Informed Consent Form

EU5395-21: Leveraging Mobile Health to Improve Oral Chemotherapy Adherence Among Women with Breast Cancer

NCT Number: NCT05086731

Document IRB Approval Date: 6/5/2022

Emory University Emory University and Saint Joseph's Hospital
Online Consent and HIPAA Authorization Script/Information Sheet
For a Research Study

Study Title: THRIVE Smart - Leveraging mobile health to improve oral chemotherapy adherence among women with breast cancer
IRB #: STUDY00002985
Principal Investigator: Ilana Graetz, PhD, Health and Policy Management
Funding Source: Developmental Funds from the Winship Cancer Institute of Emory University and NRG Oncology

Introduction and Study Overview

Thank you for your interest in our THRIVE Smart research study. We would like to tell you everything you need to think about before you decide whether or not to join the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.

The purpose of this study is to: 1) measure medication adherence using a smart pill bottle that captures the timing and number of pills removed from the bottle in real time, and 2) to measure the feasibility of a new intervention that monitors symptoms and medication adherence using the smart pill bottle and text message questions that can trigger alerts to the patient's clinical team at Winship. The study is funded by Developmental Funds from the Winship Cancer Institute of Emory University and NRG Oncology. This study will take 3 months to complete.

If you choose to participate, you will be randomly assigned (like the flip of a coin) into one of the two study groups: (1) group 1 and (2) group 2. Participants in both groups will use smart study bottle that measures each time a pill is removed for their following three cycles of their Capecitabine (brand: Xeloda). If their prescription is filled at an Emory pharmacy directly, it will be dispensed in the study bottle. Otherwise, the study bottle will be mailed to you. The researchers will ask you to complete a 10-minute survey after enrolling and another survey after 3 months. If you are assigned to group 2, you will receive text message questions about symptoms and may also receive reminders and questions when you forget to take your dose or take an extra dose. Your oncology provider will be notified if you miss multiple doses or report severe symptoms and may call you to discuss.

You should continue to report any symptoms that may require immediate attention directly to your healthcare provider or the appropriate emergency treatment facility even if you have reported these symptoms for the study.

To compensate you for your time and effort, you will receive a $20 for completing the enrollment survey and a $40 gift card for completing the follow-up survey. If you do not finish the study, we will compensate you for the surveys you have completed. You will get $60 total if you complete both study surveys.

The most common risks and discomforts expected in this study are:

- You may lose time at work or home and spend more time in the doctor's office than usual to complete the surveys.
- You will be asked sensitive or private questions which you normally do not discuss.
- You may lose time to respond to text messages inquiring the reason for your non-adherence if you miss a dose.
- You may experience anxiety not being familiar working with smart pill bottle.

The less common risks and discomforts expected in this study are:

- You may experience technical issues with smart pill bottle.

- You will be asked sensitive or private questions which you normally do not discuss.

There is always a small risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

It is also possible that you benefit from the advantages of smart pill bottle including reminder text messages if you miss a dose or take a dose at a wrong time. You may also benefit from more frequent oncology contacts if you have concerns with taking your medication.

Your privacy is very important to us. There is a law that protects your health information kept by your medical provider; this law is called HIPAA. Your health information that identifies you is your "protected health information" (PHI). The PHI for this study includes medical information about you including your medical history and present/past medications, results of exams, procedures and tests you have before and during the study, laboratory test results. To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). If you join the study, the following persons or groups may use and /or disclose your PHI for this study:

- The Principal Investigator and the research staff.
- The Winship Cancer Institute of Emory University and NRG Oncology, who funds this Research, and people or companies they use to carry out the study.
- Emory offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing.
- Grady personnel who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing.

We will disclose your PHI when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders.

You may revoke your authorization at any time by calling the Principal Investigator, Dr. Ilana Graetz. If identifiers (like your name, address, and telephone number) are removed from your PHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.

If we share your PHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your PHI to others without your authorization. Let me know if you have questions about this. We will put a copy of this informed consent form for the research study into any medical record that you may have with Emory Healthcare facilities.

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Contact Information

If you have questions about this study, your part in it, or if you have questions, or concerns about the research you may contact the following:

Dr. Ilana Graetz, Principal Investigator: [redacted]

If you have questions about your rights at research participant, complaints about the research or an issue you rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted]

Consent

If you would like to participate, please proceed to the survey.