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Official Title:	Improving Well-Being for Individuals With Persistent Pain After Surgery for Breast Cancer, Lobular Carcinoma in Situ, or Ductal Carcinoma in Situ: A Randomized Clinical Trial That Compares Three Behavioral Intervention Strategies and Examines Psychological Factors as Drivers of the Continuing Burden of Persistent Pain
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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Well-Being After Breast Cancer Surgery

CONCISE SUMMARY

The purpose of this research study is to compare three different programs to help improve well-being after breast cancer surgery. Participants will complete a baseline assessment and three follow-up assessments. Each of these assessments will include the completion of surveys. Additionally, the baseline assessment, 6-month assessment, and 12-month assessment will include testing to measure physical function as well as sensory testing to measure pain detection and pain threshold. At the end of the baseline assessment, participants will be randomized (like drawing numbers from a hat) to one of three programs, one focused on providing coping strategies and improving well-being with the help of a coach, one focused on providing healthy lifestyle information and strategies with the help of a coach, and one focused on providing healthy lifestyle information and strategies through a self-guided workbook. Participants assigned to the programs with a coach will complete weekly videoconferencing sessions once per week for eight weeks. The total study duration is about 12 months.

There are minimal risks associated with this study. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. You may experience some physical discomfort during functional assessments or sensory testing. There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are a breast cancer survivor who had pain in the area of your breast cancer surgery in the past month. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Cancer Institute will sponsor this study. Portions of Dr. Rebecca Shelby and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Shelby will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to compare three different programs to help improve well-being after breast cancer surgery.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 307 people will take part in this research study. Of those people, approximately 154 people will take part at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. Your medical record will be reviewed to obtain information about your breast cancer, treatments related to breast cancer, and other health conditions.

In this study, you will be randomly assigned (like drawing numbers from a hat) to one of three programs focused on: 1) providing coping strategies and improving well-being with the help of a coach, 2) providing healthy lifestyle information and strategies with the help of a coach, or 3) providing healthy lifestyle information and strategies through a self-guided workbook.

If you are randomized to one of the programs with a coach, you will be asked to complete eight videoconferencing sessions. These videoconferencing sessions will take place approximately once per week and may be 45 minutes to 1 hour in length. These sessions will be recorded. Recordings will be available only to authorized study personnel as necessary to review the content of the sessions. All recordings will be destroyed at the end of the study.

All participants in the study will continue to receive their usual health care and usual medical treatment as recommended by their health care provider.

All participants will complete an initial assessment and follow-up assessments 3, 6, and 12 months later. During each assessment, you will answer questions about pain and other symptoms, emotions, stress, health, and health behaviors. During each assessment and between assessments at months 1, 2, 4, 5, and 9, you will be asked to complete a Healthcare Utilization Diary. In the Healthcare Utilization Diary, you will answer questions about what healthcare services you have received in the past month.

Finally, at each visit except for the 3-month follow-up visit, participants will be asked to complete a grip strength test, complete a test to measure your shoulder range of motion, your upper arm circumference will be measured to assess lymphedema, and you will be asked to complete quantitative sensory testing (QST). QST consists of three sensory tests to measure pressure pain threshold, pain sensitivity, and central sensitization. For pressure pain testing, a device will be used to apply pressure on your upper back at a gradual rate until you first tell study staff that the pressure feels painful. This will be repeated three times. For pain sensitivity testing, blunt probes of increasing weight will be applied to the back of

your hand until you first tell study staff that you perceive a sharp, pricking or stinging sensation; probes of decreasing weight will then be applied until you tell study staff you perceive only a touching sensation, for a total of five cycles. For sensitization testing, a probe will be used to apply a single stimulus, followed by a series of ten stimuli at a rate of one per second, to the back of your hand. You will be asked to rate the unpleasantness of the single stimulus and the series of stimuli, and of any lingering sensations 15 seconds after the final stimulus. This will be repeated five times with probes of two different weights. After each set you will be offered the option of continuing with the next series or omitting the rest of the set of tests. You can also stop the testing at any time by telling the study staff you wish to stop.

Participation in research is voluntary. Also, you can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for approximately 12 months.

WHAT ARE THE RISKS OF THE STUDY?
There are minimal risks associated with this study. You may experience some physical discomfort during functional assessments or sensory testing. Also, some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Some of the topics discussed during videoconferencing sessions may make you feel uncomfortable. Discussing your health or stressors associated with your health may be upsetting. You may choose to not discuss concerns you find upsetting. Also, you may stop your participation in this study at any time.

There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
Participation in this study will provide you with an opportunity to learn skills that can help you better manage your symptoms or improve your overall well-being. We expect that the information learned from this study will benefit other patients with your condition in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

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All recordings will be stored on an encrypted laptop and a DUHS server. Recordings will be available only to authorized study personnel as necessary for purposes of study and will only be identified by a study ID number. All recordings will be destroyed at the end of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the National Institutes of Health, Duke University Health System Institutional Review Board, Duke Cancer Institute & Clinical Trials Quality Assurance. If your research record is reviewed by one of these groups, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. 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. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

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While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There is no cost to you for your participation in this study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to a total of $220 for your expenses related to your participation (parking, gas, and time). You will be reimbursed $35 per assessment for completion of quantitative sensory testing (QST) and other in-person testing, $20 per assessment for remote completion of the study questionnaires, $5 for each completed Healthcare Utilization Diary between months 1 and 5, and $10 for the completed Healthcare Utilization Diary at month 9. These payments will be made at the times shown below. If you choose to withdraw from the study, you only will receive compensation for the parts of the study that you completed.

Baseline	3 months	6 months	12 months
Questionnaires - $20 In-person - $35	Questionnaires - $20	Questionnaires - $20 In-person - $35 Healthcare Diary - $25 ($5 for months 1-5)	Questionnaires - $20 In-person - $35 Healthcare Diary - $10 (month 9)
Total up to $55	Total up to $20	Total up to $80	Total up to $65

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Rebecca Shelby at (919) 416-3410 during regular business hours and page her at (919) 970-2033 after hours and on weekends and holidays.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Rebecca Shelby in writing and let her know that you are withdrawing from the study. Her mailing address is 2400 Pratt Street, Room 7059, Durham, NC 27705. She may also ask you to complete the tests that would ordinarily occur when a person completes the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Rebecca Shelby at (919) 416-3410 during regular business hours and page her at (919) 970-2033 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time