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Research Protocol and Statistical Analysis Plan
Study Title: A Pilot Study to Evaluate the Effectiveness of Focused Massage on Pain, Mobility, and Quality of Life During Radiation Treatment for Patients With Breast Cancer

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Attached is the IRB approved research protocol and statistical analysis plan.

Sincerely,

Beth Steinberg, PhD, RN
Primary Investigator

Protocol Title: A Pilot Study to Evaluate the Effectiveness of Focused Massage on Pain, Mobility, and Quality of Life During Radiation Treatment for Patients with Breast Cancer

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1. Abbreviations and Definitions

N/A

2. Background and Rationale

Summarize and synthesize the available research, including published data, to provide justification for the study.

In patients with breast cancer, whole breast radiation (WBI) is an integral part of the treatment plan and is commonly seen as adjuvant, but radiotherapy (RT) can also be a primary treatment. Traditionally, WBI has been delivered in a supine position, with the patient lying on their back with both arms extended overhead. More recent delivery modes of breast radiotherapy involve positioning patients prone with the arms extended, usually near the head with the neck rotated away from the side of the treated breast. While data has shown WBI in the prone position is similar to supine positioning in terms of disease control and survival, prone positioning can improve radiation dose homogeneity, decrease late-stage fibrosis, and minimize radiation exposure to the heart and lungs (Schoepen et al., 2022; Vakaet et al., 2021; Vakaet et al., 2023). Despite these clear advantages, supine positioning is still the most common position for WBI. One reason may be patient comfort as it is reported that patients in the prone position experience more neck and shoulder discomfort.

While patients positioned supine have experienced pain and discomfort in their arms and shoulders associated with positioning during their radiation treatment, patients positioned prone have reported more arm, shoulder, and neck discomfort, as well as increased pressure and tension during treatment (Deysene et al., 2020; Groot Koerkamp et al., 2021). Specifically, patients describe uncomfortable head support, numbness or tingling in arms, and painful pressure areas on the shoulders, sternum, ribs, and axilla (Groot Koerkamp et al., 2021). Likely heightened by previous surgical interventions including mastectomy, reconstruction, and/or axillary node dissection, pain and musculoskeletal discomfort, exacerbated by the long duration in the prone position during WBI, are typically treated with non-steroidal anti-inflammatory medications (NSAIDS) and physical therapy. After surveying over 1000 breast cancer survivors, it was found that the most common complaint following radiation sessions was pain (Rim et al., 2017). A prospective cohort study analyzed a group of women diagnosed with breast cancer and found that the affected upper limb was at the highest frequency of pain at nine months after surgery when RT was also being given (Baungarten et al., 2021). This phenomenon of pain associated with WBI, especially with prone positioning, is widely understood by healthcare providers and requires investigation of alternative treatment methods to prevent the need for repeating the pre-radiation simulation, the preparatory patient imaging, positioning, and marking to ensure precise targeted radiation, due to pain from positioning, and prevent long-term consequences, as well as poor quality of life (Hellman et al., 2024; Lee et al., 2021).

Massage therapy is a widely accepted complementary treatment for musculoskeletal pain and muscle tension, as well as cancer-related pain (Behzadmehr et al., 2020; Boyd et al., 2016; Lee et al., 2016; Lee et al., 2015). For patients with chronic musculoskeletal pain, massage therapy has been shown to significantly reduce muscle-related pain and is a preferred method in managing symptoms and disability (Bethers et al., 2021; Elibol & Cavlak, 2019). A systematic review analyzing patients with musculoskeletal disorders and shoulder and back pain found low-to-moderate evidence suggesting that massage therapy, in isolation from other therapies, was

effective in reducing pain and improving function (Bervoets et al., 2015). In patients dealing with chronic neck pain, massage therapy has shown a dose-response effect in which increasing both duration and frequency are correlated with decreasing muscle dysfunction and pain intensity (Sherman et al., 2014). When compared to traditional physical therapy, massage therapy has proven to be just as effective in reducing pain intensity, improving function, and increasing range of motion (Kamali et al., 2014). In addition to pain, muscle tension is a commonly reported symptom following WBI in prone positioning. A recent study found that one session of quick massage on the shoulders, neck, and spine was effective in decreasing perceived muscle tension (Simao et al., 2021). Massage has been shown to reduce fatigue, physical discomfort, and bodily pain in patients with breast cancer, specifically those undergoing RT and WBI (Behzadmehr et al., 2020; Bervoets et al., 2015; Kamali et al., 2014; Listing et al., 2009; Simão et al., 2021). With reported improvements in mood, decreased stress, and increased relaxation, massage provides benefits that could further support patients undergoing breast radiotherapy (Listing et al., 2009).

Because cancer pain displays diverse manifestations and is specific to each patient, complementary and alternative therapies can be particularly helpful. Therapies such as massage, acupuncture, and music therapy also address anxiety, stress, depression, and mood disturbances in cancer patients. This makes therapies like massage distinctly effective in managing and reducing cancer-related pain (Behzadmehr et al., 2020; Maindet et al., 2019). A recent seven-arm randomized trial determined a dose-response effect for massage therapy and cancer-related pain. The odds of clinical improvement for pain, fatigue, and sleep disturbances improved with dose-escalation of the duration of massage therapy, and effect durability for doses of massage therapy at a higher weekly frequency was significantly higher (Miladinia et al., 2022). A recently published meta-analysis found that a massage duration of 10-30 minutes at a frequency of more than once per week was effective in reducing pain in cancer patients (Zhang et al., 2023).

3. Objectives

Describe the purpose of the study.

Given the prevalence of musculoskeletal complaints during radiation therapy delivery and acknowledging the emotional stress associated with breast cancer diagnosis and treatment, the aims of this pilot study are to: 1) evaluate the effectiveness of a focused upper body massage, available after radiation treatments, on the patient's muscle and joint achiness and disability/symptoms of the upper extremities; 2) evaluate the effectiveness of a focused chair massage, available after radiation treatments on health-related quality of life; 3) assess the need for repeating the pre-radiation simulation process and revising the established treatment plan; and 4) and evaluate patient acceptability of the massages offered during the course of radiation treatment. Results from this pilot study will be used to assess feasibility of the study protocol and inform a future, larger study.
Due to the frequency of musculoskeletal complaints in patients receiving RT and WBI, and the proven benefits of massage therapy, we **hypothesize** that a focused massage of the neck, shoulders, arms, and hands offered after breast radiotherapy during a prescribed course of

treatment will reduce muscle and joint achiness, musculoskeletal pain and disability, improve quality of life, and reduce the need for re-simulation and revision of the treatment plan for patients with breast cancer. We also hypothesize that patients who receive massage during the course of their radiation treatments will find them acceptable.

Primary Objectives and Outcome Measures

Describe the study objectives and outcomes.

Primary Objective: To evaluate the effectiveness and acceptability of a focused upper body massage when offered after radiation treatments to participants diagnosed with breast cancer.

Primary Outcomes: Mean change in musculoskeletal and joint pain, disability and symptoms of the upper extremities, and health-related quality of life from baseline to the participant's 4-6 week post-treatment appointment.

Secondary Objectives and Outcome Measures

Describe any secondary objectives and outcomes.

Secondary Objectives: 1) To evaluate the need for participant re-simulation during the course of radiation, specifically the preparatory patient imaging, positioning, and marking to ensure precise targeted radiation, requiring a revised treatment plan due to inability of patient to tolerate positioning because of pain or disability. 2) To evaluate participant acceptability of the massages. 3) To obtain participant qualitative feedback on the physical and emotional perceptions about the massage intervention.

Secondary Outcomes: Number of re-simulation occurrences during the course of radiation. Participant perception of acceptability of the massage intervention.

4. Study Design & Procedures

	Y	N	Comments
1. Is this a multi-site study?	☐	☒	If yes, complete the Multi-Site Research appendix.
2. Does the research involve the use of an approved drug or biologic, use of an unapproved drug or biologic, or use a food or dietary supplement intended to diagnose, cure, treat, or mitigate a disease or condition?	☐	☒	If yes, complete the Drug appendix.
3. Does the research involve the use of a device to evaluate its safety or effectiveness or use a humanitarian use device (HUD)?	☐	☒	If yes, complete the Device appendix.

Provide information about all research interventions and activities that are to be performed.

The study intervention is a chair massage, up to 20 minutes in length, focused on the neck, shoulders, back, arms and hands. The massage will be provided to participants after radiation treatments; participants will be fully clothed. The massage chair will be located at Stefanie Spielman Breast Center (SSBC), within a private space adjacent to the linear accelerators and patient changing room to facilitate privacy and accessibility. The massage will be provided by a licensed massage therapist from the OSU Center for Integrative Health with special training in oncology massage. Questionnaires to assess musculoskeletal and joint pain, upper extremity disability, and health care quality of life will be obtained at baseline and after the participant's radiation treatments are complete, at the 4-6 week post-treatment appointment. Questionnaires assessing musculoskeletal and joint pain and upper extremity disability will be obtained at each of the participant's weekly treatment appointments during the course of their radiation treatments. After radiation treatments are complete, at the 4-6 week post-treatment appointment, a questionnaire related to perceptions of the acceptability of the massage intervention will also be obtained. Two qualitative questions related to the participant's perceptions about the physical and emotional aspects of the post-radiation massages will also be obtained. The need for re-simulation during the participant's treatment period will be obtained from the electronic medical record after the radiation treatments are complete.

Patient Demographics

1. Age: in years
2. Gender: female, male, non-binary
3. Weight: in kilograms

Patient Clinical Information

1. Treatment position: prone or supine
2. Axillary Node dissection prior to radiation treatment: yes or no
3. Previously diagnosed musculoskeletal (MSK) disorders: list MSK diagnosed disorders
4. Radiation treatment frequency: number per week, total number per treatment course
5. Massage frequency: number per week, total number per treatment course
6. Physical Therapy referral: yes or no; if yes, received physical therapy during course of radiation treatment

Musculoskeletal and Joint Pain The National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®) Custom Survey will be used to measure the patient's self-reported musculoskeletal and joint pain as defined by achiness (Atkinson et al., 2017; Basch et al., 2014; Dueck et al., 2015; Hay et al., 2014). The PRO-CTCAE Custom Survey includes three questions related to "aching muscles". In question 1a, respondents are asked to describe how often they experienced "aching muscles" over the last seven days. Responses include "never", "rarely", "occasionally", "frequently", and "almost constantly". Question 1b asks respondents to describe the severity of their "aching muscles" at their worst over the last seven days. Responses include "none", "mild", "moderate", "severe", and "very severe". Question 1c asks respondents to describe how much "aching muscles" interfered with usual or daily activities over the last seven days. Responses include "not at all", "a little bit", "somewhat", "quite a bit", and "very much". The Custom Survey also

includes three questions for respondents to rate how often, over the last seven days, they have experienced “aching joints”. In question 2a, respondents are asked to describe how often they experienced “aching joints” over the last seven days. Responses include “never”, “rarely”, “occasionally”, “frequently”, and “almost constantly”. Question 2b asks respondents to describe the severity of their “aching joints” at their worst over the last seven days. Responses include “none”, “mild”, “moderate”, “severe”, and “very severe”. Question 2c asks respondents to describe how much “aching joints” interfered with usual or daily activities over the last seven days. Responses include “not at all”, “a little bit”, “somewhat”, “quite a bit”, and “very much”. Musculoskeletal and joint pain will be measured at baseline, before the patient begins the study, at each of the patient’s weekly treatment appointments, and again at the 4-6 week post-treatment appointment.

Disability/Symptoms of the Upper Extremities The QuickDASH (Gummeson et al., 2006) is an 11-item self-report scale that asks patients about their symptoms and their ability to perform certain upper extremity (hand, arm, shoulder) activities during the past week, i.e. open a tight or new jar, use a knife to cut food, wash your back, etc. The QuickDASH has been validated in breast cancer survivors reporting upper extremity disability with a Cronbach’s α=0.93 (LeBlanc et al., 2014). The first six questions focus on activities and responses include: 1 (no difficulty), 2 (mild difficulty), 3 (moderate difficulty), 4 (severe difficulty), and 5 (unable). Question seven asks to what extent has arm, shoulder, or hand problems interfered with normal social activities during the past week. Responses include: 1 (not at all), 2 (slightly), 3 (moderately), 4 (quite a bit), and 5 (extremely). Question eight asked about limitations in work or other regular daily activities as a result of their arm, shoulder, or hand problems. Responses include: 1 (not limited at all), 2 (slightly limited), 3 (moderately limited), 4 (very limited), and 5 (unable). Questions nine and 10 ask respondents to rate the severity of their arm, shoulder, or hand pain and tingling in the arm, shoulder or hand. Responses include: 1 (none), 2 (mild), 3 (moderate), 4 (severe), and 5 (extreme). Question 11 asks respondents to rate how much difficulty they have had sleeping because of pain in the arm, shoulder, or hand in the past week. Responses include: 1 (no difficulty), 2 (mild difficulty), 3 (moderate difficulty), 4 (severe difficulty), and 5 (so much difficulty that I can’t sleep). Higher scores indicate increased symptoms/disability. Symptoms/disability of the upper extremities will be measured at baseline, before the patient begins the study, at each of the patient’s weekly treatment appointments, and again at the 4-6 week post-treatment appointment.

Health-related Quality of Life

The SF-12v2 (Ware et al., 2008; Ware et al., 2002; Ware et al., 1996) is a 12-item self-report instrument that has been used to measure health-related quality of life in breast and other cancers (Lopez et al., 2017; Mokhtari-Hessari & Montazeri, 2022; Rendas-Baum et al., 2018). The questions are grouped into eight different health domains including physical functioning, role physical, bodily pain, general health, vitality, social function, role emotional, and mental health. Question 1 asks respondents to rate their health with responses including 1 (excellent), 2 (very good), 3 (good), 4 (fair), and 5 (poor). Questions 2a and 2b asks how much their health limits moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf and climbing several flights of stairs. Responses for questions 2a and 2b include 1 (yes, limited a lot), 2 (yes, limited a little), and 3 (no, not limited at all). The remaining questions ask

respondents to reflect over the past four weeks the answer the questions. Questions 3a and 3b ask respondents to how much of the time they have had problems with work or other regular activities because of their physical health. Specific questions ask if they have accomplished less than they would like and if they were limited in the kind of work or other activities. Responses for questions 3a and 3b include 1 (all of the time), 2 (most of the time), 3 (some of the time), 4 (a little of the time), and 5 (none of the time). Questions 4a and 4b ask respondents ask how much of the time they have had problems with work or other regular activities because of emotional problems. Specific questions ask if they have accomplished less than they would like and if they were limited in the kind of work or other activities. Responses for questions 4a and 4b include 1 (all of the time), 2 (most of the time), 3 (some of the time), 4 (a little of the time), and 5 (none of the time). Question 5 also asks the respondent how much pain interfered with their normal work, both work outside the home and in the home. Responses include 1 (all of the time), 2 (most of the time), 3 (some of the time), 4 (a little of the time), and 5 (none of the time). Questions 6a, 6b, and 6c ask respondents about how they have been feeling. Specific questions include if they have felt calm and peaceful, did they have a lot of energy, and if they have felt downhearted and low. Responses include 1 (all of the time), 2 (most of the time), 3 (some of the time), 4 (a little of the time), and 5 (none of the time). Question 7 asks how much of the time has physical health or emotional problems interfered with social activities. Responses include 1 (all of the time), 2 (most of the time), 3 (some of the time), 4 (a little of the time), and 5 (none of the time). Total scores can range from 0 to 100 with 0 reflecting the minimum health level and 100 the maximum health level. Health-related quality of life will be measured at baseline, before the patient begins the study, and at the 4-6 week post-treatment appointment.

Re-simulation

The need to repeat the pre-radiation simulation process, specifically the preparatory patient imaging, positioning, and marking to ensure precise targeted radiation, requiring a revised treatment plan due to inability of patient to tolerate positioning because of pain or disability. This outcome will be measured post-intervention and extracted from the electronic medical record.

Acceptability of the Massage

To evaluate patient acceptability of the massages offered during the course of radiation treatments using the AIM, Acceptability of the Intervention Measure (Weiner et al., 2017). A 4-item self-report measure, acceptability of the massage intervention by patients in this study will be offer important for a future investigation (In, 2017). Questions include: 1. The upper body massages met my approval.; 2. The upper body massages were appealing to me.; 3. I liked the upper body massages.; and 4. I welcomed the upper body massages. Responses include; 1-completely disagree; 2-disagree; 3-neither agree nor disagree; 4-agree; 5-completely agree. Total scores of the AIM range from 4 to 20 with higher total scores indicating a higher acceptability of the intervention. The patient's perception of the acceptability of the massages will be measured at the 4-6 week post-treatment appointment.

Participant Perceptions of the Post-Radiation Massages To evaluate the participant's perceptions of the physical and emotional aspects of receiving the upper body massages post-radiation, the question, "Can you describe how you felt physically and emotionally after receiving the brief upper body massages following your radiation treatments?" You may describe, in your own words, any physical sensations and emotional experiences

associated with the massages. In addition, the question, "Did you experience any radiation treatments without massages? If yes are you able to describe how you felt after treatments (this could be physical or emotional sensations) with massages vs those without?" will also be asked. These questions will be asked at the 4-6 week post-treatment appointment. Participants will write their response via the REDCap link or the questionnaire form provided to them.

Research Design

Identify the research design appropriate to answer the question(s) under study.

The purpose of this prospective, longitudinal cohort pilot study is to evaluate the effectiveness of focused massage after radiation treatments on muscle and joint achiness, disability/symptoms of the upper extremities, health-related quality of life, need for re-simulation requiring a revised treatment plan, and acceptability of the massage intervention for patients with breast cancer.

Detailed Study Procedures

	Y	N	Comments
1. Are you requesting expedited IRB review? Note: The federal regulations establish two main criteria for an expedited review: a. The research may not involve more than "minimal risk" (refer to appendix). b. The entire research project must be consistent with one or more of the federally defined categories (refer to appendix).	☐	☒	If yes, complete the Expedited Review appendix.
2. Does the research involve genetic testing?	☐	☒	If yes, complete the Genetic Testing appendix.

Describe the selected procedures sufficiently to justify their use in answering the defined research question(s).

Baseline questionnaires that will include evaluation of aching muscles and aching joints, disability/symptoms of the upper extremities, overall health status and quality of life, and will be completed prior to initiation of the prescribed course of radiation treatments. Surveys on aching muscles and joints and disability/symptoms of the upper extremities will be completed at the patient's weekly treatment appointments. To maintain consistency of survey completion and to be able to analyze effectiveness of the massage(s) on patient outcomes, the weekly surveys will be completed regardless of whether the patient has received massage(s) or not. Post-intervention questionnaires will be completed at the patient's 4–6-week post-treatment appointment and include aching muscles and aching joints, disability/symptoms of the upper extremities, overall health status and quality of life, and acceptability of the massage intervention. Demographic and

clinical data will be obtained from the electronic medical record by study staff during the study period and post-intervention. All data extracted from the electronic medical record will be entered into REDCap (Harris et al., 2019; Harris, et al., 2009).

The James Patient Appointment Schedulers will schedule the massages in coordination with the participant's radiation treatments, noting that the massage will be performed after the radiation treatment. Massage therapists will be scheduled at the SSBC to optimally accommodate participant radiation schedules. Massage appointment times will be scheduled for 30 minutes in length to allow a massage of up to 20 minutes and time for the participant to change from their radiation treatment.

Describe procedures for data collection. Be sure to specify the source records that will be used to collect data about participants. Upload all surveys, scripts, and data collection forms/spreadsheets to the Other Attachments section of the SmartForm.

Baseline questionnaires that will include evaluation of aching muscles and aching joints, disability/symptoms of the upper extremities, and overall health status and quality of life will be completed prior to initiation of the prescribed radiation treatment course per the participant's preference, either via the participant's smartphone or computer via a REDCap link via the participant's preferred email, or per paper survey forms provided by study personnel. If the participant completes the survey questionnaires via paper, the study coordinator(s) will coordinate a day/time and private place at SSBC for the participant to complete the survey questionnaires.

Surveys on aching muscles and joints and disability/symptoms of the upper extremities will be completed at the patient's weekly treatment appointments via the patient's smartphone with the REDCap link coinciding with the patient's weekly appointment or per paper survey forms provided by study personnel. To maintain consistency of survey completion and to be able to analyze effectiveness of the massage(s) on patient outcomes, the weekly surveys will be completed regardless of whether the patient has received massage(s) or not.

Post-intervention questionnaires will be completed at the patient's 4–6-week post-treatment appointment and include aching muscles and aching joints, disability/symptoms of the upper extremities, overall health status and quality of life, and acceptability of the massage intervention via the participant's smartphone per REDCap link or per paper survey forms.

The qualitative questions, "Can you describe how you felt physically and emotionally after receiving the brief upper body massages following your radiation treatment? You may describe, in your own words, any physical sensations and emotional experiences associated with the massages." and "Did you experience any radiation treatments without massages? If yes are you able to describe how you felt after treatments (this could be physical or emotional sensations) with massages vs those without?" These will also be completed at the participant's 4-6 week post-treatment appointment and will be answered via the participant's smartphone per REDCap link or per paper survey form.

Demographic and clinical data will be obtained from the electronic medical record by study staff during the study period and post-intervention. All data extracted from the electronic medical record will be entered into REDCap (Harris et al., 2019; Harris, et al., 2009). Should the patient complete paper surveys, the survey data will be transcribed into into REDCap immediately. After verification of transcription accuracy by a second study coordinator, all paper copies will be destroyed.

Describe the timeline for participant evaluations and the duration of project participation, for both individual study activities and total study participation, when applicable.

Questionnaires to assess musculoskeletal and joint pain, upper extremity disability, and health care quality of life will be obtained at baseline, before radiation treatments begin. Completion of these questionnaires will take approximately 30 minutes.

Questionnaires assessing musculoskeletal and joint pain and upper extremity disability will be obtained at each of the participant's weekly treatment appointments. Completion of these questionnaires will take approximately 15 minutes. Total duration of time during the weekly questionnaire completion is dependent upon the length of the participant's radiation schedule which may range from 4 to 8 weeks; the time for questionnaire completion may range from 1 hour to 2 hours.

After radiation treatments are complete, at the 4-6 week post-treatment appointment, questionnaires to assess musculoskeletal and joint pain, upper extremity disability, and health care quality of life, perceptions of the acceptability of the massage intervention, as well as their physical and emotional perceptions of receiving post-radiation massages during their treatment, will be completed and will take approximately 30 minutes.

Total time completing study related questionnaires will be based on prescribed radiation treatment course and may range from 2 hours to 3 hours.

Radiation treatments are physician directed and may be scheduled daily, every other day (3 times a week), or twice weekly. Participation in the massage intervention (30 minutes per session includes 20 minutes in massage room, 10 minutes to change to/from robe used during radiation treatment) may range from 2 hours (1 radiation treatment per week for 4 weeks) to 9 hours (3 radiation treatments per week for 6 weeks).

Based on frequency and length of radiation treatments, total participant study time to complete questionnaires and to receive the massage interventions may range from 4 hours to 12 hours.

Describe plans for long-term follow-up once all research related procedures are complete, if any, and specify what data will be collected during this period.

There are no plans for long-term follow-up.

Alternatives to Participation

Indicate any alternatives to participating in the research, if applicable, including available procedures or treatments outside the research that may be advantageous to the participant.

There are no alternatives to participation.

5. Institutional Approvals

1. Check all institutional approvals that apply to research being conducted at Ohio State.
☒ Comprehensive Cancer Center (CCC) Clinical Scientific Review Committee (CSRC): Approval or exemption required prior to IRB review for all cancer-related research. Upload a copy of the approval letter to the Other Attachments section of the SmartForm.
☐ Institutional Biosafety Committee (IBC): Approval required prior to IRB review for research involving biohazards (recombinant DNA, infectious or select agents, viruses, toxins), gene transfer, or xenotransplantation. Upload a copy of the approval letter to the Other Attachments section of the SmartForm.
☐ Human Subject Radiation Committee (HSRC): Approval required for research involving radiologic procedures for research purposes (e.g., non-clinical care X-rays, DEXA or CT scans, nuclear medicine procedures). Complete the Radiation appendix and upload a copy of the HSRC approval letter to the Other Attachments section of the SmartForm.

6. Participant Population

1. Specify the participant population(s). Check all participant groups that apply. For any population other than adults, complete the applicable appendix.
☒ Adults ☐ Adults with impaired decision-making capacity ☐ Children ☐ Neonates of uncertain viability ☐ Nonviable neonates ☐ Non-English-speaking individuals ☐ Pregnant women/fetuses (only if pregnant women will be intentionally recruited and/or studied) ☐ Prisoners

Describe the sample population from which the study team plans to either recruit or access private, identifiable information for the research.

All English-speaking patients with a current diagnosis of breast cancer who will begin curative intent breast radiotherapy at The Ohio State University Stefanie Spielman Comprehensive Breast Center.

Create a numbered list of the eligibility criteria that define who will be included in the final study sample (e.g., age, gender, condition).

Inclusion Criteria:

1. 18 years of age or older
2. Diagnosis of breast cancer
3. Treatment plan for curative intent radiation at SSBC
4. Radiation treatment frequency can be daily, every other day, and twice weekly
5. Agreeable to and available for focused chair massages post-radiation treatments during the prescribed treatment period

Exclusion Criteria:

1. Patients with recurrent disease (breast cancer)
2. Patients treated palliatively with radiation treatments
3. Inability to read and/or understand English (consent and questionnaires in English)
4. Patients with documented cognitive disorder that limits the ability to independently read, understand, and/or complete the survey measures; i.e. dementia, Alzheimer's
5. Patients with major psychiatric disorders not controlled by medication or other psychiatric treatments

If appropriate, describe why certain populations may be excluded (e.g., non-English speaking individuals for studies involving informed consent).

Patients with recurrent breast cancer and those treated with palliative radiation will be excluded from this study as metastases to other organs, and pain/disability related to metastases and/or end stage cancer could limit their ability to participate in the massage intervention. Those who cannot read and understand English will be excluded as the consent, all questionnaires, and study related communication with study personnel will be in English. Lastly, those with cognitive disorders that would limit independent participation and psychiatric disorders uncontrolled by medications or other psychiatric treatments will be excluded since the intervention involves the participant to provide consent, understanding of the massage intervention, and feedback relative to the massage, as well as touch by and close contact with a massage therapist.

Number of Participants

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed) even if all do not prove eligible or

complete the study. The total number of research participants may be increased only with prior IRB approval.	
1. Indicate the number of participants to be enrolled locally.	55
2. For multi-site studies, indicate the total number of participants to be enrolled across all sites.	N/A

Explain how this number was derived (e.g., meets statistical power, limited population). If applicable, explain how many individuals are expected to agree to participate and how many evaluable participants are needed to conduct the study (excluding screen failures).

The sample will be recruited from patients who have been diagnosed with breast cancer and consented for curative breast radiotherapy at SSBC, typically 50 patients per month. For this pilot study, to obtain an effect size of 0.21(primary outcome variables), significance of 0.05, and power of 0.95 (to account for lower recruitment number), a total of 55 patients will be recruited. This sample size includes 44 patients plus and an additional 25% (11 patients) to account for attrition (Faul et al., 2009). It is anticipated recruitment will take 10-11 months for this projected two-year study period.

Participant Identification

Describe how potential participants will be identified (e.g., advertising, individuals known to the investigators, record review).

Participant recruitment will occur via targeted MyChart messaging to patients with a diagnosis of breast cancer who have been prescribed radiation of the breast. As medical record review as a partial waiver of HIPAA research authorization has been requested, once potential participants respond affirmatively through the MyChart portal, a study coordinator will perform a medical record review to assess for primary English language, any documented cognitive and/or psychiatric diagnoses that would exclude the participant from study participation and verify radiation for curative intent. If the potential participant meets the criteria after the medical record review, they will reach out to the potential participant via phone to screen the patient for eligibility, provide an overview of the study, and answer any questions. Informational postcards with a QR coded link to provide contact information for potential participants will also be available within the Radiation Oncology patient waiting rooms and clinical examination areas at the SSBC. As medical record review as a partial waiver of HIPAA research authorization has been requested, once interested patients submit their name and contact information via the Qualtrics survey, a study coordinator(s) will perform a medical record review to assess for primary English language, any documented cognitive and/or psychiatric diagnoses that would exclude the participant from study participation and verify radiation for curative intent. If the potential participant meets the criteria after the medical record review, they will reach out to the

potential participant via phone to screen the patient for eligibility, provide an overview of the study, and answer any questions.

Should interested participants not meet study criteria after medical record review, the study coordinator will reach out to let participants know they are not eligible to participate in the study.

Explain how the investigator(s) will gain access to this population, as applicable, and provide evidence that you will be able to recruit the necessary number of participants to complete the study.

The James Radiation Oncology physicians, Radiation Oncology nursing staff, the SSBC patient schedulers, and the Breast Cancer Diagnostic Committee are knowledgeable about and extremely supportive of this study. In their daily roles, these clinicians interface with this patient population and have stated that patients often request complementary therapies, such as massage, to help manage the physical and emotional discomfort they experience during radiation therapy. Unfortunately, these supportive therapies are often unavailable to patients as they are not covered by insurance and paying out of pocket is usually not feasible during a medical crisis. A radiation oncologist department leader and the Radiation Oncology nursing leadership, in contact daily with these patients, are part of the research team.

Participant Recruitment and Selection

Describe how potential participants will be screened or otherwise determined to be eligible.

Once potential participants respond affirmatively through the MyChart portal or via the Qualtrics survey, a study coordinator will perform a medical record review to assess for primary English language, any documented cognitive and/or psychiatric diagnoses that would exclude the participant from study participation and verify radiation treatments for curative intent. If the participant meets these criteria after the medical record review, the study coordinator will contact the potential participant via phone to verify inclusion/exclusion criteria, provide an overview of the study, and answer any questions.

Describe the recruitment process, including the setting in which recruitment will take place.

The recruitment process will begin for participants per MyChart “Contact Me” or the Qualtrics survey. Both processes will proceed by the study coordinator accessing the patient’s medical record for initial screening and verification of the inclusion and exclusion criteria. If the potential participant meets initial screening criteria, the potential participant will be contacted by the study coordinator via phone to review and verify the inclusion and exclusion criteria. Once it has been determined that eligibility criteria have been met, the study coordinator(s) will verbally review the process for how the massages will be scheduled and coordinated with prescribed radiation treatments and note that the massages will appear on their MyChart Patient Appointment schedule (noting day, time, and location), where the massages will take place at SSBC, the

cadence of the outcome measures that participants will need to complete and how they are able to complete them, i.e. electronically via REDCap link sent to their preferred email or via paper documents.

If the potential participant expresses interest in participating in the study, the study coordinator will schedule a day/time for the participant to review and sign the consent at a private space at SSBC, prior to the initiation of the participant's radiation treatments.

Explain how the recruitment process respects potential participants' privacy.

Targeted recruitment via MyChart messages is developed based on algorithms that correlate to specific study inclusion criteria, i.e., 18 years and greater, diagnosis of breast cancer, prescribed radiation with curative intent, any frequency of radiation treatment, etc. These MyChart messages can only be viewed by participants who receive them via their password protected MyChart website or MyChart smartphone app. Study coordinators will only receive information on patients who choose "Contact Me" to indicate they are interested in study participation. The informational recruitment postcards include a QR code that directs interested participants to a Qualtrics survey requesting the potential participant's name and preferred contact information. Only the study coordinator(s) will have access to this Qualtrics information. Once the study coordinator receives the interested participant's information, recruitment screening activities and study discussions will occur via the patient's preferred phone number.

7. Cost to Participants and Incentives to Participate

Potential Costs/Reimbursements

Describe any potential costs participants or their insurer will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests). Indicate here which costs, if any, will be reimbursed or covered by the study.

There are no costs to participants relative to participation in this study.

Incentives

Describe any compensation or other incentives (e.g., free services, cash payments, gift cards, classroom credit) that will be offered to potential participants. Include the amount and timing of all incentives or compensation, the form of compensation (e.g., cash, check, gift card), and how the compensation will be received (e.g., mailed, in person, online). This information must also be included in the consent form.

Participants will not receive compensation for participation in this study.

8. Compensation for Research-Related Injury

If the research involves greater than minimal risk to participants, describe the available compensation in the event of research related injury or explain why no compensation is available.

Not applicable

9. Informed Consent Process

1. Specify the consent process(es) to be used for the study. Check all processes that apply. For any waivers or alterations, complete the applicable appendix.

☒ Informed Consent with Written Signature (e.g., on paper)
☐ Informed Consent with Electronic Signature
Note: If the method used to obtain electronic signatures does not qualify as a legally valid signature, also check "Waiver of Consent Documentation." See guidance provided by the Office of Technology and Digital Innovation.
☐ Waiver of Consent/Parental Permission Documentation
☐ Deception (i.e., procedure in which investigators deliberately mislead participants during research by withholding information or providing false information).
Note: If this is selected, also check "Waiver or Alteration of the Consent Process."
☐ Waiver or Alteration of the Consent Process
☐ Waiver of the Parental Permission Process

Describe the consent process. Explain when and where consent will be obtained and how participants or their legally authorized representatives will be provided sufficient opportunity to consider participation.

Once the patient confirms understanding of the study processes and confirms their interest in participating in the study, the study coordinator(s) will coordinate a day/time and private place at SSBC, prior to the initiation of radiation treatments, for the participant to review and sign the consent.

If the patient requests additional time to consider participation after reviewing the consent, a copy will be provided to the patient, contact information for the study coordinator(s) will be provided for any additional questions, and a day/time will be set for follow-up prior to the initiation of the participant's radiation treatments.

Only study personnel will be involved in patient recruitment activities. The patient's provider (physician/advanced practice nurse) will be informed of patient participation, via MyChart message and IHIS research study designation field, only after the patient has consented to be part of the study.

Specify who will provide consent or permission (i.e., participant, legally authorized representative, parent and/or guardian).

The participant will provide consent to participate in the study.

Explain how the possibility of coercion or undue influence will be minimized in the consent process.

A paper consent will be provided to the potential participant in a private consultation space at the SSBC. The study coordinator will provide the potential participant with adequate time to read, review, and ask questions prior to signing. If they prefer more time to consider participation and or to review the consent, a copy will be provided with instructions to contact the study coordinator for any questions or concerns.

10. Privacy of Participants

Describe the steps that will be taken to protect participants' privacy and make them feel at ease with the research situation in terms of the questions being asked and the procedures being performed.

This study involves a group of patients who may regularly see and interact with each other in waiting rooms, changing rooms, and the Radiation Oncology Department at SSBC during the course of their radiation therapy. Given this exclusive environment and the repeated nature of prescribed treatments, participant privacy will be managed in several ways. During recruitment, initial screening will take place between the potential participant and the study coordinator(s) via phone. The consent process will occur within a private consultation space at SSBC. Similarly, the study questionnaires will be completed through a REDCap link sent to the participant's preferred email or if paper forms are preferred, within a private consultation space or clinical exam room at SSBC. Consistent study coordinator(s) will be used to enhance patient privacy and comfort with the research processes.

The massage intervention will take place in private treatment spaces that are contiguous to the linear accelerators and the SSBC changing rooms to minimize extraneous interactions with other patients. The massage therapists, by virtue of their oncology training, will also include an exclusive group, promoting comfort and familiarity for the participants.

The James patient schedulers, who will be assuring massage times coordinate with radiation treatments may vary, however, they are bound by patient privacy and confidentiality as employees at The James. They are also well-versed in supporting patient research and scheduling for various studies.

Except for radiation oncology physician and nursing staff who are part of the research team, and the patient's primary radiation oncology providers who will be able to see within the electronic

medical record that the patient is part of the study, no Radiation Oncology and SSBC staff will be notified of who is participating in the study.

Participant consents and surveys will be immediately scanned (consents) and manually transcribed (surveys) into REDCap, under the participants Subject Identification Number (SID), and stored there for the duration of the study.

11. Confidentiality and Management of Study Materials

	Y	N	Comments
1. Does the research involve obtaining and storing participants' data and/or biospecimens for future, unspecified, research?	☐	☒	If yes, complete the Repositories appendix.

Describe the steps that will be taken to secure study data.

The study team will include a small team of clinical and research staff with expertise in managing patients receiving radiation oncology for breast cancer, expertise providing and integrating complementary modalities into the clinical care of patients, and expertise in implementing and managing research studies at the Wexner Medical Center. While the massage therapists providing the intervention are part of the study team, they will not have access to the participant data in order to protect patient confidentiality and prevent any potential study bias. Only study team members involved in patient recruitment, data collection, data entry, and data analysis will have access to participant data.

If the participants express interest in the study via MyChart, study staff will receive notifications via their EMR inbox only for these potential participants. OSU Qualtrics will be used to collect interested participant contact information if they express interest via the recruitment flyer. Participant contact information in Qualtrics will be accessible only by study personnel who are involved in recruitment of patients. REDCap will be used for data storage and management with participants identified only by Subject Identification Numbers (SID). Paper consents will be immediately scanned into REDCap and paper surveys will be manually transcribed immediately into REDCap, under the participants Subject Identification Number (SID) by the study coordinator and validated for accuracy by a second study coordinator. Once entered into REDCap and accuracy assured, paper copies of participant questionnaires will be destroyed immediately.

Participant screening and enrollment logs, and all data collection forms will be stored in an OSU secure Sharepoint site. Only study personnel that have responsibility for recruitment, data collection, and data entry will have access to the data. Once the study has completed, the stored

study data will be retained for a minimum of five years (ATC+5). HIPAA research authorization forms will be retained for a minimum of six years after the study has completed (ATC+6).

OSU approved laptops with two-factor authentication and encryption will be used by study personnel who have responsibility for recruitment, data collection, data entry and storage of data.

All data will be de-identified and reported only in aggregate. There will be no PHI or self-report data that will be identifiable.

Describe any procedures that will be used for quality control of collected data.

For consents and surveys completed per paper forms, the study coordinator(s) will be available to provide the forms, answer any questions related to the forms, and collect the forms once the participant has completed them. All paper consents will be immediately scanned into REDCap by a study coordinator; all paper surveys will be manually transcribed into REDCap; all entered data will be validated for accuracy and completeness by a second study coordinator. After data entry has been validated for accuracy, the paper forms will be securely destroyed.

Describe how data (and if applicable, biospecimens) will be handled study wide.

Participant consents will be stored in REDCap for the duration of the study and a minimum of six years after study closure (ATC+6). Participant survey data will be stored in REDCap for the duration of the study and a minimum of five years after study closure (ATC+5). The participant names, email addresses, contact information, Subject Screening and Recruitment Log, Data Collection Form - Participant Medical Record Data, Data Collection Form – Participant Arm Assignment, Data Collection Form - Participant Radiation/Massages per Week_Re-Simulation, and the Data Safety and Monitoring Plan Log will be stored in the secure OSU Sharepoint site for the duration of the study and at least five years after the close of the study (ATC+5).

Once study recruitment is complete, the Data Collection (for Recruitment Purposes Only) form will be securely destroyed as this data collection form will include participants who do not meet study criteria or who do not consent to participate in the study.

Specify the identifiable information that will be included in the data or associated with the biospecimens.

Limited demographic data will be extracted from the electronic medical record and will include the participant’s name and medical record number, patient email and phone number, participant age, gender, weight. Clinical information extracted from the electronic medical record will include treatment position, axillary node dissection, previously diagnosed musculoskeletal

disorders, radiation treatment frequency and massage frequency during the course of the study, physical therapy referral and re-simulation requiring a revised radiation treatment plan.

Specify where and how data or biospecimens will be stored and for how long.

Participant name and contact information, clinical study information, and study safety data will be stored in a secure OSU Sharepoint site; data will be stored for a minimum of 5 years after study closure (ATC+5). All participant consents will be stored in REDCap for a minimum of six years after study closure (ATC+6) and survey data will be stored in REDCap for a minimum of five years after study closure (ATC+5).

Specify who will have access to the data or biospecimens.

All study personnel will be IRB approved; only study personnel will have access to participant data. Specifically, study personnel who are responsible for recruitment, screening, and transcription of data will have access to participant names and contact information within OSU Sharepoint and REDCap. Study personnel responsible for data analysis will have access to the REDCap data. Study personnel responsible to participant safety and monitoring will have access to the protected files housing the Data and Safety Monitoring Plan log.

Specify who will be responsible for receipt or transmission/transport of the data or biospecimens and how will transmission/transport will occur.

The Primary Investigator, Beth Steinberg, will have oversight of scanning patient consents and transcription of paper surveys into REDCap by study coordinators. The PI will be responsible for receipt, transmission, and storage of data into REDCap and OSU Sharepoint. All storage and transmission will be electronic.

Indicate what will happen to identifiable data at the end of the study (e.g., kept identifiable, coded, deidentified). If identifiers will be maintained, provide the rationale supporting this request. If the data will be deidentified, describe the process.

At the end of the study, participant information will be de-identified using the Safe Harbor Method (HHS, 2025). The following participant identifiers will be removed from all data collected during the course of the study: participant name, medical record number, telephone number, email address.

If data or biospecimens will be shared broadly with outside groups (i.e. dbGaP), specify what will be shared, with whom, in what form (e.g., identifiable, coded, deidentified/anonymized).

Data will not be shared broadly with outside groups.

If data or biospecimens will be shared broadly with outside groups or databases (i.e. dbGaP), specify whether participants will have the ability to opt-in or remove the data/biospecimens from these outside groups later if they choose. Generally, if the materials are identifiable, a participant should be able to withdraw them unless retention is required under federal regulation (e.g., FDA).

Because identifying participant information will not be associated with any quantitative data and the quantitative data will be reported only in aggregate form, participants will not have the ability to opt-in or request their data to be removed from outside groups or databases.

12. HIPAA Research Authorization

1. Is individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements to be accessed, used, or disclosed in the study?
   - ☐ No
   - ☒ Yes

Note: The PHI obtained as part of this research must not be reused or disclosed to any other person or entity other than those with IRB approval, except as required by law or for authorized oversight of the research project, without additional approval. IRB approval must be obtained for other research involving the use or disclosure of this PHI.

2. If PHI is accessed, used, or disclosed, specify how authorization requirements will be met (check all that apply). For any waivers or alterations, complete the applicable appendix.
   - ☒ Written Authorization
   - ☒ Partial Waiver (for identification and recruitment purposes only)
   - ☐ Full Waiver (authorization will not be obtained)
   - ☐ Alteration (written authorization will not be obtained or all required elements will not be included)

Explain how the requested PHI (i.e., HIPAA identifiers and associated health information) are the minimum necessary information to accomplish the research objectives.

The demographic accessed from the electronic medical record including participant name and medical record number, email and phone number, will be used to accurately identify the patient and the email will be used to send study related questionnaire links if electronic questionnaires are preferred by the patient. As part of the Partial Waiver for identification and recruitment purposes, a study coordinator will perform a medical record review to assess for primary English language, any documented cognitive and/or psychiatric diagnoses that would exclude the participant from study participation and verify radiation treatments for curative intent.

After consent is obtained, the clinical information that will be accessed from the participant's electronic medical record provides clinical relevance to the effectiveness of the massage intervention. Age, gender, weight, prior axillary node dissection, previously diagnosed musculoskeletal conditions, radiation treatment frequency, concurrent physical therapy, and treatment position, individually and conjointly, could have direct influence on the effectiveness and acceptability of the study massage intervention and are pertinent to the outcomes of this study. The PHI obtained as part of this research will not be reused or disclosed to any other person or entity other than those with IRB approval, except as required by law or for authorized oversight of the research project, without additional approval. IRB approval will be obtained for other research involving the use or disclosure of this PHI.

13. Reasonably Anticipated Benefits

Potential Direct Benefits:

List the potential benefits that participants may expect as a result of this research study. If there are no direct benefits to individual participants, indicate so.

We anticipate that the intervention will bring physical relief and improved well-being to participants in the study. Patients diagnosed with breast cancer who have been prescribed a course of radiation experience increased levels of stress and anxiety due to the diagnosis and rigors of treatment. Participants with underlying anxiety and/or depression may experience even more stress that can negatively impact their personal and/or professional lives. Supportive interventions, such as a focused chair massage, that are acceptable and easily integrated into treatment regimens and the clinical environment are more likely to help patients with breast cancer manage the physical and emotional symptoms they may experience during the course of treatment and recovery.

Potential Societal Benefits:

List the potential benefits that society and/or others may expect as a result of this study.

Results of this study may also be applicable to patients who are diagnosed with other types of cancer and receive radiation therapy where positioning for extended periods of time may cause musculoskeletal discomfort and/or disability and negatively impact their quality of life.

14. Risks, Harms, & Discomforts

Potential Risks, Harms, and/or Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. At a minimum, include the risk of breach of data confidentiality. Discuss severity and likelihood of

occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. Consider the range of risks, including physical, psychological, social, legal, economic, and any other potential risk to the study population.

The study has minimal risks for participants. The massage intervention, while intended to provide relief of discomfort and relaxation, may cause increased discomfort and stress for the patient. Because the intervention is conveniently provided at SSBC, the same place as the patient receives their treatment, it is possible that other clinical staff and other patients may conclude that the patient is participating in a research study by their actions before and/or after their radiation treatments.

Breach of confidentiality of data is always risk, however, all precautions to maintain data security will be taken; i.e. use of REDCap and a secure OSU Sharepoint site.

Risk Mitigation

Describe how risks, harms, and/or discomforts will be minimized. Address all risks described in the section above.

The massage intervention will be provided by licensed massage therapists employed at The Ohio State University Center for Integrative Health. Trained in oncology massage; they are well versed in patient assessment and providing adaptive therapeutic massage. At each massage session, the massage therapist will assess the patient's status, their comfort with the massage intervention, and their physical, psychological, and emotional status. Due to the adjacency to the Radiation Oncology department, any concerns can be easily relayed to the clinical staff caring for the patient. The patients will be fully clothed during the massage and all massage session will be provided in private rooms adjacent to the linear accelerators at SSBC.

A Data and Safety Monitoring Plan has been developed to monitor data integrity, storage, and management. In addition, this plan details a process to document, review, and monitor any study-related adverse events.

All consents and study survey data will be stored and managed in REDCap with individual data associated with a specific SID. Any participant study survey data collected on paper forms will be immediately manually entered into REDCap with paper copies destroyed once entered and validated. Only study personnel associated with study oversight, data entry, and data analysis will have access to REDCap study data. The participant enrollment log and related data collection forms will be stored in a secure OSU Sharepoint site with access restricted only to study personnel with study oversight and those responsible for participant recruitment.

If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders), address the timing and method of testing; include how positive test results will be handled.

N/A

15. Monitoring

	Y	N	Comments
1. Does the research involve greater than minimal risk (i.e., the harms or discomforts described are beyond those ordinarily encountered in daily life or during the performance of routine physical or psychological tests)?	☐	☒	If yes, describe a data and safety monitoring plan below.

Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. If the plan is outlined in a separate document, upload it to the documents page of the application SmartForm. If not, describe it below and include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected)
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee/board)
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled/treated) and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems)

During the course of radiation therapy, patients with breast cancer have weekly treatment appointments scheduled with their oncology team to assess their physical condition, mental health, treatment tolerance, and to address any concerns or questions. In addition, the licensed massage therapist will use a trauma-informed approach during each massage session to build a trusting and therapeutic relationship with the patient. The nature of the pre-massage consultation, a routine assessment prior to any massage, will allow patients to discuss any physical concerns and have control over where and how their body is touched, something that is not always possible during their radiation treatments.

Should any concerns related to data safety or data integrity arise, the Primary Investigator, Beth Steinberg, and co-Investigator, Dr. Jhawar, will manage the monitoring and reporting processes.

16. Data Analysis

Internal/External Validity

Describe measures that have been taken to avoid study bias (consider the threats to internal/external validity).

Prescribed radiation treatment plans for patients diagnosed with breast cancer are based on characteristics of the cancer and the patient. Patient positioning during breast radiotherapy may be prone or supine. Both positions require extension of the arms, overhead or to the sides, which may cause physical and emotional discomfort, especially if the patient has a body habitus or excess weight that limits optimal positioning, or pre-existing conditions such as axillary node dissection and musculoskeletal disorders. Repeated treatments, integral to the treatment plan and curative intent, may exacerbate existing physical and mental conditions, increasing patient's stress and anxiety. As massage therapy is not currently a routine component of the radiation therapy treatment plan, recruitment of patients to better understand the physical and emotional effects of a brief chair massage, focused on the neck, back, shoulders, arms, and hand, is most feasible and appropriate for this pilot study. Participation in a massage, after radiation therapy treatments, is most beneficial when the participants are motivated to experience an intervention that may support improvements in physical and emotional symptoms. While those who choose to participate may be biased towards the massage intervention, this bias may minimize attrition of participants during the study period. Finally, the use of valid and reliable instruments also limits threats to internal validity. While this study is focused on patients diagnosed with breast cancer, results of this study may be applicable to patients with other cancer diagnoses who also require radiation therapy treatments and positioning that may lead to musculoskeletal pain, discomfort and/or disability that negatively impacts their quality of life.

Data Analysis Techniques

Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. Note: The IRB does not need the actual formulas to be used, just a description of them. If applicable, specify the proposed analytic approaches for qualitative data.

Participant Demographics, Clinical Information, Re-Simulation

Descriptive statistics will be used to describe participant demographics. Mean, median, range, and standard deviation will describe participant age and weight; gender will be described with frequencies and mode. Clinical indicators including prone or spine treatment position, axillary node dissection prior to radiation treatment, and previously diagnosed musculoskeletal (MSK) disorders will be described as frequencies and displayed in summary tables. Radiation treatments and massages provided will be described as frequencies relative to number per week and total number per treatment course. Physical therapy referrals and the need for re-simulation during the course of the radiation treatment period will be described as frequencies.

Acceptability of the Massage Intervention

Participant acceptability of the intervention will be described with a summary of the data provided statistically using mean, median, standard deviation, range and percentages as appropriate.

PRO-CTCAE Aching Muscles and Aching Joints

Data for the PRO-CTCAE Custom Survey for both “aching muscles” and “aching joints” will be reported descriptively for each attribute (frequency, severity, and interference with daily activities). The data will be described for both “aching muscles” and “aching joints” with frequencies of each attribute, mean, median, mode, presented in summary tables and graphically.

QuickDASH

QuickDASH scores will be described descriptively with summary of the data provided statistically using mean, median, standard deviation, range relative to baseline, weekly, and post-treatment time points. Inferential statistics, *ANOVA*, will be used to compare repeated measures during the study intervention period for upper extremity pain and disability.

SF-12v2 Health Related Quality of Life

SF-12v2 scores will be described descriptively with summary of the data provided statistically using mean, median, standard deviation, range relative to baseline, weekly, and post-treatment time points. Inferential statistics, *ANOVA*, will be used to compare repeated measures during the study intervention period for health related quality of life.

Correlations between participant age, treatment positioning, radiation treatments received, massages received, physical therapy appointments, and participant muscle and joint aching, upper extremity disability, and quality of life will be explored and relationships between variables presented with correlation coefficients. SPSS statistical software will be used for data analysis with limit of significance set at <0.05.

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