Informed Consent/Authorization for Participation in Research

Title of Research Study: A Feasibility and Acceptability Pilot Study Evaluating a Patient-Specific Targeted Intervention Using Patient Navigators or Routine Clinical Care

Study Number: 2022-0150

Principal Investigator: Mariana Chavez Mac Gregor

_____ _____
Participant's Name Medical Record Number or Study ID

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you have been recently diagnosed with breast cancer and your doctor has decided that you should receive chemotherapy as part of your standard care.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Receiving chemotherapy in a timely manner is important in the treatment of breast cancer, especially in lowering the risk of recurrence (the likelihood that the disease may come back). However, some patients struggle with starting chemotherapy treatment, due to problems or

obstacles related to finding adequate support such as, social support, financial support, or help with navigating the healthcare system.

The goal of this research study (called Project Let's Start) is to learn if providing breast cancer patients with patient-specific support, including the use of patient navigators, can help patients start chemotherapy more quickly. Patient navigators are individuals who help patients through the healthcare system. They provide patients with resources that might help with overcoming barriers that may prevent them from getting the care they need.

How long will the research last and what will I need to do?

You are expected to be in this research study for up to 12 weeks.

You will be asked to complete questionnaires and checklists. You may also be asked to have weekly phone calls and/or a 1-time interview with the study team.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including time commitment and possible risks (such as feeling distressed after completing questionnaires).

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Taking part in this study may help you learn more about resources available to you as a breast cancer patient. People in the future may benefit from what is learned on this study. There may be no benefits for you in this study. It cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the study doctor, Dr. Mariana Chavez-MacGregor, either by phone at 713-563-0020, or by email at MChavez1@mdanderson.org.

This research has been reviewed and approved by an Institutional Review Board (IRB - an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 40 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

Study Groups
If you agree to be in the study, you will be randomly assigned (as in the flip of a coin) to either Group 1 or Group 2. You will have an equal chance (50/50) of being in either group. Both you and the study staff will know which group you are in.

Group 1 (Investigational Group)
In Group 1, you will complete an in-depth patient needs checklist to identify patient-specific barriers that could lead to a delay with starting chemotherapy.

The checklist will be reviewed by the research team, who will then decide what type of help will be most helpful for each individual patient. For example, you may be given referrals to the social worker department, business center, patient advocates, language assistance services, education center, breast cancer survivor or support groups, supportive counseling, or mental health services through the treating doctor.

You will then continue to be followed closely by the patient navigator with weekly phone calls.

During these calls, the navigator will ask you what type of help you may need, and guidance will be given. Where appropriate, the patient navigator might provide brief education, counseling, and assistance navigating the medical system. The goal of the patient navigator will be to ensure that patients are receiving all the resources possible that will help the patient remove any barriers that may cause them to start chemotherapy treatment late.

Group 2 (Control Group)
In Group 2, you will follow routine clinical care, where chemotherapy start date is determined by the provider and patient. After chemotherapy has been started, you will be asked to partake in an in-depth exit interview evaluating your experience.

Baseline Visit
After you have been assigned to a study group, you will have a baseline visit (the first visit of this study).
At this visit:

- You will complete 7 questionnaires about yourself, your cancer history, health condition, social support, health literacy (your ability to understand health-related information), your trust in doctors, your belief in the need of chemotherapy, self-efficacy (your ability to accomplish your goals), and your engagement in healthcare. These should take about 30-40 minutes to complete.
- If you are in Group 1, you will complete the patient needs checklist. This is a brief questionnaire that will ask you questions about any educational, emotional, spiritual, financial, or logistical support you might need. The checklist should take about 5-10 minutes.

Your baseline visit may take up to 1-hour to complete.

Navigator Phone Calls—Group 1
The patient navigator will call you every week as described above in “Study Groups.” These phone calls will continue until you begin receiving chemotherapy.

Exit Interview
Within 2 weeks after you start chemotherapy, you will be asked to complete an exit interview either in person or by phone. During the exit interview:

- You will complete some of the same questionnaires that you completed at baseline. This includes questionnaires about social support, health literacy, your trust in doctors, your belief in the need for chemotherapy, self-efficacy, and your engagement in healthcare. It should take about 20-30 minutes to complete the questionnaires.
- You will answer questions about your experience participating in this study. This will take 10-20 minutes.

Your exit interview may take up to 1-hour to complete.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, there will not be any penalty or loss of benefits that are otherwise entitled to you. If you decide to leave the research, contact the study doctor so that the study doctor can remove you from the study and stop data collection. If you withdraw from this study, you can still choose to be treated at MD Anderson.

After you withdraw from the study or are removed from the study, no further information about you will be collected, and the data collected about you up to that point can be used for data analysis.

Is there any way being in this study could be bad for me? (Detailed Risks)

You should discuss the risks of **questionnaires**, and study related procedures with the study chair. The known risks are listed in this form, but they will vary from person to person. Some of the questions in the questionnaires may make you feel uncomfortable and may be sensitive in nature. You may refuse to discuss any topic or answer any question that makes you feel uncomfortable.

Your **data** will be used for research purposes only. Your responses will not be shared with your doctor. If you feel you need a doctor's opinion about anything that is asked about in the questionnaires (such as mental or emotional difficulties or symptoms), please contact either your personal doctor or the study chair.

However, if **stress** is suspected from you completing the questionnaires, you may be contacted by study staff. Possible outcomes of this contact could include referral to your primary care physician, other physician, and/or other mental health providers.

In addition to these risks, this research may hurt you in ways that are unknown.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

There is no cost to you for taking part in this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information.

Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information are being collected as part of this study. These data may be used by researchers at MD Anderson, ASCO, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you are considered unstable by your medical team, if you show signs of any active illness that may stop you from fully participating, and/or if your behavior disrupts others or stops others from participating in project related procedures.

What else do I need to know?

This research is being funded by ASCO.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to

deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

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:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - ASCO, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
   - 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.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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).

   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

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____	_____	_____
NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)