Study Title: Telephone Support for Metastatic Breast Cancer Patients

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INDIANA UNIVERSITY INFORMED CONSENT AND AUTHORIZATION FORM

Telephone Support for Metastatic Breast Cancer Patients
National Cancer Institute
Study #: 1812850942

About this research
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Indiana University Health, Eskenazi Health, Community Health Network, or IUPUI.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to see if telephone support programs help patients adjust to metastatic breast cancer. What we learn from this study may help us find new ways to help people cope with metastatic breast cancer.

You were selected as a possible participant because you have been diagnosed with breast cancer that has spread.

The study is being conducted by Dr. Catherine Mosher, Associate Professor of Psychology at the IUPUI School of Science and Dr. Elizabeth Addington at Northwestern Feinberg School of Medicine. It is funded by the National Cancer Institute.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 250 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:

- You will be asked to complete a 5-minute screening over the phone. The screening includes questions about you such as your level of fatigue and activity. You will be told at that time whether you can be in the study. If you are not eligible for this study, your screening data will be audited and then destroyed before the conclusion of the study.

- If you choose to take part in this study, you will complete an interview over the phone with a researcher. We will mail or email a sheet with response options to you for this interview. It will take about 35 minutes. The interview includes questions about you. These include:

- Your education, finances, and employment
- Current medical conditions
- Your physical symptoms
- Your emotions
- Your level of activity and quality of life
- Whether you have had treatment for medical conditions or emotional concerns

With your permission, we will audiorecord the interview. Each recording will have a code number to protect your privacy. You may ask us to stop the recording at any time. You may also skip any questions that you feel uncomfortable answering.

- You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

IF you are in Group 1:

- You will be asked to take part in six, 50-minute telephone sessions. Each telephone session will take place once per week for six weeks. You will receive a notebook in the mail with handouts that describe the topics for each session. During these sessions, you will discuss and practice ways to cope with symptoms and stress and focus on activities that are important to you. You will also be asked to practice these ways of coping outside of the sessions and answer questions about this practice and your emotions and fatigue level. With your permission, we will audiorecord the sessions. Recordings will be kept private. You may ask us to stop the recording at any time.

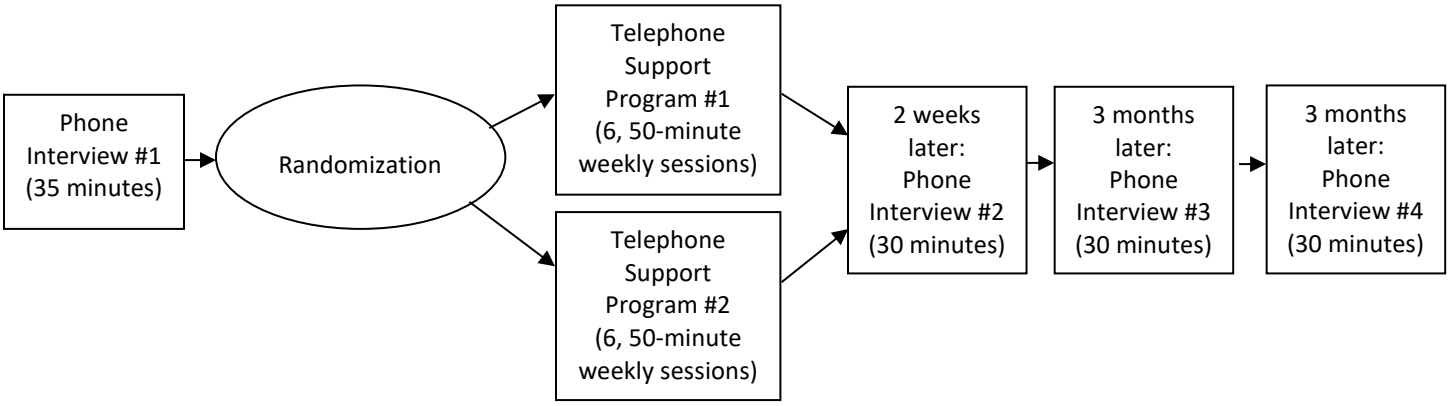
IF you are in Group 2:

- You will be asked to take part in six, 50-minute telephone sessions. Each telephone session will take place once per week for six weeks. You will receive a notebook in the mail with handouts that describe the topics for each session. During these sessions, you will receive information on services available in your medical center and community to help people cope with metastatic breast cancer and ways to evaluate health information. You will not receive the same information as Group 1. You will be asked to review this information outside of the session and answer question about your emotions and fatigue level. With your permission, we will audiorecord the sessions. Recordings will be kept private. You may ask us to stop the recording at any time.

- You will be asked to participate in 30-minute telephone interviews 2 weeks and then 3 and 6 months after the last telephone session. We will mail or email a response option sheet to you for each interview, which will include some of the same questions as the first one. With your permission, we will audiorecord the interviews. Recordings will be kept private. You may ask us to stop the recording at any time. You may also skip any questions that you feel uncomfortable answering.

If you choose to take part in this study, we will also collect information from your medical record.

You will be in the study for about 8 months.



Your answers to interview questions and medical information will be kept separate from your name and other identifying information.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While in the study, there is a risk that you may feel uncomfortable answering some of the questions. You may skip any of the questions. Another risk of taking part in the study is that you may experience some distress, including anxiety, sadness, or negative thoughts. If you do experience distress, then you may contact the study investigator and psychologist, Dr. Catherine Mosher (phone: (317) 274-6769). You may also contact Dr. Mosher with any questions or concerns about the study.

There is also a risk of possible loss of confidentiality. We will protect your information to the limit of the law. We will keep your information in passphrase protected electronic files or in lockable file cabinets in a private office. When the study ends, we will remove all identifying information from study data and materials. There is also a risk of loss of confidentiality since members of our research team will know you and the information you share. Your information will be kept confidential and only members of the research team will have access to your records. Unless law requires us, we will not share that information with anyone.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

You may benefit from the telephone sessions, but we do not know that. Your taking part in this study may benefit other cancer patients in the future.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making sure you meet the criteria to be in this study, gathering information about your medical history to include in the research data, reviewing results of your medical tests for safety purposes, checking on your health in the future to help answer our research question, and to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include:

- Age
- The date(s) you were diagnosed with breast cancer
- The stage(s) of the breast cancer and sites of disease
- Your treatments for cancer (surgery, radiation, chemotherapy, or other treatments)

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Eskenazi Health / Wishard Hospital
- Other: Community Health Network

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Research teams at other institutions or research site(s): Community Health Network, Northwestern University
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)
    - National Cancer Institute (NCI)

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored. Only the research team will have access to the audio recordings. These recordings will be destroyed at the end of the study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and her research associates, the Indiana University Institutional Review Board or its designees, the National Cancer Institute, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the National Institutes of Health, etc., who may need to access the research records.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information or documents that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information or documents protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?
You will receive payment for taking part in this study. You will receive $40 in Target gift cards for each of the four interviews mailed to you within 1 week. You will receive a total of $80 in Target gift cards for two interviews, $120 for three interviews, or $160 for four interviews.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the researcher, Dr. Catherine Mosher, at 317-274-6769. After business hours, please call the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. If you decide to withdraw, please notify the researcher in writing: IUPUI Department of Psychology, 402 North Blackford Street, LD 124, Indianapolis, IN 46202. If you withdraw your authorization, you will not be able to continue in this study. If you withdraw, information that was already authorized by you and disclosed will continue to be used until the date you cancel this authorization. This is to protect the quality of the research data. However, new information about you will not be collected or used by the researchers. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

Your participation may be terminated by the investigator without regard to your consent or authorization in the following circumstances: If the investigator feels it is in the best interest of your health and welfare.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I understand that my care from my physician will not be affected if I withdraw from this study at a later time or decide not to participate. I have been given a copy of this document to keep for my records. I agree to take part in this study.

Form date: October 4, 2021