A Comprehensive Yoga Program (SKY) as an Adjunct Therapy for Prostate Cancer - A Randomized Pilot Study

NCT03220945

Informed consent date: March 6th, 2017

You Are Being Asked to Be in a Research Study

What Is a Research Study?
The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?
No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?
This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?
1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University and St. Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Winship3059-15: A Comprehensive Yoga Program (SKY) as an Adjunct Therapy for Prostate Cancer – A Randomized Pilot Study

Principal Investigator: Omer Kucuk, MD

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

What is the purpose of this study?

The purpose of this study is to investigate the potential benefits of yoga in reducing stress. We know that unmanaged stress may cause many health problems and changes in blood parameters. This study wants to learn if yoga will improve these changes.

The studies will include not only psychological assessment through self-report questionnaires on pain, fatigue and psychological well-being, but also objective measures on basic physiological parameters, including the stress hormone cortisol and cytokine IL-6.

The breathing techniques that are part of SKY are: (a) Three-Stage Pranayama with Ujjayi or "Victory Breath", (b) three sets of Bhastrika or "Bellow's Breath", and (c) SK, and they are practiced in that order. The breathing practices are done in a sitting posture, either in a chair or on the floor. Eyes are kept closed throughout the sessions.

What will I be asked to do?

If you agree to be in this study, you will be given questionnaires to fill out about your demographic information, pain, fatigue, and psychological wellbeing. If you are assigned to the yoga group, you will receive yoga practice by trained instructors for 13 weeks. Blood, saliva, and hair samples will be taken at 3 time points during the study, as shown below. If you are assigned to the control group, you will not participate in the yoga instructions, you will continue with your normal daily activities and just fill out questionnaires and give blood, saliva, and hair samples at 3 time points. Blood, saliva, and hair samples will be used to test for markers that show oxidative stress and inflammation and changes in

the way genes are regulated. Control subjects will be offered 1-week of yoga classes after the end of the study (ie, after post-test-2)

SKY yoga includes gentle stretches (yoga postures), specific breathing exercises (see below), and cognitive coping and stressor evaluation strategies. SKY is traditionally understood to dissolve emotional distress and create the subjective experience of rest and well-being. The instructors in SKY are trained by the International Art of Living Foundation. The yoga intervention is held over 13 weeks: in Week 1, subjects will receive yoga instruction for approximately 3 hours daily on 5 consecutive weekdays, and in Weeks 2-13, subjects will attend yoga instruction once a week for about 2 hours

Below is a brief flowchart of the study timeline:

Week --	Recruitment (3 months prior to the start of yoga)
Week --	Pretest 1 (within 2 months prior to starting yoga)
Week 1-13	SKY intervention (13 weeks)
Week 2-3	Posttest 1 (within 2 weeks of the first week of yoga)
Week 14-15	Posttest 2 (within 2 weeks of the last week of yoga)

Who owns my study information and samples?
If you join this study, you will be donating your data and samples for this research. If you withdraw from the study, no further data or samples will be collected but information already collected may be still be used for this study. Samples will be destroyed at the end of the study when all record-keeping requirements have been met.

What are the possible risks and discomforts?
There may be side effects from obtaining a blood sample such as pain or inflammation but specialized training and care will be taken to minimize such occurrences. Additionally, this study involves answering questionnaires which may take 30-55 minutes to complete and may cause fatigue.

There is also the risk of a breach in confidentiality. The measures that will be taken to protect your data will be described in the section on protection of your private information.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Risk associated with blood draw
The risks of drawing blood include temporary discomfort from the needle stick, bruising, anemia, dizziness, and very rarely, an infection where the needle was inserted.

Will I benefit directly from the study?
This study is not designed to benefit you directly. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be offered compensation for being in this study.

What are my other options?
This is not a treatment study. It is entirely up to you whether or not you wish to take part in this study if you meet the eligibility requirements. The study doctor can answer any questions you may have as to any other matters concerning the study.

If you choose to participate in this study you will still be able to participate in other research studies.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

How is my Genetic Information Protected? What are the Risks?
The Genetic Information Nondiscrimination Act (GINA) is a federal law that 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 making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege
In the State of Georgia, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing

us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

Medical Record

If you have been an Emory and St. Joseph's Hospital patient before, then you already have an Emory and St. Joseph's Hospital medical record. If you have never been an Emory and St. Joseph's Hospital patient, you do not have one. An Emory and St. Joseph's Hospital medical record will be made for you if an Emory and St. Joseph's Hospital provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and St. Joseph's Hospital medical record you have now or any time during the study.

Emory and St. Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and St. Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory and St. Joseph's Hospital places may not become part of your Emory and St. Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate.

PHI that Will be Used/Disclosed

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory and St. Joseph's Hospital may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and St. Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Omer Kucuk, MD
Winship Cancer Institute, Emory University
1365-B Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Omer Kucuk at 404-778-1900:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at St. Joseph's Hospital of Atlanta and have a question about your rights, please contact Kristi McGinnis at the Emory Saint Joseph's Hospital Research Committee via phone at 678-843-7767.

Consent and Authorization

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Printed Name of Subject

_____ _____ ____:____ am / pm
Signature of Subject Date Time (please circle)

_____
Printed Name of Person Obtaining Consent

_____ _____ ____:____ am / pm
Signature of Person Obtaining Consent Date Time (please circle)