Informed Consent Document

Effects of Myofascial Massage and Patient-therapist Communication Levels on Shoulder Muscle Properties in Breast Cancer Survivors With Myofascial Pain

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Effects of myofascial massage and patient-therapist communication on shoulder muscle properties in breast cancer survivors with myofascial pain
Principal Investigator: David B. Lipps, Ph.D., School of Kinesiology
Study Sponsor: National Institutes of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

- The purpose of the study is to quantify improvements to shoulder muscles following a single 30-minute session of massage (targeting the muscles around the shoulder) in women previously diagnosed and treated for breast cancer who are experiencing pain in their upper chest.
- If you choose to participate, you will be asked to provide informed consent and complete surveys prior to your visit. You will visit the School of Kinesiology Building at the University of Michigan for one 2-hour session. During this session, the research team will take ultrasound images and videos from key shoulder muscles before your massage, immediately after your massage, and 60 minutes after your massage. A certified massage therapist accustomed to working with breast cancer survivors will massage your chest, upper arm, back, and neck for approximately 30 minutes. After the massage is completed, you will again complete surveys.
- Risks or discomforts from this research include discomfort and soreness from the ultrasound probe or massage and loss of confidentiality.
- There are no direct benefits of your participation, but some participants may feel temporary relief from pain from the massage.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Pain in the upper chest is common in breast cancer survivors, but there is no standard of care to manage this pain. Massage may effectively reduce this pain, but it is difficult to quantify exactly how massage can reduce pain in breast cancer survivors. The purpose of this study is to use ultrasound images of muscles to better describe the benefits of massage therapy for breast cancer survivors.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

You are eligible to participate in this study if all of the following criteria apply to you:

- Female sex
- Age 18 years or older
- Previous unilateral breast cancer diagnosis
- Treatment for primary breast cancer was completed 3 months to 2 years prior to enrollment (defined as completion of all treatments except oral maintenance therapies)
- Myofascial pain in upper quadrant of the chest
- Ability to understand and willingness to sign a written informed consent.

You are ineligible to participate in this study if any of the following criteria apply to you:

- Chronic neuromuscular or orthopaedic injury currently affecting upper extremity function that is unrelated to their cancer diagnosis
- Currently undergoing physical therapy, occupational therapy or other treatment side effects related to their cancer diagnosis or other injury to the upper extremity
- Broken or bruised skin in the chest/shoulder area
- History of fibromyalgia
- Diagnosed with metastatic breast cancer
- Currently receiving treatment for other forms of cancer

3.2 How many people are expected to take part in this study? We will recruit up to 30 individuals to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Prior to your visit

- A member of the research team will reach out to discuss the study outlined in the consent form and answer any questions over the phone or email (your preference).
- You will sign this consent form digitally.
- You will then be sent a screening questionnaire via an emailed link. In the event you are ineligible for this study, a member of the research team will contact you and all information collected will be destroyed.
- Eligible individuals will be scheduled for their appointment.

During your visit and prior to massage

- You will come to the University of Michigan School of Kinesiology Building for one testing session (~120 minutes).
- You will be asked to change into a tank top – we can provide one, or you can wear your own from home.

- You will complete a brief health assessment, including providing general information on your prior breast cancer treatments, your age, your height, and your weight.

- Ultrasound images and videos will be collected from up to 11 sites around your chest and shoulder before your massage

Massage therapy

- A certified massage therapist will provide you with a 30-minute myofascial massage therapy session. Their techniques will include skin gliding, stroking, scar tissue rolling, strumming, stretching, circular friction, deep tissue release, and arm pulls.
- You will be asked to remove all upper body clothing, lie down on a massage table, and cover your body with the provided sheets and blanket in a private room. The massage therapist will enter the room after you are ready.
- You can communicate with the massage therapist during the treatment.
- The massage therapist will carefully expose any areas of the chest or shoulder to perform the treatment.
- The massage therapist may apply massage oil to your skin. You may opt out of having massage oil applied to your skin.
- After the massage session is over, the therapist will leave the room and you will be asked to change back into a tank top.
- No research personnel will be in the room during the massage session.

After the massage

- The research team will collect another set of ultrasound images and videos from the same sites immediately after the massage therapy session is completed and you have changed.
- You will be asked to wait for one hour. During this time, you will be asked to complete some surveys related to your treatment. You are welcome to use your phone, read a book, or watch television during this time.
- The research team will collect a final set of ultrasound images and videos from the same sites 60 minutes after the massage therapy session is completed.
- You are welcome to leave after the final data collection.

4.2 How much of my time will be needed to take part in this study? The screening questionnaire prior to your visit will be completed in approximately 10 minutes. Your visit to the University of Michigan School of Kinesiology Building for data collection and the massage therapy will last approximately two hours.

4.2.1 When will my participation in the study be over? Your participation in the study will conclude after your single visit to the University of Michigan.

4.3 If I decide not to take part in this study, what other options do I have?
There may be other ways of treating your condition if you do not want to be in this research study. Check with your health care provider to discuss other options.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
There may be some discomfort from the ultrasound transducer indenting the skin. There also may be some discomfort and soreness from the massage treatment. There is a risk of an allergic skin reaction to the massage oil. Finally, there is a risk for loss of confidentiality.

The researchers will try to minimize these risks by communicating with you during the visit to make sure you are comfortable. We can take breaks as needed and stop massage techniques that make you uncomfortable. If you have known allergies or skin sensitivities to massage oils, please let the research team know as we can perform the massage without the use of massage oil.

You do not have to answer any questions you do not want to answer on provided surveys or screening documents.

Because this study collects information about you, one of the risks of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study? How could others benefit?
You might benefit from being in the study, as you may experience temporary relief of pain symptoms as a result of the massage session.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive a $30 gift card for your participation in the study. If you withdraw from the research before the end of the study, you will be compensated for the amount of time you participated in the research at a rate of $15/hour (rounded to the nearest 20-minute interval). You will also be provided with free parking in a lot adjacent to the School of Kinesiology building.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Only authorized research personnel will have access to identifiable information. Coded identifiers will be used, with a list housed within a locked cabinet inside of a secure office or a password-protected file with access restricted to authorized research personnel. This list includes name, your coded ID, age, height, weight, and race/ethnicity as this information may be necessary covariates to include within our data analysis as well as for reporting to federal agencies. No identifiable information will not be written on paperwork or saved on electronic documents or devices where research data is collected and stored. Paperwork will be shredded and devices will be permanently destroyed or securely wiped 12 months after study completion.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc/information-protected-coc.htm

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you for study recordkeeping. Your name and other information that can directly identify you will be maintained and stored securely on REDCap, which is a password protected data management website, with only study team members able to access identifiable information.

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). 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.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: David Lipps, Ph.D.
Email: dlipps@umich.edu
Phone: (734) 647-3131

Study Coordinator: Kayla Russell-Bertucci
Email: kaylarb@umich.edu
Phone: (734) 764-3832

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study
By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

11. OPTIONAL CONSENT

Consent to be Contacted for Participation in Future Research
Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

_____ Yes, I agree for the researchers to contact me for future research projects.

_____ No, I do not agree for the researchers to contact me for future research projects.