THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A pilot study assessing the effectiveness of use of guided imagery for treatment of pain and symptom management in women with post-mastectomy pain syndrome.
2020-1104

Study Chair: Uzondu Osuagwu, MD

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

Guided imagery is a type of visualization exercise that helps you picture or imagine images in your mind that helps you feel positive, helps focus your thoughts, and helps to calm or relax you, which may reduce feelings of stress and anxiety.

Deep breathing exercises, which are typically done with guided imagery exercises, focuses on you taking deep, slow, even breaths. This type of breathing may also help to relax you and increase your feelings of well-being.

The goal of this research study is to learn if using guided imagery and deep breathing techniques can help with pain management in patients who have post-mastectomy pain syndrome. Researchers also want to learn if guided imagery and deep breathing can help to improve general quality of life and manage other symptoms of post-mastectomy pain syndrome, such as fatigue, inability to sleep, depression, anxiety.

In this study, guided imagery and deep breathing will be compared to the current standard of care. The current standard of care for post-mastectomy pain syndrome is pain medications, physical therapy, and/or Cognitive Behavioral Therapy (CBT) without

guided imagery.

This is an investigational study.

If you are assigned to the guided imagery and deep breathing group, these techniques may help to improve your quality of life, emotional well-being, and symptoms related to post-mastectomy pain syndrome. Future patients may benefit from what is learned on this study. There may be no benefits for you in this study

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Your active participation in this study may last up to 4 weeks.

There will be no cost to you for taking part in this study. You and/or your insurance provider will be responsible for the cost of your surgery and any standard-of-care medications given.

You may choose not to take part in this study. Instead of taking part in the study, you may choose to receive the current standard of care. This will be discussed with you, including the possible risks and benefits of these treatments. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for pain at all. In all cases, you will receive appropriate medical care.

1. STUDY DETAILS

Study Groups

If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one group is better, the same, or worse than the other:

- **In Group 1** (The Intervention Group), you will receive guided imagery and deep breathing technique exercises.
- **Group 2** (The Control Group), you will not receive any relaxation techniques. You will receive the current standard of care.

You will have an equal chance (50/50) of being assigned to either group. The study doctor will tell you which group you are in.

Up to 62 participants will be enrolled in this study. All will take part at MD Anderson.

All participants will be given handouts and resources about the benefits of guided imagery, including a list of resources about meditation and relaxation applications (“apps”). You can choose which apps or websites interest you and the study staff will

help you download these resources onto your personal device. These apps/websites may include Calm, Insight Timer, Aura Omvana, Breathe and Think, and Headspace.

Group 1
In Group 1, you will complete a 20-minute guided imagery exercise (which includes deep breathing exercises) every day at home using the selected app and/or resource you downloaded at the beginning of this study.

In addition to the at-home exercises, you will meet with a social worker either in person or during a virtual video call 1 time a week for up to 3 weeks. During these calls, the social worker will lead you through guided imagery and deep breathing exercises.

You will complete a daily journal before and after completing the guided exercises to document your levels of pain and your mood level. It should take about 5-10 minutes every day to complete this journal entry.

Group 2
In Group 2, you will continue to receive your current care, but will not receive guided imagery or deep breathing exercises from a social worker. During the study and at your own pace, you can use the selected app and/or resource you downloaded at the beginning of this study.

You will complete a daily journal every day after you use the app and/or selected resource to document your levels of pain and your mood level. It should take about 5-10 minutes every day to complete this journal entry.

Study Visits (All Participants)

Every week in this study (Days 0, 7, 14, 21, and 28), you will be asked about which pain medications you are taking. Except for Day 28, you will also have visits with the study team. During these visits, the study team will ask you about your medications, review your pain and mood journal with you, and ask how you are liking the guided imagery and breathing techniques (if you are in Group 1). These visits may be done in person or through telehealth video conferencing methods, whichever you prefer.

On **Day 0 and Day 28,** you will complete 6 questionnaires about your feelings of anxiety and depression, symptoms, pain level, fatigue, sleep, and overall quality of life. They should take no longer than about 45 minutes to complete. Questionnaires may be completed on paper or online through a program called REDCap. If you choose to complete the questionnaires electronically, you will be emailed a link.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, they will vary from person to person.

No known risks are associated with **guided imagery or deep breathing exercises.** However, this study uses techniques that are meant to lower pain, anxiety, and improve your mood. Therapy is often about making changes or about looking at yourself differently. This can make some people uncomfortable. Thinking about your feelings and emotions may make you feel worse at first, as the therapy continues.

If the study team thinks you are in extreme distress and may be in need of help, the study chair will reach out to you. You may be treated by the Department of Psychiatry or referred to a community psychiatrist or mental health provider, if needed.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires, you are encouraged to contact your doctor or the study chair.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets for at least 3 years and will continue to be stored securely after the study. Only people who are directly involved with this research study will have access to study data.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Uzondu Osuagwu, at 281-787-8818) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____

SIGNATURE OF PARTICIPANT DATE

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PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____

PERSON OBTAINING CONSENT DATE

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PRINTED NAME OF PERSON OBTAINING CONSENT