a smartphone app is an effective replacement for home health services following total knee replacement surgery.

If you qualify for the study, you will receive:

- Two visits from a licensed physical therapist to collect initial and follow-up data
- A smartphone application with relevant information regarding prescriptive exercise and other post-operative important information
- Contact information for a physical therapist to address any questions/concerns regarding the study and/or the participant's (your) recovery

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HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will last from when you are discharged home from the hospital until you transfer to outpatient physical therapy, which is usually about 2 to 4 weeks after being discharged from the hospital following your surgery. The study protocol requires 2 at-home visits by the investigator, Dr. Eric M Rippetoe, PT, DPT. About 30 men and women, ages 45 through 64, who are undergoing total knee replacement on only one knee, and who have been discharged directly to home, are expected to be in this study.

TO BE IN THIS STUDY

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator if you change your mind about staying in the study.
- Be willing to use the smartphone app 3 to 5 times per day as able and follow all instructions to the best of your ability
- The app must be used at least once in every 24-hour period and within 24 hours of returning home from the hospital, if not, the participant will not be allowed to continue with the study and will require transfer of care to a home health provider of the participant's choosing.

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to sign this consent form, give your health history, and tell the investigator of all medications currently being taken.

Study Procedures:

- Upon being discharged to home from the hospital, the investigator, Dr. Eric M Rippetoe, PT, DPT, will perform the initial visit within 48 hours to collect initial data and to demonstrate proper use of the app to the participant
- The participant is to use the app 3 to 5 times daily as able according to the instructions in the app
- The investigator, Dr. Eric M Rippetoe, will be available by phone or e-mail to address questions or concerns related to the participant's recovery or the use of the app
- The investigator will check-in periodically with the participant to ensure proper participant compliance with the app and the app's instructions.
- If the participant does not engage with the app over any 24-hour period, the investigator, who is a licensed physical therapist, will obtain orders from the participant's physician for the participant's care to be transferred to a home health provider. The participant may choose their home health provider. Once the participant's care has been transferred to a home health provider, the participant will no longer be under the care of Dr. Eric M Rippetoe, PT, DPT. **Any costs associated with**

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receiving home health services will be billed directly to the participant or their insurance company.

- Once the participant is ready to begin outpatient physical therapy, usually 2 to 4 weeks following hospital discharge, Dr. Eric M Rippetoe, PT, DPT will perform a follow-up visit for the final data collection.

POSSIBLE RISKS

If you do not understand what any of these risks mean, please ask the investigator or study staff to explain these terms to you.

Because this smartphone app is investigational, all of the risks may not be known. Some risks may be life threatening.

You must tell the investigator or study staff about all negative events that occur. If you are not honest about negative events, you may harm yourself by staying in this study. Such events may include: falls, suspected blood clots, suspected infection, or worsening overall condition of post-operative knee.

POSSIBLE BENEFITS OF THE STUDY

Participants in this study will save on costs associated with the home-bound portion of recovery from total knee replacement surgery, which can range anywhere from about $500 with insurance to about $3700 without insurance. Additionally, you will receive a chance to be in a research study that may help others save significant costs in the future.

There is no promise that your condition will get better. It might stay the same or it might get worse.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study. A study participant may opt-out at any time during the study. If a participant opts out of the study, Dr. Eric M Rippetoe, PT, DPT will obtain orders on the previous participant's behalf to receive home health care at the previous participant's home health care provider of choice. This is done to ensure that the previous participant receives the appropriate standard of care to ensure optimal outcomes following total knee replacement surgery, not as punishment for failing to complete the study. **Any costs associated with receiving home health services will be billed directly to the participant or their insurance company.**

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- State or federal regulatory agencies
- IntegReview IRB

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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 the results. You can search this Web site at any time.

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, **your name will not be used.**

IN CASE OF STUDY RELATED INJURY

No other form of compensation is offered in case of study-related injury.

If serious injury occurs during this study, the participant should contact the medical doctor who performed the surgery, if they are not available, go to the emergency room.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Dr. Eric M Rippetoe, PT, DPT
Phone: 318-560-5726
E-mail: errippetoe@aol.com

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

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If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study. However, the participant will save money by participating in the study rather than receiving traditional home health services. The participant may be saving between $500.00 and $3700.00.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. You can switch to using traditional home health services at any time.

The investigator, the sponsor company, IntegReview, or the FDA may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health
- If you do not engage with the smartphone app over any 24-hour period while involved with the study
- If you do not engage with the app within 24 hours of returning home from the hospital following surgery

If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study may still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

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THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will receive a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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HIPAA AUTHORIZATION

- The private health information (PHI) to be disclosed includes only hospital discharge destination, age of participant, type of surgery performed, knee range of motion (ROM), and a questionnaire called the ShortMAC that scores the participant's functional abilities
- The participant's PHI will be obtained from the participant by the investigator.
- Use of the above PHI will be used in the research study and may be published. Only the PHI necessary to determine the outcomes of the treatment will be used, all identifying information for the participant (name, address, date of birth, etc.) will be kept private and not disclosed.
- The PHI received in the study will be used to determine if the treatment is effective.
- This HIPAA Authorization remains effective until the end of the research study.
- The individual's signature and date, and if signed by a personal representative, a description of his or her authority to act for the individual
- The individual may, at any time, revoke this authorization in writing. To do so, please write to the investigator, Dr. Eric M Rippetoe at the following e-mail address: errippetoe@aol.com with the subject: HIPAA Authorization Removal
- The study participant may choose to re-disclose their PHI, at which time, it will no longer be protected by the Privacy Rule under federal or state law.

_____

Signature of Study Subject Date