COMIRB
APPROVED
For Use
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Principal Investigator: Dr. James Genuario
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Study Title: Comparison of Methods in Post-Operative Knee Arthroscopy Rehabilitation

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part

Why is this study being done?

This study plans to learn more about the efficacy of blood flow restriction (BFR) therapy in patients after surgery. You are being asked to be in this research study because you will have, or have recently had, an arthroscopic procedure in your knee.

Other people in this study

Up to 120 people from your area will participate in the study.

What happens if I join this study?

If you agree to participate in this study, you will randomly be placed in one of the groups. This study will have two different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care. Each group will complete a different exercise program for 12 weeks. Following the 12-week point, both groups will continue with the same standard of care exercise program for therapy.

Group 2 will use a Saga Fitness Blood Flow Restriction cuff as a part of their exercise program. This is an automated cuff that placed on the upper thigh to restrict blood flow to effect muscle growth from exercise. The cuff is controlled via a mobile app that uses Bluetooth capabilities. If you are randomized into this group, and you have a smartphone, you will be provided training on the cuff use and provided with an instruction sheet on how to use the app to reference at any time. You will complete your physical therapy exercises while using the cuff, vs Group 1 will complete the same exercises without the use of the cuff. These exercises are standard of care. *Please note that to use the app, you will need to read and accept the app's terms and conditions.*

Regardless of your group, you will be expected to complete surveys at baseline, 3 weeks, 6 weeks, 12 weeks, 6 months, 9 months, 1 year, and 2 years from surgery. Some of these surveys are considered standard of care, however there are some that will be asked more frequently than if you were not in the study. Surveys will be sent by and stored in an electronic system called PatientIQ. A link will be sent by PatientIQ via text or email to be completed in a prompt manner. An athletic trainer will measure strength, motion, and function measures to be collected at 6 weeks, 12 weeks, and 6 months from

surgery, and at discharge to add to the study's data collection. They will not be aware of your exercise group.**What are the possible discomforts or risks?**
Discomforts you may experience while in this study include muscle soreness from exercise. There is a very small risk of rhabdomyolysis, venous thrombosis, and pulmonary embolism from the exercise programs as well.

The definitions of these risks provided by the CDC are as follows: Rhabdomyolysis- "(often called rhabdo) is a serious medical condition that can be fatal or result in permanent disability. Rhabdo occurs when damaged muscle tissue releases its proteins and electrolytes into the blood. These substances can damage the heart and kidneys and cause permanent disability or even death." Venous Thrombosis & Pulmonary Embolism-"Deep vein thrombosis (DVT) is a condition in which a blood clot develops in the deep veins, most commonly in the lower extremities. A pulmonary embolism occurs when a part of the clot breaks off and travels to the lungs, a potential life threat."

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed. If you become pregnant, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus, which are currently unclear

You will be assigned to a study treatment by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments. The study may include risks that are unknown at this time.

What are the possible benefits of the study?
This study is designed for the researcher to learn more about specific rehabilitation programs and how they affect recovery. There is a possibility that the exercise program may help in your recovery, but it is not guaranteed.

Are there alternative treatments?
There may be other ways of treating your rehabilitation after knee arthroscopy. These other ways include standard of care physical therapy. You may also elect to receive knee rehabilitation at an outside physical therapy location of your choice. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?
This research is being sponsored by Saga Fitness, the manufacturer of the device, through the donation of the devices.

Will I be paid for being in the study?
You will not be paid to be in the study.

Will I have to pay for anything?

You and your insurance will have to pay for all of the visits, procedures and care described in this consent form. You will be responsible for co-payments and deductibles that are standard for your insurance coverage. There will be no additional research specific visits or procedures that will be billed to you.

The study device will be provided at no cost to you. However, you will be expected to return the device at the end of your treatment period.

If you need more information about these costs, please discuss this with your study team or contact UCHealth Billing and Estimates at 877-349-8520.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time. If you become pregnant during your participation in the intervention portion of the study, you will be removed from the study.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should call Dr. James Genuario immediately. His phone number is 720-516-9824.

In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

Who do I call if I have questions?
The researcher carrying out this study is Dr. James Genuario. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Alexandra Orahovats at 720-516-9824 or Lauren Heylmun at 720-516-9823. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. James Genuario with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.
A description of this clinical trial will be available on http://www.Clinical Trials.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.

Who will see my research information?
The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:
- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation. We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. James Genuario
175 Inverness Drive West
Englewood, CO 80112

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:
- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private. You have the right to request access to your personal health information from the Investigator.
The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to: Rocky Vista University.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Billing or financial information

What happens to data that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

[**If Applicable**, Signature Line for studies including children ages 16-17 who can read this form]

- Use the following only if applicable - - - - - - - - - - - - - - - - - -

Signature: _____ Date:_____

(Child Subject 16-17 years old; ***In addition*** to Parent Signature)

Print Name:_____

Arm: _____

Cuff Number: _____

Return by: _____