Telephone Support for Advanced Gastrointestinal Cancer Patients and Caregivers

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Telephone Support for Advanced Gastrointestinal Cancer Patients and their Family Caregivers

National Cancer Institute

Study #: 1904388865

(PATIENT VERSION)

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 consent 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 the Indiana University Health Simon Cancer Center, Eskenazi Health, or IUPUI.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if telephone support programs help patients and their family members adjust to advanced gastrointestinal cancer. What we learn from this study may help us find new ways to help people cope with advanced gastrointestinal cancer.

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

The study is being conducted by Dr. Catherine Mosher in the Department of Psychology at IUPUI. It is funded by the National Cancer Institute.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 100 participants (50 patients and 50 family members of patients) 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 in clinic or over the phone. The screening includes questions about you such as your symptom experiences and ability to do activities. You will be told at that time whether you can be in the study.

- We are also requesting your permission to contact your family member/caregiver to see if he or she is interested in taking part in this study.

- If you choose to take part in this study and allow us to contact your family member/caregiver about the study, you will complete a phone interview with a researcher. It will take about 30 minutes. We will give a sheet with response options to you for this interview. The interview includes questions about you. These include:

    - Your education, finances, and employment
    - Current medical conditions
    - Your physical symptoms
    - Your emotions and social well-being
    - Whether you have had treatment for medical conditions or emotional concerns

- You and your family member/caregiver 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 and your family member/caregiver will have an equal chance of being placed in either group.

  IF you are in Group 1:

  - You and your family member/caregiver 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 stress and symptoms 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 symptoms and emotions.

  IF you are in Group 2:

  - You and your family member/caregiver 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 gastrointestinal 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 sessions and answer questions about your symptoms and emotions.

- About two weeks after the telephone program ends, you will complete a phone interview with a researcher. It will take about 25 minutes. We will mail or email another response option sheet to you. The interview includes some of the same questions as the first one. We will also ask for your feedback on the telephone sessions.

- Up to 2 weeks after this interview, you may or may not be invited to complete another phone interview with a researcher. It will take about 30 minutes. During the interview, we will ask for your feedback on the telephone program and ask about any changes that you may have made as a result of participating in the program.

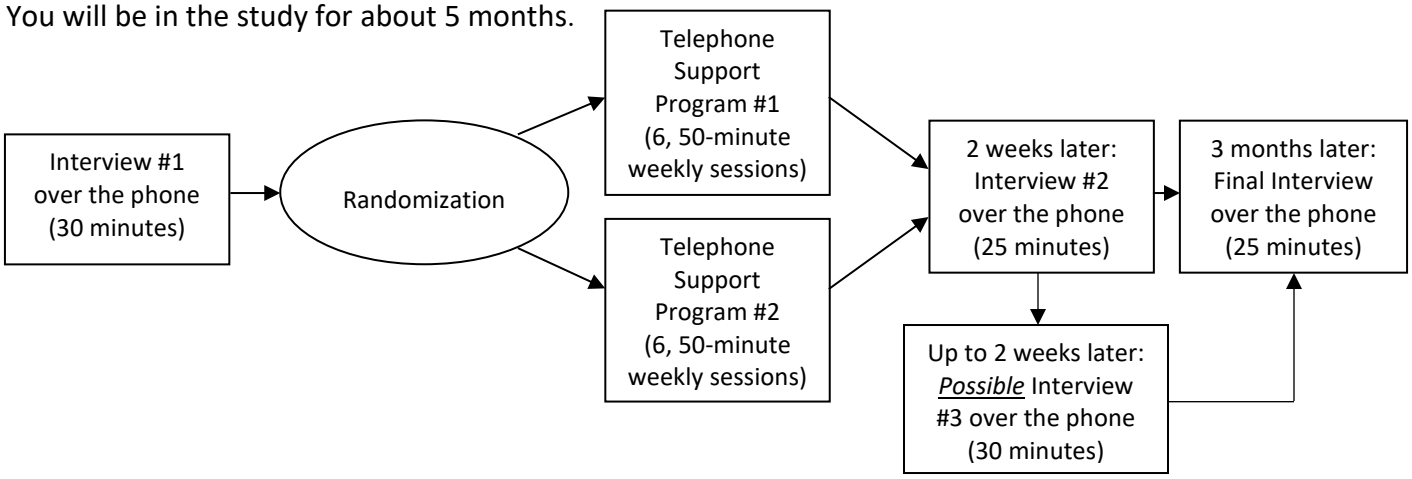
- The final phone interview will take place about 3 months after the telephone program has ended. It will take about 25 minutes. We will mail or email another response option sheet to you. The interview includes some of the same questions as the first two interviews.

- With your permission, we will audio record all interviews and telephone sessions. Each recording will have a code number to protect your privacy. You may ask to stop the recording at any time.

If you choose to take part in this study, we will collect the following information from your medical record:

- The date you were diagnosed with gastrointestinal cancer
- The type of gastrointestinal cancer and the stage of the illness
- Your cancer treatments (surgery, radiation, chemotherapy, or other treatments)

You will be in the study for about 5 months.



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.

Because this study includes some people with distress, some participants may report thoughts of hurting themselves. This could happen during a telephone call. IF this occurs, our protection plan will be used. You will first be asked follow-up questions. Dr. Mosher or Dr. Johns (both psychologists) will review the information the same day to determine the right course of action. If we believe that you are in immediate danger of harm, we will have to report it, potentially to authorities including the police, for your own protection. We may also refer you to mental health services.

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 and their family members in the future.

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. Only the research team will have access to the recordings. These recordings will be destroyed at the end of the study. If you are found to be ineligible for this study or decline study participation, your screening information will be stored separately from identifying information (e.g., your name) and will be kept for auditing purposes for three months before being destroyed.

A description of this clinical trial will be available on **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.

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 state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP) or National Cancer Institute.

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 three or possibly four interviews mailed to you within 1 week. You will receive a total of $80 in gift cards for two interviews, $120 in gift cards for three interviews, or $160 in gift cards 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. The study team will help you withdraw from the study. If you decide to withdraw, please contact Dr. Catherine Mosher or another member of the study team.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: (1) we are unable to contact you by phone for interviews or telephone sessions; (2) your family member/caregiver is no longer able to participate or decides to stop participating in the study; or (3) the investigator feels it is in the best interest of your health and welfare.

PARTICIPANT'S CONSENT
In consideration of all of the above, I give my consent 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 will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____

IF CONSENT WAS CONDUCTED VIA TELEPHONE:

Participant's Printed Name:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**_____

Form date: June 9, 2020