Official Title: An Evaluation of Virtual Psychiatric Transition of Care Offered in Behavioral Health Settings
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AN EVALUATION OF VIRTUAL PSYCHIATRIC TRANSITION OF CARE

Verbal Informed Consent Form to Participate in Research

Jason Roberge, PhD, MPH Principal Investigator

You are invited to participate in a research study. The purpose of this research is to determine if a virtual care program will prevent people from coming back to the hospital. You are invited to be in this study because you are being treated at a behavioral health facility within Atrium Health. Your participation in this research will involve periodic phone calls and follow-up for 45 days after you are discharged from the hospital.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include receiving normal care without additional phone follow-up. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Jason Roberge. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [redacted]

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at [redacted].

If you are having a behavioral health crisis:

- you may contact the Mecklenburg County Mobile Crisis at 704-566-3410 option 1 to speak with a licensed clinician or
- contact behavioral health at Atrium Health [redacted]

WHAT ARE THE OUTCOMES?

We are looking at the readmission rate to the hospital and to the ED. We are also assessing how this program affects depression and suicidal ideation.

WHAT ARE THE RISKS OF THE STUDY?

The risk of additional data being collected for the research study is minimal. There is a risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

This program is a new way to care for patients that are discharged from a hospital. The researchers are uncertain if it will help people avoid hospitalizations in the future. That is the purpose of this study.

As part of this study, you will be asked questions about your mental health. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may benefit from participation in the program, but the research study will not directly benefit you.

WHAT ARE THE COSTS?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information

might be re-identified.

WHAT ABOUT MY HEALTH INFORMATION?
In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** survey responses, mental health issues, and medications.

The information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, and to provide required.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; the Institutional Review Board; other representatives of Atrium Health Wake Forest Baptist.

Some of these people, agencies and businesses may further disclose your health information. If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed, or it will be de-identified You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Roberge that you want to take away your permission to use and share your Protected Health Information at any time.

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?
You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, new information becomes available, or because the entire study has been stopped. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you. You can also participate in the program and decline the research data collection.

I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.