Official Title: Utilization of Virtual Care in Postoperative Patients to Improve the Patient Experience
IRB-Approved Date: 7/9/2019
NCT03258177

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Utilization of Virtual Care in Postoperative Patients to Improve the Patient Experience
Principal Investigator: Caroline Reinke, MD

Instructions:
This form may have words that are new to you. If you read any words that you do not know, please ask the person who gave you this form to explain them to you.

INTRODUCTION

Dr. Caroline Reinke and Kristen Harkey, DNP are asking you to participate in this research study to evaluate virtual care visits after surgery for patients who have had an appendectomy (removal of the appendix) or a cholecystectomy (removal of the gallbladder). This study is being done at Carolinas Medical Center - Main, Carolinas Medical Center - Mercy, Myers Park General Surgery Clinic, and Atrium Health (AH). You are being asked to take part because you are going to have or have had your appendix or gallbladder removed. After your surgery, you will have a follow-up visit.

The purpose of this study is to better understand whether virtual care visits after surgery will:

- not increase the number of hospital visits after surgery
- help save time and costs
- give the same or better patient satisfaction and convenience.

About 1,000 people will take part in this study at Atrium Health. Taking part in this study will last 30 days or until your care after surgery is complete. This depends on whichever occurs last.

This study is partly supported by a grant from the American College of Surgeons. Part of the research team's salaries is paid for by this grant.

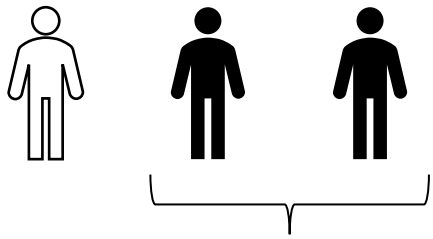
Participation in research studies is completely voluntary. If you are interested in learning more about this study, please continue reading.

HOW THE STUDY WORKS

If you agree to be in this study, your follow-up visit after surgery will be either:

- A virtual visit, or
- A typical in-person clinic visit.

You will be given the type of visit at random (like drawing numbers from a hat). You have a 2 out of 3 chance of receiving a virtual visit.



Out of 3 people taking part in this study, 2 people will have a virtual visit.

The paperwork you receive when you leave the hospital (at discharge) will tell you what type of follow-up visit you will have and how to schedule your visit.

A virtual visit will allow you to receive care from a medical professional via a tablet, smartphone, or computer. It will need to have a camera, microphone, and internet access. The virtual visit technology uses a patented system that makes sure each visit is secure and confidential.

Virtual Visit Group

How to Enroll and Register:
If you are put into the virtual visit group, you will get information about how to enroll in virtual care.

You will get instructions about how to download the Atrium Health Virtual Visit mobile application (app) or access the website. You will use the app or website to register for virtual care and complete your follow-up visit. You will be given a Virtual Surgery Care helpline phone number that you may call for help downloading the app and registering.

The Atrium Health Virtual Visit app is available on the Apple App Store and Google Play Store. This app and website were created by American Well which is a telehealth service provider. American Well connects patients with medical professionals using mobile and web technology. You should read the terms of use for the app and website. If you mark that you accept them, the terms will apply to you.

You will need to enter information about yourself to enroll in a virtual visit. This information includes your name, date of birth, gender, and contact information. You will also need to create a password. It is free to download the app and enroll in virtual care. You must do these steps before having a virtual visit.

Scheduling a Virtual Visit:
Please call the Virtual Surgery Care helpline to schedule your virtual visit and confirm registration. You will need to be in North Carolina or South Carolina at the time of your visit.

You will need to use your own device and use an internet connection. The virtual visit will use either your device's data or Wi-Fi. This depends on how you are connected. We recommend you use Wi-Fi for the best video connection. If you do not have an unlimited data plan and you do not use Wi-Fi, you may have more charges to your data plan.

The Virtual Visit:
The virtual visit will follow the same format as a visit in a clinic, but we will not take your vital signs (heart rate, temperature, and blood pressure). Also, a medical professional will not be able to touch where you had your surgery. Virtual visits will be scheduled for the start of the week. This is so if you need more care you can go to an in-person clinic visit in the same week.

You may be asked to go to an in-person clinic visit if:
- you are admitted to the hospital before your scheduled follow-up visit;
- there is a problem with the virtual visit technology that cannot be fixed;
- during the virtual visit the medical professional is unable to fully evaluate you; or
- you need more care.

In-Person Visit Group
If you are put into the in-person visit group, you will schedule a follow-up visit at a clinic. You will not register for a virtual visit.

Both Groups
You will be asked to complete a confidential survey. It will help us know more about your experience with your follow-up visit. The survey will be emailed to you on the day of your follow-up visit. You will be emailed a second survey 30 days after your surgery. This survey will ask about problems you may have experienced. If you do not complete the surveys, you will be sent an email reminder. Also, research staff may call you to complete the survey over the phone or follow-up with you if you had any problems.

We will collect more information about you to learn more about virtual visits after surgery. This includes:

- your demographics (age, sex, race, etc.)
- your medical history
- the amount of time your follow-up visit took
- travel cost and time,
- if you need more follow-up care, and
- if you had complications (other health problems) because of or after your surgery.

RISKS AND DISCOMFORTS

We will do all we can to keep your information confidential. However, there is some risk of loss of confidentiality. Some items in the survey may make you feel uneasy. If you feel uneasy, you may choose to not complete the survey.

If you are a part of the virtual visit group, when a complication is diagnosed may affect your care. To lower this risk, virtual visits will be scheduled for the start of the week. This will let you go to an in-person clinic visit in the same week if you need more follow-up care or you cannot be fully evaluated during the virtual visit. If you have an extra visit, it could be an inconvenience.

BENEFITS

There are no anticipated direct benefits to you if you choose to take part in this study. The information we learn from this study may help others with your condition.

EXCLUSION CRITERIA

You are not eligible (allowed) to take part in this study if you:

- cannot complete a virtual visit because you do not have the needed technology, needed technology skills, or other reason;
- do not have an email address;
- do not live in North Carolina or South Carolina;
- are admitted from or discharged to an assisted living facility, skilled nursing facility, or a location other than home; or
- have chronic (long-lasting) pain for which you take narcotic medication.

ALTERNATIVE PROCEDURE/TREATMENT
The alternative to participation is to complete a typical in-person clinic visit as your follow-up visit and not complete the surveys.

ADDITIONAL COST
You will not pay extra money to take part in this study.

COMPENSATION
You will not be paid for taking part in this study.

WITHDRAWAL
Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

The researchers may choose to remove you from the study if there is a medical condition, event, or situation that makes taking part in the study not in your best interest.

CONFIDENTIALITY
The records of this study will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

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.

AUTHORIZATION
If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study investigator to collect and process any relevant personal health information

collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigators (Caroline Reinke, MD and Kristen Harkey, DNP), and research staff,
- regulatory or other governmental authorities of the United States and other countries,
- Atrium Health employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- compare and pool results with those of other subjects in the research study,
- evaluate postoperative virtual visits.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Atrium Health.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor, Caroline Reinke, MD (phone: [redacted]) in writing at the following address: CMC Surgery, [redacted]. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL INTEREST OF INVESTIGATOR

The doctors will receive no financial benefit in any form by asking you to participate in this study.

QUESTIONS

The researchers doing the study at Atrium Health are Dr. Caroline Reinke and Kristen Harkey, DNP. You may ask them any questions you have now. If you have questions later, you may contact Dr. Caroline Reinke at:

Department of Surgery
[redacted]

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Atrium Health for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling [redacted] or by email at [redacted]

(This space intentionally left blank.)

CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. I will receive a signed copy of this form.

_____	_____	_____
Patient [representative] Print Name	Date	Time
_____	_____	_____
Patient [representative] Signature	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____	_____	_____
Investigator Signature	Date	Time

Identity of representative:
___Next of Kin
___Parent/Guardian
___Healthcare Power of Attorney