Current: eConsent (01/31/2022)

Please read the Consent document in its entirety before signing. If you are not comfortable with reviewing the document electronically and would prefer a hardcopy of the consent form, please notify a member of the study team.

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

CARILION CLINIC
CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

TITLE: A Comparison of the Effectiveness of Telepsychiatry with a Randomized Waitlist Control Utilizing Patient Reported Outcome Measures (PROMs)

IRB#: 21-1426

INVESTIGATOR:
Virginia O'Brien M.D.
2200 S Jefferson St
Roanoke, VA 24014
540-981-8025
vcobrien@carilionclinic.org

SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study staff. A brief summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join this study, you can still stop at any time.
- Do not join this study unless all of your questions are answered.
- This study is being conducted to learn whether we can improve patients' experience and time to being seen while they await an appointment in our clinic. A triage clinician will make initial contact with patients to orient them to the clinic and collect information about their symptoms. Some patients will be randomized (like the flip of a coin) to receive an educational video as well.
- You may choose to participate in the study to help us know what works best for patients and to expedite appointments with the proper clinician for you based on your symptoms.
- The study procedures include a discussion about the study (this consent process), completion of monthly patient rated measures (1-6 times) and watching educational videos, depending on which group you are assigned.
- Your participation is expected to last 10-30 minutes over 1-6 study visits
- Possible benefits to you are being matched with the correct type of clinician for your needs, help getting connected to our electronic medical record and OWL Insights, a cloud-based program that helps track symptoms with patient rated measures. It is not expected that you will personally benefit from this research.
- The most likely risks to you are that participation takes time and is not guaranteed to result in improvement in care. During the time between the initial agreement to

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

participate in the study and first seeing your assigned provider, you may complete measures that indicate how you are feeling and you may feel worse simply by answering these questions. However, the severity of your symptoms will be monitored and adjusted to access a provider or get urgent intervention as necessary to ensure your safety.

- Your options other than participating are to remain on the wait list without talking to a triage clinician.
- Being in the study will not cost anything, although your insurance will be billed for standard medical care and you will be responsible for any medical costs your insurance does not cover. There are no additional charges related to the intervention group.
- Other information that may be important for you to consider so you can decide whether to take part in this research is that completion of patient rated measures are a routine part of medical care prior to seeing a provider in our clinic. This study focuses on the time between your triage intake assessment and your first provider appointment to assess if monitoring symptoms and educational videos may be beneficial during the waiting period.

The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may receive an unsigned copy of this consent form to think about and discuss with family or friends.

DETAILED RESEARCH CONSENT

Please read this entire consent form carefully.

You are being asked to take part in a research study that will study the outcomes of having a clinician touch base with you while you are waiting to be seen by a nurse practitioner or physician in our psychiatry clinic. The research are sponsored by 1) the Department of Psychiatry and Behavioral Medicine at Carilion Clinic and 2) the National Institutes of Health (NIH). The person running this study locally is Dr. Virginia O'Brien. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research participant. Being in this study is voluntary.

This consent form may have words or information you do not understand. The research staff will explain anything that you do not clearly understand. Please ask as many questions as you need to make sure that you know what will happen to you in this study and why you are being asked to be in it.

WHAT IS INFORMED CONSENT?

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study including tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

You will participate in the consent process electronically (eConsent) or with hard-copy consent/signature.

1.) eConsent Obtained in Person – you will be approached in-person at the Psychiatry and Behavioral Medicine ambulatory clinic and accesses the REDCap eConsent via a Carilion Clinic portable electronic device. During the in-person consent process the IRB approved team member will review the study design and patient responsibilities with the patient and ask questions to determine research participation understanding. If you agree to participate (and are capable of doing so) then you will type in your name on the portable electronic device and a PDF of the signed document will either be downloaded to give to the participant, emailed or mailed to you.

2.) eConsent Obtained Remotely with Required Remote Consent Process (e.g. video/telephone) – The eConsent form will be accessed on your personal electronic devices (e.g., computers, portable tablets, smart telephones). During the remote consent process the IRB approved team member will review the study design and your responsibilities with you. You will be asked questions to determine research participation understanding. The IRB approved team member will verify identification by name, DOB, address and visual confirmation (if picture available in the EPIC record). If you agree to participate (and are capable of doing so) then you will type in your name on their personal device and a PDF of the signed document will either be downloaded and emailed or mailed to the participant.

The study team will request verbal permission to send the eConsent via a REDCap (secure) link. The email/text must not include Personal Health Information (PHI). The request will state: "Because Carilion Clinic can't control the security of email or text messages once we send them, we need your permission to text or email you. Do you want to receive the link

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

to the eConsent via text or email?" The permission will then be documented.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this study is to determine whether having a clinician assess patients on our waiting list will allow them to have shorter wait times to be seen, better access to our patient reported outcome measures via Owl Insights (a secure, cloud-based scale system), better education about their condition, and experience a better match with clinicians for their needs. All patients referred to our clinic will be offered participation. The research is expected to last a year, but your participation will be weeks to months, depending on the time it takes to be seen by a physician or nurse practitioner.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

After the initial clinician triage assessment, you will be randomized (like the flip of a coin; your probability of being assigned to either group 1 or 2 is 50%) to one of two groups (if you agree and are able to participate in the study):

- Group 1: Receive monthly repeat scales to complete through Owl Insights and educational videos to watch relevant to your condition until you see your assigned nurse practitioner or physician in clinic
- Group 2: Complete initial scales through Owl Insights and remain on the wait list until you see your assigned nurse practitioner or physician in clinic

Scales are to be completed through email or smartphone at your convenience when prompted by Owl Insights. Scales include measures of depression (PHQ-9), anxiety (GAD-7), day-to-day functioning (BASE-6) and alcohol (USAUDIT) and drug use (DAST-10) screening. These scales are used in clinical care frequently but for the purpose of this study you will complete them as assigned to allow the researchers to assess those individuals on the waitlist in our clinic. Completion of scales take approximately 10-30 minutes (total) and you are expected to stay in the study for 1-6 months depending on the wait time to see a clinician.

You will be asked at your first visit with your physician or nurse practitioner to complete some of these scales again. These scales will be compared among the two groups of participants to determine whether our intervention conferred any benefit. It is not clear which of the randomized groups will do better. For this reason, participants will be randomized, which means they will be assigned to a group by chance. Your chance of being randomized to one group is 1 in 2.

We also would like to have permission to look at your medical records from time to time. We will review and collect your medical history by accessing your medical records. The information will include your demographic information like gender and age, medical

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

history, diagnosis, treatments, medications, and diagnostic images as well as the outcome of your illness. This helps researchers link their research results and their meaning to different aspects of human disease and the effects of treatment. The confidentiality section below provides details about how we will keep your information private.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to complete scales through Owl Insights about depression, anxiety, day-to-day functioning, alcohol and drug use either repeatedly each month while on the waitlist (Group 1) or only once prior to the triage assessment with our intake coordinator (Group 2) until your first visit with the clinician. If your psychological symptoms worsen you will be asked to contact the intake coordinator who can provide more information about when you will see the clinician for your first visit and/or help with crisis intervention.

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

- Loss of time it takes to participate (mild)
- No change in outcomes from being enrolled compared to usual care and wait (mild)
- Emotional reaction to seeing your symptoms translated to a measure/number (mild)

Your expected wait-time from triage assessment by the intake coordinator until the first visit with a clinician ranges from 1-6 months. If your psychological symptoms worsen during the wait for your first clinician appointment you will be asked to relay this information to the intake coordinator. This includes documenting any of your thoughts of suicide as part of filling out the depression scale. Crisis intervention for your safety is a part of the intake coordinator's training and specific step-by-step interventions will be communicated to you to ensure your safety should these safety concerns arise. As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening.

Text messaging or receiving an email link to complete scales is part of this research study. You will receive 1 text message/1 email from research staff 24 hours prior to your intake assessment. Your mobile phone provider may charge you for receiving text messages. You will be responsible for these costs. Text messages/emails to you will not contain any of your personal information and you will not be asked to send any personal information to the research team via text or email. We can make no

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

guarantees about the confidentiality of the text messages/emails, as these are not considered secure communications.

There are no risks to you if you are either pregnant or nursing while participating in this study.

WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

The benefits of being in this study are that participants will have help connecting to scales via Owl Insights prior to their appointment with their physician or nurse practitioner. A participant's overview of why (s)he is entering the clinic will be available to the physician or nurse practitioner at the time of the initial appointment, rather than taking up appointment time to enter in all of that data. Those in the group randomized to an educational video might learn more about their symptoms and diagnosis. In addition, the knowledge gained from this research may benefit others on clinic waitlists in the future.

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?

Options include not participating, in which case you would remain on the waitlist as usual practice. Other options include that you may choose not to treat your condition at all.

WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. If you decide you no longer wish to participate, they will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

We provide you with individual results from the study of the scales you complete when you attend your first appointment with a provider. This clinician will share your scale results at your first visit in the clinic and with each follow up visit as applicable for treatment planning.

WHAT ABOUT CONFIDENTIALITY?

Your completed scale scores will be kept in a secure cloud-based system (Owl Insights) and be kept private on a password-protected computer in a locked office. Your assigned clinician will have access to your scores at your initial visit to help with decisions about

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

treatments. All research data will be coded with a unique number. Your name and medical record number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

"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 this website at any time."

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

Identifiers on your research data might be removed so that your identity can no longer be linked to them. Your private information may then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Even though your identifiers will be removed, there still may be a chance that someone could figure out that the information is about you.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

- Personal identifiers such as name, address, telephone number or medical record number
- Demographic information such as age, race, gender
- Current and past medications or therapies
- Family medical history
- Results of physical exams, laboratory tests, x-rays and other diagnostic procedures
- Tests and procedures that will be done in the study
- Other personal health information that will be obtained from other sources to use in the research, including past medical history, tests or records from other sites.
- Information from surveys or questionnaires done for this study

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Laboratories and other individuals and organizations that analyze your health information in connection with this research.
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.
- Researchers at the following non-Carilion facilities: Virginia Tech Department of Psychology
- The following sponsor or funding agency for the research: National Institute of Health

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

You will not be eligible to participate in this study if you do not sign this consent and authorization form. Refusing to sign will not affect the present or future care you receive at Carilion.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not cost you any money.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

You will not be paid for taking part in this research.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time (to be completed in writing). Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion.

CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You are unable to keep your scheduled appointments

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

The reason for any exclusion will be explained to you.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If you need emergency care, call 911 or go to your nearest hospital or emergency room right away. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

Call the person in charge of this study as soon as you are able. They will need to know that you are hurt or ill.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

The principal investigator or at least one member of the research staff will receive money or other benefits from the company that is funding this study.

WHO ARE THE CONTACT PERSONS?

If you encounter complications or have any questions about the study, you may call:

Virginia O'Brien M.D.
2200 S Jefferson St
Roanoke, VA 24014
540-981-8025
vcobrien@carilionclinic.org

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (540) 853-0728 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

IRB NUMBER: IRB-21-1426
IRB APPROVAL DATE: 01/31/2022

SIGNATURE SECTIONS

RESEARCH SUBJECT: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time. I will receive a signed copy of this consent form.

Do you agree to participate in the study?

⊗ Yes
◯ No

Your First Name:

[*DATA REMOVED*]

Your Last Name:

[*DATA REMOVED*]

Please click the link below to add your signature.

[*DATA REMOVED*]

Today's Date

_____

IRB SURVEY:
The IRB committee is a group of people that reviews research to protect the rights of research subjects. One job of the IRB is to make sure the research is done in a way that is respectful to subjects. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please indicate whether you agree to allow the Carilion IRB to send you a survey.

◯ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in the research.
⊗ No, I do not want Carilion IRB to send me such a survey.