Office of Research Services

Consent to Participate in Research

Study Title:

Advancing Patient Care for Lymphatic Pain and Lymphedema

Authorized Study Personnel

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KEY INFORMATION

You are being asked to take part in this research study because you have been treated for breast cancer and has pain in your affected body side, that is the body side where you have received breast cancer treatment. Research studies are voluntary and only include people who choose to take part. The purpose of the research study is to evaluate The-Optimal-Lymph-Flow (TOLF), a non-pharmacological, behavioral program, as a part of routine patient care to reduce pain and abnormal lymph fluid build-up (i.e., lymphedema in medical term) in the affected body side, that is the body side where you have received breast cancer treatment. The total amount of time you would be in this study is 12 weeks and involves 2 research visits of 40-60 minutes, either in-person or telehealth virtual visit as you preferred (Week 0 and Week 12). During your participation you will be involved in completing assigned daily self-care strategies, completing several questionnaires, measure your weight and height. Taking part in this research involves no known harms and the burden of taking part in the study is minimal. There are minimal risks associated with practicing the self-care strategies. No injuries and complaints have been reported from our previous studies. Loss of confidentiality is a potential risk of participating in the study. However, strategies will be taken to minimize the risk (See Detailed Consent.) There are some direct benefits that you may expect from your participation in this study: (a) May feel empowered by learning about self-care strategies to manage pain and prevent lymph fluid build-up or lymphedema; (b) May relieve your pain and prevent lymphedema by carrying out the self-care strategies. For a complete description of benefits please refer to the Detailed Consent.

The alternative to taking part in this study is not to participate in the study.

Please read this consent form carefully and take your time making your decision. As the researcher(s) discusses this consent form with you, please ask him/her to explain any words or information you do not clearly understand. To help in your decision-making process you may wish to talk with your family and/or 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.

Dr. Mei Rosemary Fu will conduct the study and portions of the research team's salaries will be paid by this grant. The study is funded by BioNexus KC.

WHY IS THIS STUDY BEING DONE?

The purpose of the research study is to evaluate The-Optimal-Lymph-Flow (TOLF), a non-pharmacological, behavioral program, as a part of routine patient care to reduce pain and abnormal lymph fluid build-up (i.e., lymphedema in medical term) in the affected body side, that is the body side where you have received breast cancer treatment. This study is a single group clinical trial. This means, you and all participants will be assigned to receive the same behavioral education program. If you take part in the research, you will be asked to participate in either in-person or telehealth virtual training session to learn and enhance self-care strategies to manage pain and prevent lymphedema. Your time in the study will take 12 weeks and will also involve 2 in-person or telehealth virtual research visits of 40-60 minutes (Week 0 and Week 12) at University Health Kansas City (UH) Breast Center to complete several questionnaires, measure your weight and height.

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You are being asked to take part in this research study because you have been treated for breast cancer and have persistent or intermediate pain in your affected body side, that is the body side where you have received surgical breast cancer treatment. You must be 18 years of age or older and able to speak and understand English to participate.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately **35** people will take part in this study from University Health Kansas City (UH).

WHAT IS INVOLVED IN THE STUDY?
You and all participants will be assigned to receive the same behavioral education program to learn self-care strategies to manage pain and prevent lymphedema. Self-care strategies focus on information about lymphedema, diagnosis and measurement of lymphedema, lymphatic system, risk of lymphedema, self-care strategies to promote lymph fluid flow.

At Study Visit #1 (Week 0), you will be asked to learn lymphatic system, lymphedema, lymphedema diagnosis and measurements, and self-care to promote lymph flow as well as training and practicing lymphatic exercises.

During Week 1 to Week 12, (1) You will be provided the access to a website and YouTube Videos to review and enhance your learning on lymphatic system, lymphedema, lymphedema diagnosis and measurements, and self-care to promote lymph flow as well as training and practicing lymphatic exercises. (2) You will be asked to practice lymphatic exercises twice a day (Morning and Evening). It take about 5-8 minutes to complete the lymphatic exercises. You may practice lymphatic exercises 3-4 times a day to better manage your pain and symptoms.

You will be asked to participate in TWO (2) in-person or virtual zoom research visit of 40-60 minutes to (Week 0 and Week 12). No audio-recording will be conducted during the virtual zoom research visit. During the visit, you will:

- Complete several questionnaires about your background (age, education, etc.), pain and symptoms, and quality of life.
- Very few questions may be considered sensitive (e.g., questions on substance use, illegal drug, use, etc.).
- **You are free to skip any questions that you prefer not to answer.**
- The researchers will measure your weight and height.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

HOW LONG WILL I BE IN THIS STUDY?
This study will last 12 weeks and will involve 2 in-person or telehealth virtual research visits as you prefer.

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WHAT ARE THE RISKS OF THE STUDY?
The risks and discomforts associated with participation in this study are not expected to be greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

There are minimal risks associated with practicing the self-care strategies. No injuries and complaints have been reported from our previous research studies.

There are minimal risks associated with completing the study questionnaires, that is, you may experience frustration that is often experienced when completing the study questionnaires. Some questions may be of a sensitive nature, and you may therefore become uncomfortable as a result. If, however, you become uncomfortable by questions, you may stop at any time or choose not to answer a question.

Loss of confidentiality is a potential risk of participating in the study. However, strategies will be taken to minimize the risk (See Section "WILL MY INFORMATION BE KEPT CONFIDENTIAL?")

What happens if I believe I am injured because I took part in this study?
This study does not relate to medical diagnosis or treatment. There are no anticipated risks to the participation in this study. Therefore, no costs will be incurred by the participants, nor any compensation will be given for injuries sustained.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are some direct benefits that you may expect from your participation in this study.
(a) May feel empowered by learning about self-care strategies to manage pain and prevent lymph fluid build-up or lymphedema.
(b) May relieve your pain and prevent lymphedema by carrying out the self-care strategies.

Can I be removed from the research without my permission?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include:
(a) You do not follow the study researchers' instructions.
(b) Worsening of your health or other conditions that prevent you from taking part in the study.
(c) You do not keep appointments or follow directions.
(d) You have the need for treatment that is not allowed in the study.

At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. Please note all the data that has been collected on you to the point that you leave the study will remain part of the study.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
There are no alternative treatments available. Your alternative is not to take part in this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

The University of Missouri System, Authorization No. 00-018 requires research data to be retained for 7 years after the final report.

Reasonable steps will be taken to protect your privacy and the confidentiality of your study data. All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

We will make every effort to protect your confidentiality. You will be assigned a unique study ID; study data recording for the research will only use the subject study ID without your identifying information. Your study information will be stored in locked files accessible only to the research team members, co-investigators, and the PI. Electronic data will be stored in a password protected computer accessible only to the PI, co-investigators, and the research team members. Data analysis will be carried out and reported in the aggregate data so that individual identities are not revealed. You may choose to use paper-pen format for self-reported information or the electronic assessment using a study iPad. Your confidentiality will be protected for the electronic assessment since you will use your unique study ID to access the electronic assessment.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The University of Missouri-Kansas City Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- 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.

The data in paper form will be stored in a locked cabinet in the investigator's office and will only be seen by the research team during the study and for 7 years after the study is complete.

The data will be stored electronically through a secure server and will only be seen by the research team during the study and for 7 years after the study is complete.

The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. The information from this study may be published in scientific journals or presented at scientific meetings but the data will be reported as group or summarized data and your identity will be kept strictly confidential.

WHAT ARE THE COSTS TO YOU?

There is no cost to you to be in this research study.

WHAT ABOUT COMPENSATION?

You will receive up to a total of $ 65 physical gift card for taking part in this study according to the following schedule:

- $30.00 at your first visit (0-week visit)
- $35.00 at your second visit (12-week visit)

You will receive the physical gift card during your in-person visit, or you will receive the physical gift care via UPS to the address that you provide to the researchers.

WHAT SHOULD YOU DO IF YOU HAVE A PROBLEM DURING THIS RESEARCH STUDY?
Your well-being is a concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form.

This study does not relate to medical diagnosis or treatment. There are no anticipated risks to the participation in this study. Therefore, no costs will be incurred by the participants, nor any compensation will be given.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
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 the researcher first to make sure it is safe to do so.

You can decide not to be in this research study, or you can stop being in this research study ("withdraw') at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the researcher(s) or with the University of Missouri Kansas City or University Health. 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. If you do decide to withdraw, we ask that you contact Dr. Mei Rosemary Fu (UMKC/UH) and let her know that you are withdrawing from the study. The contact information is:

- Dr. Mei R Fu (UMKC): 973-986-1758 (Mobile), 816-235-5963 (office), email: mei.fu@umkc.edu

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
Dr. Fu, or the researchers have described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigators, Dr. Fu, can also be contacted if you have any questions, concerns or complaints about the study in the future:

- Dr. Fu (UMKC): 973-986-1758 (Mobile) 816-235-5963 (office)

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the UMKC Institutional Review Board (IRB) Office

- Phone: (816) 235-5927 Email: umkcirb@umkc.edu

Consent to Participate in Research

Authorization to Use and Disclose Protected Health Information for Research

Principal Investigator ("PI"): Mei R Fu (PhD, RN, FAAN) PI's Phone Number: 973-986-1758
Title of Study: Advancing Patient Care for Lymphatic Pain and Lymphedema
Institutional Review Board (IRB) #: 2134300 University Health project #: 26-043

Privacy laws, including the Health Insurance Portability and Accountability Act ("HIPAA"), protect the use and disclosure of protected health information about you ("PHI"), and generally requires your permission to use and disclose your PHI for research purposes.

To participate in this Study, you must give the research team permission to collect PHI about you and use and share that information with others by signing this Authorization.
What protected health information about me may be used or shared for this Study?

The research team at UH will use and disclose your PHI, including the PHI they collect for the Study. It also includes information in your medical records such as:
results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition

PHI may include records relating to mental health care, communicable disease, HIV/AIDS, and/or treatment of alcohol/drug abuse.

How will protected health information about me be used for the research?
Protected health information about you will be used to:
conduct the study and perform the research

Who will receive the protected health information about me?
The health information listed above may be used by and/or disclosed for research, quality assurance, and data analysis to:
· Sponsors who want access to PHI or who will actually own the research data; and/or
· Institutional Review Boards or Data Safety and Monitoring Boards.

The Research Team may also share protected health information about you with federal and state agencies that have oversight of the Study or to whom access is required under the law. These may include but are not limited to:
· Regulatory agencies in the U.S.
· The Office for Human Research Protections.
· Public Health Authorities.

Once the Research Team discloses your protected health information as described in this Authorization, it may no longer be protected by HIPAA and other privacy laws and recipients could possibly use or re-disclose it in ways other than those listed here.

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Will I be able to see my Study records?
You have a right to see and make copies of the protected health information collected about you for the Study. However, by signing this Authorization you agree that you may not be able to see or copy this information until the sponsor has completed all work related to this Study.
When does this Authorization to use my protected health information expire?
This authorization will not expire unless you change your mind and withdraw it in writing. There is no set date at which your information will be destroyed or no longer used.

Am I required to sign this Authorization?
No. However, if you choose not to sign this Authorization, you may not take part in this Study. If you decide not to authorize the use and disclosure of your PHI for the Study, your decision will have no impact on your ability to receive care at University Health and will have no impact on any other benefits to which you would otherwise be entitled.

Can I change my mind about giving permission to use my protected health information?
You may change your mind at any time. If you take back your permission, the Research Team may still keep and use any patient information about you that they already have. But they can't obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

To withdraw your permission, you must write to Barbara Zubeck, Chief Compliance Officer, at barbara.zubeck@uhkc.org, stating that you are withdrawing this Authorization.

Who can answer any additional questions that I have?
If you have any questions relating to your rights under HIPAA and other applicable privacy laws, please contact barbara.zubeck@uhkc.org. If you have any questions relating to the Study, please contact the PI.

By participating in this research project, you agree that your research-related health information can be used and shared as described above. You will receive a copy of this Authorization.