THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Study Title: Yoga Therapy During Chemotherapy and Radiation Treatment for Local-regional Cervical Cancer
2019-0919

Subtitle: MD Anderson Consent

Study Chair: Lois M. Ramondetta

_____ _____
Participant's Name Medical Record Number or Study ID

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

You are being asked to take part in this study because you are a cervical cancer patient who is planning to receive chemotherapy and radiation therapy (CRT).

The goal of this research study is to learn if a yoga therapy program during CRT can help improve physical and emotional well-being. No prior yoga experience or starting level of flexibility is needed to participate in this study. The program will be tailored for your comfort and ability level.

There are two groups in this study: the **Yoga Group (YG)** and the **Wait List Control (WLC)** group.

This is an investigational study.

Your physical and emotional well-being may improve after doing yoga therapy. Future patients may benefit from what is learned. 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 potential expenses and time commitment. You may not want to take part in this study because sensitive topics are discussed.

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

Your participation on this study will be over after you have completed the yoga sessions (YG) and/or the surveys (YG or WLC group). If you are in the WLC group, you will be offered a chance to complete yoga sessions later in the study.

The study will be performed at no cost to you. Any yoga instruction materials you are given as part of this study (such as manuals or DVDs) will be yours to keep at no cost.

You may choose not to take part in this study. The study doctor will discuss with you the possible risks and benefits of your options.

1. STUDY DETAILS

Baseline Visit (First Visit)

Up to 40 participants will be enrolled in this study. Up to 20 will take part in the **Yoga Group (YG)** and up to 20 will take part in the **Wait List Control** (**WLC)** group. All will be enrolled at MD Anderson.

If you agree to take part in this study:

- Blood (about 1-2 tablespoons) will be drawn for tumor marker testing. Tumor markers may be related to the status of the disease.
- You will be asked to complete a set of Quality of Life (QOL) surveys on paper or electronically about your symptoms and demographic information (such as your age, sex, and race). They should take about 30 minutes to complete.
- Your medical history and demographic information that is not in the surveys will be collected from your medical record.

After completing these tests, you will be assigned randomly (like a flip of a coin) to 1 of the 2 study groups: the **YG** or **WLC** group. You will have an equal chance (50/50) of being assigned to either group. You and the study staff will know which group you have been assigned.

The yoga exercises in this study will focus on:

- Joint loosening and stretching
- Different yoga postures and a deep relaxation technique
- Breathing control
- Meditation techniques

Study Visits

All participants will have the following tests/procedures:

- At the **end of CRT**, **1 month after CRT**, and **3 months after CRT**, blood (about 1-2 tablespoons) will be drawn for tumor marker testing.
- In the **middle of CRT**, at the **end of CRT**, **1 month after CRT**, and **3 months after CRT,** you will retake the QOL surveys about symptoms. They should take between 10-25 minutes to complete.

If you are assigned to **YG**:

- **Before starting CRT**, you will complete a pre-treatment survey. The survey will take about 10 minutes to complete.
- **During CRT**:
    - You will receive up to 15 yoga classes at MD Anderson. Due to COVID-19 restrictions on social gatherings, classes will be offered in person, via Zoom (a videoconferencing technology), or a combination of the two based on your preference and current safety measures. For teleconference classes, you will use your personal handheld device (such as a smartphone or internet-connected tablet). Each class, whether face-to-face or teleconference, should take about 60 minutes.
    - A Yoga Therapist (YT) on the study team will help you complete a weekly survey during the yoga class. It should take about 5 minutes to complete.
    - You will receive a yoga manual and video for home practice during and after CRT. These materials will be yours to keep.
- **About 1 month after CRT**, you will complete a post-treatment survey. It should take about 5-10 minutes to complete.

If you are assigned to **WLC**:

- You will be asked to avoid participating in any new stress management activities while on study.
- **About 3 months after CRT**, you will be offered 4 yoga classes in person, via Zoom (a videoconferencing technology), or a combination of the two based on your preference and current safety measures, and you will be given a video for home practice that will be yours to keep. **After you complete all 4 yoga sessions,** you will complete a questionnaire about your feelings towards yoga and how you think it may affect your health, quality of life, and mood. It should take about 5-10 minutes to complete.

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, but they will vary from person to person.

You should discuss the risks of **questionnaires** with the study chair. Some questions may make you feel upset or uncomfortable. You may refuse to answer any question. If you have concerns about participating in the surveys, you are encouraged to contact

your doctor or the study chair. If you score high on self-reported measures of distress, the study staff/doctor will speak with your oncologist and you may have additional tests.

If at any time you show that you may be having emotional difficulties, depression, or risk of harm to yourself during the yoga practice, and the study staff think it is needed, you will be contacted by a psychiatrist working in the Department of Psychiatry

Mild to moderate **physical activity** may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

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. Only researchers involved in this study will have access to the 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 or the study sponsors 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.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

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

You will receive $25 each time more than half of the surveys are completed at **end of CRT, 1 month after CRT, and 3 months after CRT** (up to $75 total). Participants in the yoga group will also have up to 3 hours of parking validated on each of the in-person yoga session days.

Additional Information

4. You may ask the study chair (Dr. Lois Ramondetta at 713-745-0307) 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 withdraw from this study, you can still choose to be treated at MD Anderson.

If you withdraw from the study, you will not receive the gift cards. In addition, already collected data may not be removed from the study database.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair 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, including the results of all of your standard tests performed as part of this research, 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.

9. This study is sponsored and/or supported by: Institutional Research Grant (IRG), the Cervical Cancer Research Fund, and the Christina Scott Cervical Cancer Research.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about

this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson, the Institutional Research Grant (IRG), the Cervical Cancer Research Fund, the Christina Scott Cervical Cancer Research, and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. Leftover samples stored by Institutional Research Grant (IRG), the Cervical Cancer Research Fund, and the Christina Scott Cervical Cancer Research will be used in future research.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. 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 or research samples 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 and/or research samples 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 and/or samples.

Genetic Research

Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

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

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - Institutional Research Grant (IRG), the Cervical Cancer Research Fund, and the Christina Scott Cervical Cancer Research, who are sponsors or supporters of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

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

   To protect your identity, the samples and data collected from you will be labeled a unique number instead of your name or other identifying information. Only the study doctor or study staff will have access to the code that can link you to your samples.

B. Signing this consent and authorization form is optional but you cannot take part in this study 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, health authorities 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 of MD Anderson 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.

E. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2019-0919.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)