THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Informed Consent

Development of an application-based digital navigator for perioperative breast surgery patients
2021-1211

Study Chair: Cristina Checka, MD

Studies show that patients only remember 20% of information discussed at health appointments. The current practice is to give patients a paper packet of instructions. These packets are often lost or not read, and it is also difficult for a patient to remember and explain the information accurately for her caregiver.

"JEEVA" is a new digital health navigator app. This app can be used on a mobile phone or tablet. JEEVA has all of the surgical teaching information from the traditional paper packet and also has additional resources like brief videos, checklists, and reference photos. For instance, a common surgical instruction is to look for signs of infection like redness. JEEVA includes photos of normal skin color changes around surgical incisions and also includes examples of infected incisions, represented in a range of skin tones and colors.

The goal of this research study is to learn how accessible JEEVA is for patients during the perioperative period (the time after the pre-operative surgical appointment, and up to 30 days after surgery).

If you agree to use the app, you will provide informed consent and will be guided to download the JEEVA app to your mobile phone. When the app is opened for the first time, there will be brief instructions and navigation cues for its use; no other instructions are necessary.

On post-operative Day 30 (thirty), you will receive a mobile "push notification" reminding you to answer a brief questionnaire about your experience using the app. Your participation in this study will be over after the questionnaire.

Data Collection

Your personal information is being collected as part of this study. Your medical record will be accessed and information will be collected about you and your treatment, such as diagnosis and information about the tumors and medical tests performed. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

This study will be performed at no cost to you.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study. Only the study staff (study chair and collaborators) will have access to study data.

Participation Statement

You have read the description of the study, and have decided to participate in the research project described here. You understand that you may refuse to answer any (or all) of the questions at this or any other time. You understand that there is a possibility that you might be contacted in the future about this, but that you are free to refuse any further participation if you wish. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled.

You may withdraw your authorization at any time, in writing, for any reason as long as that information can be connected to you. You can learn more about how to withdraw your authorization by calling 713-792-6477 or by contacting the study chair at (713-563-0670)

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT