Does a Virtual Coach Offer a Better Solution for Weight Reduction in Ventral Hernia Patients with Obesity?

PI: Dr. Jana Sacco

NCT05797974

Informed Consent Form

03/20/2023

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM to Participate in Research, and AUTHORIZATION to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Does a Virtual Coach Offer a Better Solution for Weight Reduction in Ventral Hernia Patients with Obesity?

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Dr. Jana Sacco at 904-244-3943

4. Who is paying for this Research Study?

The sponsor of this study is the University of Florida.

5. In general, what do you need to know about this Research Study?

This research is to use a virtual coach to assist hernia patients overcome the difficulties that prevent weight loss before having ventral hernia surgery. Agreeing to become involved in any research is always voluntary. By signing this form, you are not giving up any of your legal rights. If you decide not to take part in this research, it will not be used against you in any way and you will not lose any benefits to which you are allowed. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of the research is to judge the value of a virtual coach for persons with a hernia who are advised to lose weight before any surgery can be carried out. You will be part of the study for six months.

b) What is involved with your participation, and what are the procedures to be followed in the research?

A smart phone or computer is necessary to use the virtual coach through MyChart. The virtual coach will be available for you to ask questions about obesity and advice on weight loss. The virtual coach will also involve a monthly weight check in to record your progress in losing weight.

c) What are the likely risks or discomforts to you?

This research does not involve anything done to you, so there is likely no risk of discomfort from taking part in the study. The investigators for this research feel there are no identified risks or discomforts associated with your participation. Although there are currently no identified risks or discomforts associated with your participation in this research study, there may be risks that are unknown at this time.

d) What are the likely benefits to you or to others from the research?

There are likely no direct benefits to you. However, the information learned through this research could possibly effect the preoperative care for hernia patients in the future.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

There are no other techniques or practices for your care. You may choose not to take part in this study and undergo your hernia repair surgery after losing weight by following a weight loss program of your own choosing without taking part in the research.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

As part of your normal clinical care, you will receive preoperative treatment prior to your hernia surgery.

7. What will be done only because you are in this Research Study?

If you agree to take part in this research study, you will be asked to either 1) use the MyChart-enabled virtual coach to assist with weight loss prior to your hernia surgery, or 2) engage in your own method to lose weight before your hernia surgery.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Demographic information (age, sex, race, ethnicity, Body Mass Index, address with zip code)
- Results of physical exams (weight)
- Medical history and prior hernia surgeries
- Area Deprivation Index (a measure of neighborhood disadvantage)

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- government agencies which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state and local health departments,
- and the IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Your participation in this research will last six months. This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

At least 60 people are expected to take part in this Research Study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

The investigators for this research feel there are no identified risks or discomforts associated with your participation. Although there are currently no identified risks or discomforts associated with your participation in this research study, there may be risks that are unknown at this time.

This Research Study may also include risks that are unknown at this time.

Please note, taking part in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

There are likely no direct benefits to you.

13b. How could others possibly benefit from this Research Study?

Information learned through this research could possibly improve the preoperative care for hernia patients in the future.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

You may choose not to take part in this study and undergo your hernia repair surgery without being a part in the research.

You may also refuse to give permission to use your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other care you may be able to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise allowed. If you decide to withdraw your consent to take part in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or released to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be removed from this Research Study without your consent for the following reasons:

- You no longer meet the study conditions to be included.
- The study is cancelled and/or other administrative reasons.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

Any medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, or co-payments for those services, and any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information.

17. Will you be paid for taking part in this Research Study?

You will receive a $25 gift card upon completion of all research activities.
Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address,

date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured while in this Research Study?

Since this is an observational study, there is a very low risk of study-related injury. However, If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands/UFHJ hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered.

The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Sacco at (716) 901-5355 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

I understand the two options associated with taking part in this Research Study and agree to participate in the group identified by my initials below.

☐ I agree to participate in the group that will use the MyChart-enabled virtual coach to assist with weight loss prior to hernia surgery.

☐ I agree to participate in the group that will not use the MyChart-enabled virtual coach to assist with weight loss prior to hernia surgery.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You freely agree to take part in this study. You hereby give permission to collect, use and share your protected health information as described above. By signing this form, you are not giving up any of your legal rights.

Signature of Person Consenting and Authorizing Date