The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Evaluating patient satisfaction with 2-week post-operative virtual visits compared to in-office visits: A randomized control trial
Principal Investigator: Lindsay Valentine, MD; 216-445-1735

After hours phone contact #: 216-444-2200, ask for GYN on call

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are having a minimally invasive (tiny cuts in the skin) hysterectomy (removal of the uterus). Currently, our surgeons offer either in-office or virtual postoperative visits. The purpose of this study is to look at patient satisfaction with virtual postoperative visits compared to in-office postoperative visits after minimally invasive hysterectomy.

You will either have a two week in-office postoperative visit or a two week virtual postoperative visit with a certified nurse practitioner (CNP). You will fill out questionnaires asking about how you feel. Everyone will have a six week in-office postoperative visit.

Your participation in the research will last about 6 weeks.

More detailed information can be found under the section labeled: “Information on the Research.”

Why might you choose not to participate in this research study?

You may choose not to participate in this research study if you want to have your first postoperative visit in office.

More detailed information about the risks of this study can be found in the section labeled “Risks.”

Why might you choose to volunteer for this study?

You may not receive direct benefit from being in this study. However, taking part may help patients undergoing hysterectomy receive better care in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?

The alternative to being in this study is to not take part. Your care will not be affected if you do not take part.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

This study is being done to evaluate safety and patient satisfaction with virtual postoperative visit compared to in-office postoperative visits after minimally invasive hysterectomy (removal of the uterus). You are being asked to participate in this research because you are undergoing a minimally invasive hysterectomy, either a laparoscopic hysterectomy, vaginal hysterectomy, or robotic hysterectomy.

How Many People Will Take Part in this Study?

Approximately 180 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

If you decide to take part in this study, you will be assigned to either a virtual two week postoperative visit or an in-office two week postoperative visit. A process will be used to assign you, by chance like the flip of a coin to one of the study groups. Neither you nor your doctor can choose which group you are in. You will have an in-office six week postoperative visit. You will fill out a questionnaire sent to your email about your care and how you feel after your two-week postoperative visit. You may receive a phone call by study staff reminding you to complete the questionnaire.

How will my data be used?

Your data will be used within the Cleveland Clinic. Information you provide us will be de-identified, or stored without your name or other personal information with it.

Use of Mobile Devices/Apps
One requirement for participation in this study is the ability to complete virtual visits. This requires use of your personal electronic device, whether a smartphone, tablet, or computer with video capability. Virtual visits are conducted via MyChart using Zoom.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

The alternative to participation in this research study is to not take part. If you do not take part, we currently offer both in-office or virtual visits as our standard of care. You will be able to choose whether you want an in-office or virtual two week postoperative visit. All two week postoperative visits (within and outside the research study) will be with certified nurse practitioners (CNPs).

3. RISKS

What are the risks of participating in the research study?

The Cleveland Clinic has instituted telemedicine and virtual visits in all specialties. There is no data that virtual postoperative visits are less safe than in-office visits. Therefore, there is no known increased risk of participating in this study.

Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards:

If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

If you are assigned to have a virtual visit as part of this study, you will be asked to use a personal electronic device (smartphone, tablet, or computer with video capability) to complete that visit. Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that

collected for research purposes may be captured and used by others not associated with this study.

Questionnaire/Survey Research

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

4. BENEFITS

What are possible benefits of participating in the research?

There is no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society or science.

5. COSTS

Are there any costs to you if you participate in this study?

There is no additional cost to you to be in this research study. All postoperative visits (both within and outside of the study) are included in the cost of your surgical procedure. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

6. PAYMENT

Are there any payments to you if you participate in this study?

There is no financial compensation for participating in this study.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

There is minimal risk associated with this research study.

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If

you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to

ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, **Lindsay Valentine MD, 9500 Euclid Avenue, Mail Code A-81, Cleveland, OH 44195**. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Language

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Lindsay Valentine MD, 9500 Euclid Avenue, Mail Code A-81, Cleveland, OH 44195 or 216-444-1735. During non-business hours, weekends and holidays, please contact 216-444-6601 and ask for the GYN on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

If you wish to withdraw from the study, please contact the PI, Lindsay Valentine.

You may be withdrawn from the study if your surgeon requests an in-office two week follow up visit. You will be contacted by your surgeon or your surgeon's office notifying you of removal from the study and rescheduling your virtual visit to an in-office visit, if needed.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date