Study Title:

Acceptance and Commitment Therapy for Fear of Recurrence in Breast Cancer Survivors

NCT Number:

NCT05364450

Principal Investigator:

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Document Date:

August 1, 2022

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Facilitating Adaptive Coping with Fear of Recurrence Among Breast Cancer Survivors: A Three-Arm Randomized Controlled Trial (FACing Fear)

IUSCC-0706

ABOUT THIS RESEARCH
You are invited to participate in a research study for breast cancer survivors experiencing fear of cancer recurrence. Scientists do research to answer important questions that might help change or improve the way we do things in the future.

This Consent and Authorization form will give you information about the study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form and ask any questions you have before agreeing to be in the study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to test three different approaches to supporting breast cancer survivors in managing fear of cancer recurrence. You were selected as a possible participant because you have a history of breast cancer and may have had similar fears. The study is being conducted by Dr. Shelley Johns at Indiana University School of Medicine. It is funded by the National Cancer Institute of the National Institutes of Health.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will participate for up to 1 year and do the following:

- You will sign up for the study over the phone with a study team member. You will be asked to give us permission to review your medical records so we can obtain accurate information about your cancer diagnosis, treatments, and timeline.

- You will complete a 45-60 minute baseline survey online with questions about demographics, cancer history, fear of recurrence, coping strategies, mood, and quality of life.

- You will be randomly assigned to one of three groups: **(1) Coping Skills Training A**, **(2) Coping Skills Training B**, or **(3) Survivorship Coaching**. Random assignment is like rolling dice—neither you nor the study team will know your group assignment until after you complete your baseline survey.

    - If assigned to **Coping Skills Training A**…
        - You will meet in a group with 8-12 other women for 6 weekly 90-minute coping skills classes online via Zoom Health. These Zoom classes will be audio recorded for quality assurance.
        - You will be encouraged to practice class material at home, including listening to audio recordings that will be provided to help build your coping skills.

- If assigned to **Coping Skills Training B**…
  - You will meet in a group with 8-12 other women for 6 weekly 90-minute coping skills classes online via Zoom Health. These Zoom classes will be audio recorded for quality assurance.
  - You will be encouraged to complete short homework assignments (e.g., readings, worksheets) to complement what you learn in class.

- If assigned to **Survivorship Coaching**…
  - You will attend a single 90-minute group orientation session online via Zoom Health.
  - During this single group session, you and 8-12 other women will receive supportive survivorship coaching.
  - You will receive materials from the National Cancer Institute and American Society of Clinical Oncology. You will be coached briefly on how to use these materials to create a personal plan to manage your fears of cancer recurrence.

- You will complete 4 additional surveys that generally take about 45 – 60 minutes online at the following time points:
  - 3 weeks after enrollment *(this survey should be shorter than the others)*
  - 2 months after enrollment
  - 6 months after enrollment
  - 12 months after enrollment

Note: You will not receive the results of any of these procedures during the study because they are being done only for research purposes. However, you may request more information about study results after the study has ended.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
The risks of participating in this study are minimal and include the following:

- You may feel uncomfortable answering some of the survey questions.
  - If this happens you are welcome to skip over any questions you don't want to answer.

- You may find that facing your fears of cancer recurrence is difficult or distressing at times.
  - If significant anxiety or distress arises, you are encouraged to discuss this with any member of the study team at any time.

- There is a risk of possible loss of confidentiality of your survey responses or medical record information.
  - We will take every step possible to minimize this risk, including storing files in locked filing cabinets within locked offices and securing electronic information in secure, password-protected files.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
Although this study is experimental, it is possible that you may experience reduced fear of cancer recurrence, decreased anxiety and distress, and improved quality of life. You may also develop more adaptive ways of coping with the stressors of cancer survivorship. However, we cannot guarantee that you will experience these benefits.

WILL I BE PAID FOR PARTICIPATION?
You will be offered a $40 gift card to a major retailer each time you complete one of the 5 study surveys for a total of up to $200. Gift cards will be mailed to your home address.

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

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. These purposes include: (1) making sure you meet the criteria to be in this study, and (2) verifying your medical history to ensure it matches information reported on your surveys or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include:

- Information you provide on surveys
- Cancer history, including dates, timelines, and results of:
    - Diagnostic notes
    - Pathology reports
    - Radiology records and other diagnostic imaging reports
    - Staging information
    - Cancer treatments received, including:
        - Chemotherapy records
        - Radiation records
        - Operative reports (i.e., surgeries)
        - Endocrine/hormone therapy use
- General medical history/treatment, including medical conditions and comorbidities
- Medications
- Mental health records/psychotherapy notes
- Alcohol/substance abuse

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

- Indiana University Health (IUH), including:
    - Indiana University Health Oncology Physicians
    - Indiana University Simon Comprehensive Cancer Center (IUSCCC)
    - IUH North Hospital/IUH Schwarz Cancer Center/Spring Mill
    - IUH Ball Memorial Hospital
    - IUH Bloomington Hospital
    - IUH Arnett Cancer Care Clinic
    - IUH Bedford Hospital

  - IUH Morgan Hospital
  - IUH Methodist Hospital
  - IUH West Hospital

- Eskenazi Health, including Eskenazi Health Physicians

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

- The researchers and research staff conducting this study at IU School of Medicine
- The cooperative researchers assisting with this study from other institutions:
  - The University of Texas Health (UTHealth) Science Center
  - Fred Hutchinson Cancer Research Center
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- 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)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by US 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.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. To protect your identity, we will use a unique study ID number to identify you and the information we collect from you. Data will be stored on secure password-protected network drives or in locked filing cabinets in the secured study team office.

Recordings of all Zoom Health group sessions will be captured for quality assurance. These recordings will only be used for research and to ensure the group teachers convey the material correctly. All study data, including Zoom Health recordings, will be stored for a minimum of 7 years in accordance with Indiana state law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information or documents that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

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

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher Dr. Shelley Johns by emailing care4u@iupui.edu or by calling (317) 274-9127. After business hours or in the event of an emergency, you may reach Dr. Johns at (317) 362-3077. For questions about your rights as a research participant; to discuss problems, complaints, or concerns about a research study; or to obtain information or offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after agreeing to participate, it will not affect your usual medical care or treatment or relationship with Indiana University Health or Eskenazi Health. If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please call or email the study team.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Shelley Johns at 1101 W 10th St, ATTN: RF-226, Indianapolis, IN 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you verbally provided your authorization and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I verbally agree to participate in this research study. I will be given a copy of this document to keep for my records.