UCSF University of California San Francisco
IRB NUMBER: 16-21259
IRB APPROVAL DATE: 12/10/2018
IRB EXPIRATION DATE: 12/09/2019

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Treatment of breast cancer-related lymphedema with a negative pressure device: a pilot randomized controlled study

This is a research study about the safety and effectiveness of a new massage treatment for arm lymphedema after breast cancer treatment. The study researcher, Betty Smoot, PT, DPTSc**,** from the UCSF Department of Physical Therapy and Rehabilitation Science, and her colleagues from the School of Nursing, will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have had lymphedema for at least one year, in one arm, as a result of your breast cancer treatment.

Why is this study being done?

The purpose of this study is to learn if treatment with a new negative pressure massage device called PhysioTouch, is safe and effective at decreasing swelling, improving the condition of the skin, and improving movement in the arms of women with lymphedema, compared to manual lymphatic drainage massage. PhysioTouch is approved by the United States Food and Drug Administration for use by healthcare professionals as a therapeutic massage device, but not specifically for treatment of lymphedema. PhysioTouch has been used in the clinic for treatment of breast cancer related lymphedema but no randomized controlled studies have been done.

Who pays for this study?

This study is being funded by the Foundation for Physical Therapy Magistro Family Foundation Research Grant.

How many people will take part in this study?

About 80 people will be enrolled at UCSF to take part in this study.

What will happen if I take part in this research study?

If you agree, the following measurement procedures will take place at the UCSF Parnassus Campus, in the School of Nursing:

- Your height and weight will be measured
- The fluid content of your body and each arm will be measured using a bioelectrical impedance machine. In this test, you will be lying down and electrodes will be placed on

your hands, wrists, ankles, and feet. A very small amount of electricity will pass through your body. This test is completely painless and has no side effects.

- We will measure the size of both of your arms and hands with a tape measure.
- We will measure the flexibility of both of your shoulders. We will use a small ruler (goniometer) that measures the amount of movement at your shoulder joints. You will be asked to raise your arm over your head and also move your arm out to the side away from your body. We will measure each movement twice.
- You will be asked to demonstrate the strength of your grip. The force will be read from a meter (dynamometer). This will involve squeezing two handles together as hard as you can, three times on each hand.
- The firmness of your skin will be tested in 7 areas on both of your arms, using a device with a measuring pad (a fibrometer). The device pad is gently pressed against the skin. There is no discomfort during these tests. The testing areas will be marked with a washable marker. The testing locations are the thumb web space, two spots on the forearm, and 2 spots on the upper arm.
- We will obtain your responses to questionnaires about your health, your activity, your lymphedema symptoms, the function of your arm, your quality of life, and how you feel about your body.

After all measurements are completed, you will be "randomized" into one of the two study groups described below. Randomization means that you are put into a group by chance. A computer program will place you into one of the groups. Neither you nor the researchers can choose the group you will be in. You will have an equal (50-50) chance of being placed in either group. You will be asked not to reveal information about group assignment to the research associate who performs the final measurements.

- If you are in Group 1 you will receive the negative pressure massage treatment to your lymphedema arm.
  - You will be asked to wear clothing that will allow treatment to the skin of your upper body and your lymphedema arm. You will be asked to lie on your back, and either your stomach or side, for the treatments. Each treatment will take 45 to 60 minutes.
  - The treatments for Group 1 will be scheduled preferably 2 to 3 days each week, for 4 to 6 weeks. Efforts to adjust the schedule of treatments according to your availability will be made. No treatments will be scheduled on Sundays or holidays.
  - For Group 1, the massage will be done using the negative pressure massage device. It is a hand-held device that produces a light suction that gently pulls the skin into the suction cup. This suction gently stretches the skin and tissue just beneath the skin and is thought to improve lymph flow and decrease skin tightness and stiffness.
  - The negative pressure massage treatment sequence is based on the current clinical treatments for arm lymphedema. The steps are:
    1. Deep breathing
    2. Massage to the lymph nodes above the collarbone, in the armpit of the non-lymphedema arm, and the groin on the lymphedema side.

3. Massage across upper chest, upper back, and down the side of the trunk
4. Massage to the shoulder, the upper arm, the forearm, and then the hand

- We will ask you to wear your compression sleeve for at least one hour following the treatment. If you do not have a compression sleeve, we will provide you with one.
- You will be asked to complete a weekly diary during the 4 to 6 week treatment period. In the diary, you will record any self-treatments you performed for your lymphedema such as lymphedema self-massage, exercise, and use of your compression sleeve or night garment.
- At each visit, we will ask you if you have any change in your symptoms or increase in arm swelling, and we will look at your skin for any changes.
- We will measure your arm circumference once each week to monitor for any increases in swelling.
- We also ask that you do not receive any other lymphedema treatment (other than your usual self-care activities) during the 4 to 6 week study period.

- If you are in Group 2 you will receive the manual lymph drainage massage treatment to your lymphedema arm.
  - You will be asked to wear clothing that will allow treatment to the skin of your upper body and lymphedema arm. You will be asked to lie on your back, and either your stomach or side, for the treatments. Each treatment will take 45 to 60 minutes.
  - The treatments for Group 2 will be scheduled preferably 2 to 3 days each week, for 4 to 6 weeks. Efforts to adjust the schedule of treatments according to your availability will be made. No treatments will be scheduled on Sundays or holidays.
  - For Group 2 the massage will be done using manual lymphatic drainage. Manual lymphatic drainage massage is a gentle manual massage technique that uses very light pressure to stretch the skin, with rhythmic movements to stimulate lymph flow.
  - The manual lymphatic drainage treatment sequence is based on the current clinical treatments for arm lymphedema. The steps are:
    1. Deep breathing
    2. Massage to the lymph nodes above the collarbone, in the armpit of the non-lymphedema arm, and the groin on the lymphedema side.
    3. Massage across upper chest, upper back, and down the side of the trunk
    4. Massage to the shoulder, the upper arm, the forearm, and then the hand.
  - We will ask you to wear your compression sleeve for at least one hour following the treatment. If you do not have a compression sleeve, we will provide you with one.
  - You will be asked to complete a weekly diary during the 4 to 6 week treatment period. In the diary, you will record any self-treatments you performed for your lymphedema such as lymphedema self-massage, exercise, and use of your compression sleeve or night garment.
  - At each visit, we will ask you if you have any change in your symptoms or increase in arm swelling, and we will look at your skin for any changes.

- We will measure your arm circumference once each week to monitor for any increases in swelling.
- We also ask that you do not receive any other lymphedema treatment (other than your usual self-care activities) during the 4 to 6 week study period.

After the study treatments have been completed, the measurements will be taken again within 2 weeks of the last treatment at the UCSF Parnassus Campus in the School of Nursing:

- Measure your height and weight
- Measure the fluid content of your body and each arm with bioelectrical impedance.
- We will measure the size of both of your arms and hands with a tape measure.
- We will measure the flexibility of both of your shoulders.
- You will be asked to demonstrate the strength of your grip.
- The firmness of your skin will be tested in 7 areas on both of your arms, using a device with a measuring pad (a fibrometer).
- We will obtain your responses to the same questionnaires, plus ask you how you liked the treatment.

Four months after the last treatment, we will ask you to complete an online survey about your lymphedema symptoms and if you had any additional lymphedema treatments since finishing the study treatments.

Here is an overview of the study schedule:

Schedule of Study Procedures									
Procedure		**Treatment week**							
	First assess-ment	**1**	**2**	**3**		**5 If needed**	**6 If needed**	**Final assess-ment**	**4 month follow up**
Informed consent	X								
Questionnaires	X							X	X symptom only
Limb circumference	X	X	X	X	X	X			
Shoulder mobility	X								
Grip strength	X							X	
Skin firmness	X							X	
Height	X							X	
Weight	X							X	
Bioelectric impedance	X							X	

Schedule of Study Procedures									
Procedure		**Treatment week**							
	First assess-ment	**1**	**2**	**3**	**4**	**5 If needed**	**6 If needed**	**Final assess-ment**	**4 month follow up**
Study treatments		X	X	X	X				
Treatment satisfaction								X	

Study location: All study measurements and treatments will take place at the UCSF Parnassus Campus in the School of Nursing.

How long will I be in the study?

Participation in the study will take a total of about 26 hours over a period of 5 to 8 weeks, with an additional 30-minute online survey after 4 months.

Here is a summary of the time for each visit:

Enrollment physical assessment at UCSF Parnassus Campus, School of Nursing	1½ hours
Enrollment questionnaires	2 hours
Treatment visits (12 scheduled visits)	1 to 1½ hours each
Final physical assessment visit	1½ hours
Final questionnaires	2 hours
Follow up online survey	½ hour

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- The researcher will measure your strength and ability to move each shoulder through two different positions. You may have some discomfort or pain with these movements. You can refuse to do any or all of these movements.

- The bioelectrical impedance measurement takes less than 5 minutes to do. You should not be able to sense when the measurement is taking place. If you do sense any discomfort, immediately inform the researcher. Bioelectric impedance measurements are used to evaluate the relative amounts of fluid in your arms. This is done by passing a harmless, very low strength, electrical signal from the bioelectric impedance device through your arm. Increased fluid means the electrical signal will travel more easily through the arm. The bioelectric impedance device compares how easily the electrical signal travels in the unaffected versus the affected (or at-risk) arm.
- Randomization Risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects that the other study treatment, or other available treatments.
- It is possible that you may have some slight discomfort during the treatments in this study. Both treatments involve very light massage techniques. If you do sense any discomfort, immediately inform the researcher.
- Study data will by physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Your name will not be used in any published reports from research performed for this study. The research staff will not release any identifying information about you to their collaborators.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

You may experience an improvement in your lymphedema symptoms. However, while there may be no direct benefit to you from participating in this study, the information that you provide may help health professionals better understand/learn more about treatments for lymphedema after breast cancer.

If you are in the group that receives the PhysioTouch, and it proves to treat your condition more effectively/with fewer side effects than Manual Lymph Drainage, you may benefit from participating in this study, but this cannot be guaranteed.

What other choices do I have if I do not take part in this study?

Your other choices may include not getting treatment, getting standard treatment for your condition without being in a study, or taking part in another study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Study information will be coded and kept in a password secured and encrypted server and in locked files at all times. Only Dr. Smoot and the research team will have access to these files.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- The Foundation for Physical Therapy
- The University of California
- Food and Drug Administration (FDA)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site 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.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

In return for your time you will be paid a total of $50 for taking part in this study. You will be paid $25 at the completion of the enrollment visit, and $25 immediately after the final assessment visit. These payments will be provided in the form of the gift card. If you park in the UCSF parking garage, your parking expenses for the UCSF parking garage will be reimbursed at the end of each study visit. Bridge toll or ride service costs will be reimbursed as needed, after the study visit.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Betty Smoot, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her [redacted].

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor (Foundation for Physical Therapy), depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact your research investigator, Betty Smoot, PT, DPTSc, [redacted]

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form and the Experimental Subjects Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent
Date	Witness – Only required if the participant is a non-English speaker