ADULT CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary.You do not have to take part.

Here is a summary of the purpose, methods, risks, benefits, and alternatives to help you decide whether or not to take part in the research.

The purpose of this study is to test a smartphone app in women receiving chemotherapy for breast cancer. You are being asked to be in this study because you have breast cancer and are receiving or will receive chemotherapy.

During this study, you will receive an app for your phone, a Fitbit, coaching, and weekly emails. You will answer surveys. You will be asked questions to look at your memory and activity level. We will train you how to use the app and Fitbit. There will be five study visits.

There may be a risk of discomfort in participating in physical activity. You may be anxious or bored answering questions or using the app. It is possible others may see your personal information.

You may benefit by the daily support and participation in physical activity. This study will help to develop future studies using health apps.

You can chose not to participate. There are many ways to improve your health during your cancer treatment.

Why are you being asked to be in this research study?

You are being asked to participate in this study because you are scheduled to receive your first or second cycle of chemotherapy cycle, with a total chemotherapy length of 3-6 months.

This study will involve up to 40 volunteers from Nebraska Medicine and the community. If you are pregnant or plan to become pregnant during this study, you

may not be in this study.

What is the reason for doing this research study?
Many women who are being treated for breast cancer experience declines in memory and attention that go beyond those of normal aging. This study is designed to examine memory and attention, lifestyle behaviors, and quality of life in women receiving chemotherapy for their breast cancer.

The purpose of this study is to evaluate a smartphone app, and findings will be used to develop additional programs aimed at improving quality of life in women with breast cancer.

What will be done during this research study?
As a part of this study, you will be asked to complete an orientation and two initial testing appointments before your first or second chemotherapy cycle and to participate in a smartphone based health behavior program.

Orientation
During the orientation, you will complete a short assessment to ensure you are eligible for the study. You will be asked a series of short questions and be asked to complete a series of short tasks. The results will be used to confirm the absence of cognitive impairment prior to your participation in the study. If your results show that you may have cognitive impairment, you will not be eligible to participate in this study.Results will only be shared with your physician if we determine that your results require further evaluation.

First Testing Appointment
The first testing appointment will take place in the Department of Neurological Sciences.

This appointment includes cognitive tasks, receipt of a Fitbit, and receipt of a research activity monitor to wear for the following two weeks. It is designed to last 1.5 hours.

The cognitive tasks will involve completion of a memory task and a series of iPad-based cognitive games. Your performance on the tasks will not be shared with your physician.

At the end of this visit, you will be given a Fitbit to wear for the entire study. A researcher will provide you with instructions on using the Fitbit during the first

appointment. You will be asked to sync the Fitbit with your phone multiple times per day by opening the Fitbit app (with your Fitbit nearby) for several seconds. You will also be asked to wear the Fitbit continuously throughout the study. If you already have a Fitbit, you will be asked to wear the Fitbit we provide during the study period. The Fitbit will be yours to keep at the end of the study and we will remove the study Fitbit account from your phone.

You will also be given an activity monitor to wear for 14 days. The activity monitor, called an accelerometer, is a small device that is worn on your right thigh in a waterproof sleeve. The activity monitor measures your movement throughout the day and we will use the information to determine how much time you spend sitting and in physical activity. You will return the activity monitor at one of your next appointments or by mail.

After your First Appointment

You will be emailed a set of 20 questionnaires to complete between your first appointment and third appointment. The questionnaires are designed to be completed in 45-60 minutes.

The questionnaires asks about your life (demographics, general medical history, lifestyle behaviors, physical activity self-confidence, breast cancer symptoms, anxiety and depressive symptoms, self-esteem, quality of life, memory abilities, and dietary habits).

You can choose not to answer any items you are not comfortable answering. Paper copies of the questionnaires will also be available if preferred. The research team may share the results of the anxiety and depressive symptoms questionnaire with your physician if we determine that further evaluation is needed.

Second Testing Appointment

During the second appointment teach you how to complete daily surveys on your smartphone. You will complete the daily surveys over three different 14-day periods during the study:

- During your first or second chemotherapy cycle (pre-intervention)
- During mid-chemotherapy cycle (mid-study)
- One month after you complete chemotherapy (post-intervention)

We will assist you in setting reminders on your phone to complete the surveys during each 14-day period.

This appointment is designed to last 30 minutes and does not need to be completed in person.

Third Testing Appointment
This appointment will be held in-person in the Department of Neurological Sciences. During the third visit you will view a presentation on the study, schedule the coaching sessions, and receive training on using the mobile app. You will also return your research activity monitor at this visit.

During the training, you will participate in a session called a "think-aloud" where you will use your Smartphone app to talk aloud about your thoughts. This session will help us understand what is good or bad about the app so we can make design changes to improve satisfaction while using it. This appointment is designed to last one hour.

After Completion of Testing Visits
After you complete the testing visits, you will be randomly assigned (flip of a coin) to receive different components on the Smartphone app that are designed to support your health behaviors.

These components may include 1-on-1 telecoaching sessions with an interventionist and monitoring of your physical activity as measured by your Fitbit. Some participants will also receive badges in their app for achieving activity goals. The telecoaching sessions are designed to provide you with ongoing support for your health behaviors during your cancer treatment. Interventionists will also send weekly emails to participants with feedback on their activity behaviors as measured by the Fitbit.

End of the Study
All participants will be offered full features of the Smartphone app (except telecoaching) at the end of the study.

What are the possible risks of being in this research study?
Physical Activity
Participation in physical activity may increase your risk of musculoskeletal injury, although, activity in this study is limited to walking which has a very low risk of injury. In general, light and moderate activity will not cause a cardiovascular event in normal adults.

Questionnaires and Cognitive Games
Other assessments, such as the questionnaires and cognitive games, may cause

some boredom, fatigue, frustration, or minor discomfort.

Fitbit

Because this study requires a smartphone and access to the internet, there is a small risk of exceeding your allotted data provided by your phone service's data plan. If needed, we will provide you with instructions for manually syncing your Fitbit to limit your data use.

It is also possible that Fitbit may learn information about your heart rate and steps. We are taking precautions to limit the likelihood that Fitbit can identify any information about you by storing your activity data on secured servers at UNMC and using a Fitbit username and password that was created specifically for this study and does not include any identifying information about you. The IDs used for the Fitbit and smartphone app will be different from your study ID and the key linking these IDs will be stored in a separate, secured document maintained by the principal investigator.

Exposure to Covid-19

When meeting in-person with research personnel at one of the study sites, there is a risk of exposure to COVID-19 (or other public health risk). However, we have taken many steps to reduce the risk of spreading COVID-19. Our procedures follow Nebraska Medicine requirements for minimizing risk of COVID-19. These include, but are not limited to, screening of research personnel and research participants for possible COVID-19 exposure before and upon arrival to data collection appointments, use of proper personal protective equipment among research personnel and research participants during visits, thorough disinfection of equipment and spaces before and after visits, and use of technology to remotely deliver as many aspects of the study as possible.

Other Risks

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before. Participants will be reminded throughout the study to engage in physical activity only to the extent their symptoms permit it.

What are the possible benefits to you?

Many studies have indicated that social support and participation in regular physical activity has shown to have health benefits, such as reduced risk of heart disease and improvements in fitness, weight maintenance, well-being, fatigue, anxiety and depressive symptoms, and chemotherapy treatment adherence.

However, you may not get any benefit from being in this research study.

What are the possible benefits to other people?
The understanding of the effects of physical activity on brain health is crucial to developing future interventions to improve quality of life in women receiving chemotherapy for breast cancer.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?
There is no cost to you to be in this research study. However, it is possible that you may incur costs associated with data usage if you go over your allotted amount of cellular data.

Will you be paid for being in this research study?
You will not be paid to be in this research study,but you will be able to keep your Fitbit upon completion of the study.

Who is paying for this research?
This research is being paid for by funds from the National Institute of General Medical Sciences (Great Plains IDeA-CTR Network; NIH/NIGMS 1U54GM115458) and the Fred and Pamela Buffet Cancer Center.

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

Who will have access to information about you?
By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at UNMC/Nebraska Medicine.

Your PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office for Human Research Protections (OHRP)

The HIPAA Privacy Rule requires the following groups to protect your PHI:

- The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC)

Your PHI may also be shared with the following groups. However, these organizations do not have the same obligation to protect your PHI:

- National Institute of General Medical Sciences, which sponsors this research and provides funds to the Institution to conduct this research
- Fred and Pamela Buffett Cancer Center Data and Safety Monitoring Committee (DSMC)
- The National Cancer Institute's (NCI) Clinical Trial Reporting Program

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly

confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: Diane Ehlers, PhD, 988440 Nebraska Medical Center, Omaha, NE 68198-8440 or by email at diane.ehlers@unmc.edu.

A description of this clinical trial will be available on 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.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or UNMC/Nebraska Medicine. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or UNMC/Nebraska Medicine. You will not lose any benefits to which you are entitled. You may be taken off the study if you do not follow instructions of the investigator or the research team. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "*What Do I Need to Know Before Being in a Research Study?*" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in "The Rights of Research Subjects" that you have been given. If

you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of "The Rights of Research Subjects"
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____
Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel

Principal

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Participating Personnel

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