TEXAS WOMAN'S UNIVERSITY & PRESBYTERIAN HEALTHCARE SERVICES
CONSENT TO PARTICIPATE IN RESEARCH

Title: The Effect of Hand Mobility and Grip Strengthening Exercise on Upper Limb Volume, Quality of Life, and Hand Function in Breast Cancer Survivors

Investigators:

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Summary and Key Information:

Women who have had surgery, chemotherapy, and/or radiation for breast cancer may develop swelling in an arm, called lymphedema. This swelling can make it difficult to perform daily tasks. Physical and occupational therapists treat this type of swelling with hands-on therapy, compression bandaging, exercise, and education. The swelling can make it difficult to perform daily tasks.

Elisabeth Wise, a licensed physical therapist at Presbyterian Healthcare Services and doctoral student at Texas Woman's University, is conducting this research study to see if specific exercises will improve your ability to complete daily tasks and help decrease the swelling in your arm. You have been invited to participate due to your diagnosis of lymphedema of the arm following treatment for breast cancer.

In order to participate in this research study, you must be a woman diagnosed with lymphedema of the arm, at least 18 years of age, and have completed surgery and/or radiation treatment for breast cancer, with no open wounds on your arm. If you are still receiving chemotherapy, we will need additional information to see if you can participate. You may choose to continue with the usual care for your swollen arm after this research is over if your arm is still swollen and ongoing care is needed.

This study will last eight weeks, including 2 visits each week for people who wish to participate. There will be a 1-hour initial evaluation as part of your regular treatment for arm swelling, with the remaining treatment sessions lasting up to 45 minutes, your likely time commitment in the clinic is approximately 12 hours. Everyone will be asked to complete a home program, too. Typically, these home exercises are done every day, for up to 1 hour per day. As part of the home program, you will receive a compression garment, at no cost, you may keep after the study ends. The greatest risks of this study include possible loss of confidentiality and increased swelling of your arm. We will discuss these risks and the rest of the study procedures in greater detail below.

Your participation in this research study is completely voluntary and you may stop participating at any time, and still receive care for your swollen arm. If you are interested in participating, please review this consent form carefully and take your time deciding whether you would like to participate. Please feel free to ask the researcher any questions you have about this study at any time.

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Description of Procedures:

As a participant in this study, you will receive education and treatment with the primary researcher, Elisabeth Wise, or another Presbyterian Healthcare Services therapist. During the first session, the size of both your arms will be measured with a tape measure, your grip strength will be measured with a simple tool called a dynamometer. Additionally, we will ask you to move pegs in and out of a pegboard as quickly as you can and complete two brief surveys so we know more about you, your breast cancer history, and how you are managing your swollen arm.

Everyone will get the usual care provided to people with arm swelling after breast cancer treatment. Usual care involves attending therapy sessions twice per week for 8 weeks, each lasting about 45 minutes. During these sessions, you will participate in exercise, and receive both hands-on treatment with Manual Lymphatic Drainage and compression applied to your swollen arm. The specifics of each in-person therapy session will be customized for you. Your therapist will give you a folder with your exercises to perform at home, as well as a log to track how often you complete your exercises and home program, including self-manual lymphatic drainage, compression, skin care, and exercise. After 4 weeks of visits, the therapist will re-measure your arm and you will fill out the survey about how you are doing with your swollen arm. Finally, after 8 weeks of treatment, the therapist will conduct an exit interview to ask about your experiences and measure your arm one final time. Lastly, you will fill out the survey to show how you are managing your swollen arm.

The researcher will randomly assign you to one of the treatment groups. The only difference between the two treatment groups is that the exercises are slightly different. You will be informed regarding the other intervention following the conclusion of this study.

Potential Risks:

One potential risk of participation is increased swelling of your arm. While the goal of this study is to reduce the arm swelling while improving your strength, unexpected situations may result in more swelling. Should this occur, you will be immediately notified and provided with alternatives, including treatment by a different therapist or facility, referral back to your oncologist or primary care provider, or other options as appropriate.

A second potential risk of participation is fatigue, related to your cancer or cancer treatment. Should your severe fatigue impact your ability to participate in the treatment sessions, you will be provided with alternate treatment options and referred back to your oncologist or primary care provider as appropriate.

Another potential risk is the loss of confidentiality due to your participation. Confidentiality will be protected to the extent allowed by law. As a patient in this clinic, your contact and treatment information will be maintained in secure documentation software on computers owned and secured by Presbyterian Healthcare Services. The additional information collected as part of this research study will be separate from your medical record. All hard copy paperwork for this research study, including this consent form, will be stored in a locked filing cabinet within the Presbyterian Santa Fe Regional Medical Center building,

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with 24/7 security onsite. Information from the research paperwork will be entered into the password protected laptop. Your name and identifying information (i.e., your contact information and date of birth) will only be on this consent form. All other documentation will use a participant number separate from your medical record number to keep track of your progress. This will not be linked to your identifiable information. There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings, and internet transactions. After all identifiable information is removed, the information collected for this study may be used for future research without additional informed consent.

If you would like to participate in the current study, but not allow your de-identified data to be used for future research, please initial here _____.

All research-specific information will be destroyed as a protection of confidentiality 5 years after completion of the study, including shredding paper documentation and deleting and overwriting information collected and stored on the primary researcher's computer. However, your separate medical record and treatment notes will be maintained per Presbyterian Healthcare Services documentation policies.

Disclaimer Statement:

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU and Presbyterian Healthcare Services do not provide medical services or financial assistance for injuries that might happen because you are taking part in this research. Should an illness or injury result from this study, medical care will be provided to you. This care may be billed to you or your insurance. You may seek medical care at the hospital of your choice.

Participation and Benefits:

Your participation is completely voluntary, and you may withdraw from the study at any time, without penalty. As a participant, you will learn how to manage the swelling in your arm and reduce the risk for increased swelling in the future. You will also receive a compression garment and associated items for free as part of the treatment for your swollen arm. These items are yours to keep, whether or not you complete the study.

Questions Regarding the Study:

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study you should ask the researchers; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378 or via email at IRB@twu.edu.

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Signature of Participant Date