Study Protocol with Statistical Analysis Plan

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

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Effects of myofascial massage and patient-therapist communication on shoulder muscle properties in breast cancer survivors with myofascial pain

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STUDY SYNOPSIS

Title	Effects of myofascial massage and patient-therapist communication on shoulder muscle properties in breast cancer survivors with myofascial pain
Methodology	Longitudinal
Study Duration	1 year
Study Location	School of Kinesiology Building, University of Michigan
Objectives	To assess how myofascial massage and patient-therapist interaction alter the stiffness and microvascular perfusion of shoulder muscles
Number of Subjects	30 participants
Inclusion Criteria	• 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.
Exclusion Criteria	• Chronic neuromuscular or orthopedic injury currently affecting upper extremity function that is unrelated to their cancer diagnosis • Currently undergoing physical therapy, occupational therapy or other treatment for side effects related to their cancer diagnosis or other injury to the upper extremity • History of fibromyalgia • Broken or bruised skin in the chest/shoulder area • Diagnosed with metastatic breast cancer • Currently receiving treatment for other forms of cancer
Study Product(s)	Participants will be randomized 1:1 to receive one 30-minute myofascial massage either with patient-therapist communication permitted or restricted. Stiffness and microvascular perfusion of shoulder muscles will be measured non-invasively before the intervention, immediately afterward, and 60 minutes afterward. Muscle stiffness will be measured using ultrasound shear wave elastography, and microvascular perfusion will be measured with ultrasound-Doppler techniques. Participants will complete a questionnaire to assess the satisfaction with their treatment.
Statistical Methodology	A repeated-measures analysis of variance will be used to compare muscle stiffness and microvascular perfusion between intervention groups and their interaction. A two-sided independent t-test will be used to test for differences in treatment satisfaction between the groups.

1) Study Objectives:

The objective of the proposed study is to assess how myofascial massage alters stiffness and microvascular perfusion of shoulder muscles and how these changes are influenced by patient-therapist communication. Specifically, we will examine superficial shoulder muscles in breast cancer survivors before and after they receive one session of myofascial massage. Participants will be randomized 1:1 to receive massage where communication with the massage therapist is permitted or restricted. Our primary hypothesis is that stiffness of shoulder muscles will be decreased, and microvascular perfusion will be increased after a 30-minute myofascial massage, and that the addition of patient-therapist communication will result in greater changes than massage alone with patient-therapist communication restricted. Our secondary hypothesis is that treatment satisfaction will be higher when communication is permitted compared to when communication is restricted.

2) Specific Aims

Specific Aim 1: *To assess how myofascial massage and patient-therapist communication alter stiffness and microvascular perfusion of shoulder muscles.* We will determine stiffness and microvascular perfusion of superficial shoulder muscles non-invasively in breast cancer survivors with upper quadrant myofascial pain before a 30-minute myofascial massage, immediately afterwards and 60 minutes afterwards. We will additionally investigate the interaction between the massage treatment and the communication environment. A total of 30 female breast cancer survivors will be randomized 1:1 to receive either myofascial massage of the chest and shoulder with patient-therapist communication permitted or restricted.

The following hypotheses will be examined:

> *Hypothesis 1*: Shoulder muscle stiffness will be decreased, and microvascular perfusion will be increased after myofascial massage and these effects will be enhanced when patient-therapist communication is permitted.
>
> *Hypothesis 2:* Participants in the communication-permitted group will be more satisfied with the treatment than participants in the communication-restricted group.

3) Background

Upper quadrant myofascial pain affects nearly half of all breast cancer survivors. Most local breast cancer treatments are risk factors for this pain as they directly or indirectly affect the major shoulder muscles (1–3). Treatment-induced scarring and fibrosis of the pectoralis major leads to muscle shortening and stiffening (4,5), which can cause a forward depressed shoulder girdle, contributing to shoulder co-morbidities and pain (6). Side effects can also include myofascial trigger points in shoulder muscles (7). Myofascial massage can effectively reduce pain, increase shoulder range of motion and improve quality of life in breast cancer survivors with upper quadrant myofascial pain (8–10). However, the underlying mechanisms that cause these positive effects are unclear. Massage likely breaks up fibrotic muscle tissue and increases blood flow to the area. Prior studies in non-clinical populations showed that myofascial massage can reduce soft tissue stiffness (11–13) and increase arterial blood flow (14,15), but these effects have not been shown in the shoulder muscles of breast cancer survivors.

Furthermore, contextual factors like patient-therapist communication can have a therapeutic effect (16,17) and may result in further improvement of these outcomes. Prior work showed that massage with warm, empathic therapist-patient communication significantly improves irritable bowel syndrome compared to massage with neutral communication (18). Placebo treatment with positive communication was almost as effective at relieving tension-type headaches as ultrasound treatment with positive communication (17). There is no prior research on how positive therapist-patient communication during massage influences the response of the treated soft tissues.

The purpose of the proposed study is to establish the effect of myofascial massage on shoulder muscle properties and the interaction with patient-therapist communication in breast cancer survivors with upper quadrant myofascial pain. We will determine muscle stiffness using ultrasound shear wave elastography, a recent development that allows the non-invasive measurement of tissue stiffness *in vivo* (19). It has been shown that changes in muscle stiffness due to muscle length changes and muscle contraction can be detected with this method (20). Work from our laboratory showed increases in muscle stiffness of the pectoralis major after breast cancer treatment (21,22). Furthermore, we will determine blood flow to the treated muscles with ultrasound Doppler imaging techniques. The color pixels representing microvascular flow Doppler signals will be counted after deleting soft tissue gray-scale background in single frames of an ultrasound video (23). These techniques can non-invasively provide information about microvascular perfusion.

4) Research Methodology:

Participants:

We will recruit 30 female breast cancer survivors from the Ann Arbor area.

Inclusion Criteria:
- 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.

Exclusion Criteria:
- Chronic neuromuscular or orthopedic injury currently affecting upper extremity function that is unrelated to their cancer diagnosis
- Currently undergoing physical therapy, occupational therapy or other treatment for 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
- Allergy or skin sensitivity to massage oils
- Currently receiving treatment for other forms of cancer

Experimental Design:

Participants will be recruited from the Ann Arbor area via an advertisement on UMHealthResearch.org. This advertisement will provide contact information (a phone number and email address) for additional information if an individual is interested in participating. On UMHealthResearch.org, potential participants will be asked if they meet specific inclusion and exclusion criteria. Their eligibility will be contingent upon the answers they give for these questions. To be eligible, participants must answer 'Yes' to all questions related to inclusion criteria (except when asked for a date, which must be more than 3 months prior) and 'No' to all questions related to exclusion criteria. If ineligible, participants will be notified immediately through a message on UMHealthResearch.org and all information collected (including identifiable information) will be destroyed. If eligible, participants will be messaged on UMHealthResearch.org to inform them of their eligibility. They will then be sent a digital consent form, which they can review, and they will have the opportunity to ask questions about the study procedures. Participants will sign this document through the secure online platform SignNow. An e-signature of the participant will be collected on SignNow after they have read the document in its entirety either by typing their name and either (1) checking an accompanying checkbox with a statement noting an intent to affix a legal signature (e.g., "By checking this box and typing my name below, I am electronically signing this consent form") or (2) signing inside a designated box with a mouse, stylus, or touch screen. After providing consent, participants will have the opportunity to download a copy of the consent form for their records.

After signing of the consent form, participants will be sent screening questionnaires via email. If a participant becomes ineligible after completing these screening questionnaires, they will be informed immediately via email, all information collected will be destroyed, and they will be taken off the study. Participants eligible after completing the screening questionnaires, will be informed of their eligibility and contacted via email to schedule an appointment for their study visit. The screening questionnaires will confirm the location of pain and ask for experiences related to pain severity and interference in the indicated area. To be eligible, participants must indicate on the Michigan Body Map that pain is present in the upper quadrant of the upper body. For inclusion, at least one of the following criteria must be met: 1) Score of at least 5 in first question about pain at its worst in the BPI Pain Severity questionnaire, 2) Score of at least 3 in the third question about average pain in the BPI Pain Severity questionnaire, and 3) score of at least 3 in the third question about pain interference in the PEG questionnaire.

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To be eligible, participants must indicate on the Michigan Body Map that pain is present in the upper quadrant of the upper body. For inclusion, at least one of the following criteria must be met: 1) Score of at least 5 in first question about pain at its worst in the BPI Pain Severity questionnaire, 2) Score of at least 3 in the third question about average pain in the BPI Pain Severity questionnaire, 3) score of at least 3 in the third question about pain interference in the PEG questionnaire, 4) score of at least 3 in first question about pain on average in the past week in the PEG questionnaire.
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For their appointment, participants will come to the Musculoskeletal Biomechanics and Imaging Laboratory located in the School of Kinesiology Building at the University of Michigan for one testing session lasting approximately 2 hours. All participants will be compensated for any parking expenses. Upon arrival, participants will be informed about the study procedures and have the opportunity to ask the research team questions before the start of the experiment.

Demographic data will be collected about the participant, including age, height and weight, and participants will complete a short questionnaire asking about their cancer diagnosis and treatment history. Participants will then be asked to change into a tank top. Baseline measurements of muscle stiffness and microvascular perfusion will be made with the participant sitting in a chair with the arm 90° abducted. Ultrasound shear wave elastography images will be obtained from 9 regions of the pectoralis major, one location on the serratus anterior and one location on the middle trapezius. Three images will be recorded from each location, resulting in 33 images. Ultrasound Doppler images will be obtained as a video clip as the muscle is swept top to bottom with the ultrasound transducer. The length of this video clip will vary but will be no longer than 90 seconds long and much shorter (<30 seconds) for most.

After baseline measurements are completed, participants will be taken to the massage room where they will meet the massage therapist. Participants will be asked to remove all upper body clothing before lying down face up on the massage bed. They will be asked to cover their bodies, including chest and shoulders, with a sheet and woolen blanket. The massage therapist will leave the room while the participants get ready. Once the participant is ready, the massage therapist will re-enter the room and begin the myofascial massage. The treatment will last 30 minutes and focus on the chest and shoulder of the side that received the cancer treatment. Techniques applied during the intervention will include skin glide (variable time), stroking (2-3 minutes), scar tissue rolling (2-3 minutes), strumming (2-3 minutes), fascial stretch (3-5 minutes), circular friction (1-2 minutes), deep fascial release (3-5 minutes) and arm pull (60 seconds). The timing and order of each element will be varied based on tissue response and patient feedback. The massage therapist will carefully expose areas of the chest and/or shoulder to perform the treatment. A massage oil may be applied to the participant's skin if necessary. After the conclusion of the massage treatment, the massage therapist will leave the room so that the participant can get dressed again. No research personnel will be present in the massage room during the entire time.

Immediately afterward, participants will return to the examination room, where the measurements conducted at baseline will be repeated. Participants will then remain in the clinical suite (or an adjacent waiting room) for 60 minutes, after which all measurements will be repeated a second time. During their 60-minute wait period, participants will be asked to fill in the treatment satisfaction questionnaire. Additionally, participants will be allowed to keep themselves occupied (e.g., reading), and they will be allowed to use the TV entertainment system provided in the examination room.

Participants will be randomized into two groups. One group will receive the massage treatment while the massage therapist will be permitted to more readily communicate with the participant, and one group will receive the same massage treatment while the massage therapist will restrict communication with the participant to only essential exchanges. When communication is permitted, the therapist will have a short consultation with the participant, explaining the massage techniques used and asking for specific areas of shoulder/chest discomfort/pain to focus the treatment on. During the treatment, the therapist and the participant will be allowed to converse freely. The therapist will ask for feedback regarding the massage technique applied and will adjust the technique (duration, intensity) accordingly. When communication is restricted, the massage therapist will only provide essential information about the treatment (how to get ready, when treatment will start and finish) to the participant. The participant will not be instructed to limit conversation (e.g. to alert the therapist if the intensity is too much), but the therapist will limit their responses.

We will withhold information about grouping and randomization from the participants until they complete the study visit to avoid a possible confounding effect of having this knowledge. We do not expect any adverse effects from withholding this information from the participants as all participants will receive the same standardized massage treatment. All participants will be handed a sealed envelope after the study which includes a letter informing them of the restricted/unrestricted communication component of the research study as well as the group for which they had been assigned.

Randomization will be done using covariate adaptive randomization controlling for the covariates of age and body mass index. A study coordinator will randomize participants and print each participant's group membership on a piece of paper, which will be placed in a sealed envelope. The envelope will be given to the massage therapist before meeting with the participant. Only the study coordinator and the massage therapist will have knowledge of each participant's group membership. All other research personnel involved in data collection (including those actively collecting ultrasound images) and analysis will be blinded to group membership until data analysis is complete for all participants.

This experiment carries a small ($30) nominal payment that is not contingent upon successful completion of the study. Compensation will be in the form of a gift card. This study provides a small direct benefit to the participants resulting from the massage treatment. Risks associated with the treatment intervention are no more than minimal and include mild soft tissue discomfort during the massage treatment and possible muscle soreness the next day. To avoid/minimize discomfort during the treatment, the massage therapist will adjust the treatment accordingly. For participants that withdraw early, we will prorate this payment at $15 per hour, rounded to the nearest 20-minute interval, up to a maximum payment of $30.

All data will be stored by randomized study ID for each participant. All data collected during the appointment will be kept in a secure U-M database. There will be one document linking the ID numbers to the identifiers, which will be kept in a locked cabinet within a card-locked laboratory or key-locked office. Only members of the study team will have access to the document. This will be kept for 12 months after the study is completed, as it may be needed during the analysis of the data. Twelve months after the conclusion of the study, all identifiable information will be destroyed.

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All data will be stored by randomized study ID for each participant. All data collected during the appointment will be maintained in REDCap, which is password-protected, with only the study team members able to access identifiable information. There will be one document linking the ID numbers to the identifiers, which will be kept in a locked cabinet within a card-locked laboratory or key-locked office. Only members of the study team will have access to the document. This will be kept for 12 months after the study is completed, as it may be needed during the analysis of the data. Twelve months after the conclusion of the study, all identifiable information will be destroyed.

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All data collected during the research, including self-reported information from breast cancer survivors about their diagnosis and treatment, will be saved only under their randomized study ID. Data will be stored on password-protected devices inside a card-locked laboratory and separate from any documents containing any personally identifiable information.

There are some potential risks to this experiment. There may be some discomfort from the ultrasound transducer indenting the skin. We expect the risk probability of this to be infrequent and the risk severity to be minor. To mitigate this risk, researchers will inform the participant prior to applying the transducer to skin and consistently ask participant if they are comfortable. There is also a small risk of an allergic reaction to the massage oil, if applied. We will minimize this risk by only using massage oil if necessary and asking the participants about known allergies before doing so. If an allergy may exist, we will not use massage oil. Finally, there is a minor risk of soreness and discomfort in the massaged regions which will subside within two days of treatment.

Loss of confidentiality is expected to be rare but is of major seriousness. To minimize the risk of loss of confidentiality, only authorized research personnel will have access to the data. Coded identifiers will be used, with a list housed within a locked cabinet inside of a secure office. This list includes name, subject ID, height, weight, and ethnicity as this information may be necessary covariates to include within our data analysis. PHI will not be written on paperwork and will be saved on separate from 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.

5) Statistical Design:

The objective of this study is to assess muscle stiffness and microvascular perfusion before and after a 30-minute myofascial massage and to investigate the additional effect of patient-therapist communication. Our primary hypothesis (H1) is that muscle stiffness will be decreased and microvascular perfusion will be increased and that these effects will be enhanced when patient-therapist communication is permitted. We will test this hypothesis with a repeated-measures ANOVA. The outcome variables will be shear wave velocity as representative measure of muscle stiffness and color pixel density indicating microvascular blood flow. Time (before, immediately after, and 60 minutes after massage) will be the within-subjects factor, and communication (permitted or restricted) will be the between-subjects factor. Interaction between time and type of communication will also be assessed. Our secondary hypothesis (H2) is that scores on the Global Satisfaction with Treatment questionnaire will be higher when patient-therapist communication is permitted during the massage treatment compared to communication restricted. We will test this hypothesis with a two-sided independent t-test.

The proposed study is a pilot investigation with shear wave velocity of the pectoralis major as primary outcome. Changes in shear wave velocity after myofascial massage have not been investigated previously. Thus, a formal power analysis was not completed. We estimate that if a moderate-to-large effect size is observed (f = 0.25-0.4), our analysis plan can detect a significant within-between interaction (e.g., time by type of communication) with 8-18 participants (assuming alpha = 0.05, power = 80%, 2 groups, 3 repeated measures and correlation = 0.7). Accounting for data loss and study dropouts, we request to recruit 30 participants to complete this work.

6) Objectives and Endpoints:

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
1. To quantify changes in muscle stiffness in response to myofascial massage.	*Change in muscle stiffness of the pectoralis major will be assessed by ultrasound shear wave elastography before and after myofascial massage*	*Muscle stiffness is hypothesized to decrease after myofascial massage is completed compared to baseline.*
Secondary		
1. To quantify changes in muscle perfusion in response to myofascial massage.	*Change in muscle perfusion of the pectoralis major and upper trapezius weill be assessed by Doppler imaging and superb microvascular imaging before and after myofascial massage*	*Perfusion to muscle tissue undergoing massage is hypothesized to increase after myofascial massage is complete compared to baseline.*
2. To evaluate the effect of patient-therapist communication on changes in muscle stiffness in response to myofascial massage.	*Change in muscle stiffness of the pectoralis major will be assessed by ultrasound shear wave elastography and compared between patients randomized to a group with restricted or unrestricted communication with the massage therapist.*	*Effects of myofascial massage on muscle stiffness is hypothesized to be enhaced in patients without restricted communication with their massage therapist.*
3. To evaluate the effect of patient-therapist communication on satisfaction with treatment	*Responses to the Global Satisfaction with Treatment questionnaire will be compared between patients randomized to a group with restricted or unrestricted communication with the massage therapist.*	*Satisfaction with treatment is hypothesized to be enhanced in patients without restricted communication with their massage therapist.*

AME00156146:

We are required by the study funder (NCCIH) to screen for adverse events after the intervention. An adverse event questionnaire has been added to Section 29 of the IRB application to help our team identify adverse events (AE) and severe adverse events (SAE). This screener will be performed 7 – 10 days following the intervention. This can be delivered digitally, with a follow-up phone call if our team requires additional information from the participant or if the participant is unresponsive. Pain assessments taken at intake will also be reassessed during the screener.

The PI will maintain an adverse event log to grade the severity, study intervention relationship, action taken regarding study participation, outcome of the AE, expectedness, and SAE grading, along with the participant ID# and investigators initials and date of logging.

The potential risks of this project are anticipated to be no more than minimal risk with essential safeguards to protect the welfare of study participants. Only Adverse Events related to the study procedures (e.g., ultrasound imaging, myofascial massage) will be assessed for grade/attribution and recorded in the study database. These adverse events will be reported in aggregate form in conjunction with the completion of an annual continuing review application with the University of Michigan IRB board.

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The potential risks of this project are anticipated to be no more than minimal risk with essential safeguards to protect the welfare of study participants. Only Adverse Events related to the study procedures (e.g., ultrasound imaging, myofascial massage) will be assessed for grade/attribution and recorded in the study database. These adverse events will be reported per the standard IRB-HSBS reporting guidance.

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Per current institutional guidelines, the research team must report any serious adverse events resulting in death, life-threatening outcomes, hospitalization, or significant disability/permanent damage to the local IRB within seven calendar days of becoming aware of the event. Serious adverse events unrelated to the study procedures will be reported in aggregate form in conjunction with the completion of an annual continuing review application.

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