Title of Research: Role of Gut Microbe Composition in Psychosocial Symptom Response to Exercise Training in Breast Cancer Survivors

UAB IRB Protocol #: IRB-300003230

Principal Investigator: Laura Q. Rogers, M.D., M.P.H

Sponsor: National Cancer Institute (NCI)

Pre-Study Participant Consent

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of this portion is to find out if you are able to participate in the study to determine the effects of diet and exercise on the number, distribution, and types of bacteria in the gut of breast cancer survivors.
Duration & Visits	You will be in this portion of the study for 1 hour. This portion is the first part of the screening visit for this study.
Overview of Procedures	This portion of the study will include the following procedures and assessments: • Peak VO_2 Testing You will be asked to perform a graded treadmill or stationary bicycle test. You will walk on the treadmill or pedal on the bike at increasing intensity until you feel you can no longer walk. We will measure you total aerobic fitness by measuring oxygen consumed when performing this test. • Weight • Height • Body mass index (BMI) • Blood pressure • Heart rate
Risks	The most common risks include: • Muscle soreness • Fatigue (tiredness) • Shortness of breath during and/or after performance of peak VO_2 • Dry mouth • Embarrassment during height and weight collection
Benefits	You will not benefit directly from taking part in this portion of the study.
Alternatives	The alternative to this study is to not take part in it.

Purpose of the Research Study

The purpose of this research study is to determine diet and exercise effects on the number, distribution, and types of bacteria in the gut of breast cancer survivors. This study will enroll 200 participants at UAB.

Eligibility

You are eligible to participate in this study if you(r):

- Are a woman aged 18 to 74 years with a history of breast cancer stage 0, I, II, or III

- Are one to five years post completion of primary treatment for breast cancer (chemotherapy and/or radiation)
- Average fatigue over the past week is rated as ≥3 on a 1 to 10 Likert scale
- Are English speaking
- Have physician medical clearance for study participation
- Are able to ambulate (walk) without assistance
- Have not taken antibiotics for the past 90 days
- Are willing to avoid taking probiotics for the duration of the study
- Peak VO2 is ≤30 ml/kg/min (note: will measure peak VO2 if you meet all other criteria and consent to lab-based screening)

You are not eligible to participate in this study if you(r):

- Have metastatic or recurrent cancer
- Have another diagnosis of cancer in the past 5 years (not including skin or cervical cancer in situ)
- Unstable angina
- Have New York Heart Association class II, III, or IV congestive heart failure
- Have uncontrolled asthma
- Have interstitial lung disease
- Have current steroid use
- Have been told by a physician to only do exercise prescribed by a physician
- Have Dementia or organic brain syndrome
- Have Schizophrenia or active psychosis
- Have connective tissue or rheumatologic disease (i.e., systemic lupus erythematosus, rheumatoid arthritis, amyloidosis, Reiter's syndrome, psoriatic arthritis, mixed connective tissue disease, Sjogren's syndrome, CREST syndrome, polymyositis, dermatomyositis, progressive systemic sclerosis, vasculitis, polymyalgia rheumatic, temporal arteritis)
- Anticipate elective surgery during the study period
- Anticipate changes in usual medications during the study period
- Plan to move residence out of the local area during the study period
- Plan to travel out of the local area for >1 week during study participation
- Have contraindications to engaging in moderate-to-vigorous intensity aerobic exercise
- Are currently pregnant or anticipate pregnancy during study participation
- Live or work >50 miles from study site or do not have transportation to study site
- Have a BMI >50
- Anticipate needing antibiotics during the study period

Study Participation & Procedures

If you agree to join the screening portion of the study, you will undergo Peak VO_2 testing, have your height and weight measured to calculate your body mass index (BMI), and have your blood pressure and heart rate measured. If the results from the Peak VO_2 test and the BMI results are within the eligibility criteria, and you sign the Consent Form for full study participation, you will be started on the controlled feeding diet.

Procedures

Height, Weight, Blood Pressure, and Heart Rate: We will measure your height, weight, blood pressure, and heart rate, similar to how they are measured in a doctor's office.

Peak VO_2 Testing: Peak VO_2 will be measured while you perform a graded treadmill or stationary bicycle test. During this test, we will also measure your heart rate and blood pressure. This test requires you exercise until exhaustion.

Risks and Discomforts

You may have some risks from taking part in this study.

The risks are:

Moderate likelihood:
- Muscle soreness
- Fatigue
- Shortness of breath during and/or after performance of peak VO_2
- Dry mouth
- Embarrassment during height and weight collection.

Low likelihood:
- Injury to muscle, joint, ligaments, tendons, or bones
- Inconvenience
- Exacerbation of musculoskeletal condition
- Lightheadedness
- Dizziness
- Difficulty swallowing, coughing, or nausea when performing peak VO_2 test

Very low likelihood
- Cardia ischemia or arrest during peak VO_2 test or exercise training

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Information for Women of Childbearing Potential

Women who are pregnant or breastfeeding are not permitted to participate in this study. During the study, you may use any form of birth control that you wish; we simply ask that you not change the type of birth control that you use or its dose during the study.

Benefits

You will not benefit directly from taking part in this portion of the study. Your participation may qualify you to screen for the entire research study.

Alternatives

Your alternative is to not participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

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

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections(OHRP)
- the U.S. Food and Drug Administration(FDA)
- Department of Health and Human Services (DHHS)agencies
- Governmental agencies in othercountries
- Governmental agencies to whom certain diseases (reportable diseases) must bereported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and some 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 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 it protect you against genetic discrimination by all employers.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

There will be no payment for this portion of the study.

Payment for Research-Related Injuries

UAB, UAB-Lakeshore Research Collaborative Exercise Center, and NCI have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Laura Rogers at 205-934-9735.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this portion of the study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date