MBSR During AI Therapy for Breast Cancer
NCT03253627

Informed Consent Form

08-23-2018

Research Subject Informed Consent Form

Title of Study: Mindfulness-Based Stress Reduction To Improve Cognitive Function During Aromatase Inhibitor Therapy
17-00995

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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary, which means you can choose whether you want to take part in this study.

People who agree to take part in research studies are called “subjects,” “research subjects,” or “participants”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this consent form with your family, friends, or healthcare provider. If you have any questions about the study or about this form, please ask us. If you decide to take part and enroll in this study, you must sign this form. We will give you a copy of the signed form to keep.

Your healthcare provider may be involved in this study. As both your healthcare provider and a research investigator, she or he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another healthcare provider who is not associated with this research study. You are not under any obligation to participate in any research study offered by your healthcare provider.

2. What is the purpose of this study?

The purpose of this research study is to learn whether Mindfulness-Based Stress Reduction (MBSR) or Health Enhancement Program (HEP) can improve cognitive function for women with breast cancer who take aromatase inhibitors. Cognitive function includes things like your ability to concentrate and remember things. We will compare MBSR and HEP using a brain imaging technique called Magnetic Resonance Imaging (MRI), cognitive tests, and surveys. We will also explore whether any differences we find between MBSR and HEP are associated with inherited factors (genes) or the products of genes by collecting three sets of blood samples.

This study is a randomized study. Like flipping a coin, you will be randomly assigned to one of the intervention groups to receive either MBSR or HEP for eight weeks. There are no special requirements or criteria to be in one group over the other, so you will have a 50% chance of being in either group.

You are being asked to participate in this study because you are a postmenopausal woman who has been diagnosed with breast cancer and you were determined to be eligible.

3. How long will I be in the study? How many other people will be in the study?

The study will last about seven months and will involve 13 visits, which are described below. About 40 subjects between the ages of 18 and 79 will be in the study. The study assessment visits will be at the NYU Meyers College of Nursing on First Avenue near 26th Street, the Bluestone Center for Clinical Research on First Avenue near 25th Street, and the New York University Center for Brain Imaging at 6 Washington Place.

4. What will I be asked to do in the study?

If you decide to take part in this research study, you will be asked to sign this consent/authorization form before the procedures listed below will take place. These procedures are not part of your standard medical care.

Baseline Assessment – Visits 1 and 2
Before being randomly assigned to MBSR or HEP, you will be asked to complete a two-part baseline assessment after enrollment. You must complete the two parts of the baseline assessment within three days of each other, either on separate days or on the same day if you prefer. They can be completed in either order. Each assessment is described below.

Cognitive Function Tests, Surveys, and Blood Draw
This part of the baseline assessment should take about 2 and a half hours.

Cognitive function tests. Cognitive function tests are also called neuropsychological tests. Some of these tests will be done using pencil and paper and some tests will be done on an iPad. You do not need to know how to work with computers to complete these tests.

Surveys. You will complete surveys about your mood, symptoms, and quality of life. We will ask questions about your medical history, any medications you are taking, and your demographics (things like age, ethnicity, and whether you work).

Blood draw. You will be asked to provide a sample of blood (about 1 tablespoon, 15 ml) at this baseline assessment visit. If you complete the study, three sets of blood samples totaling 3 tablespoons (45 ml) of blood will be collected.

MRI
The other part of the baseline assessment will take place at the New York University Center for Brain Imaging. This session should take about 2 hours.

During this session, you will be asked to complete an MRI scan, which is also called neuroimaging. An MRI scan produces images similar to x-rays, except that is does not use any radiation. Instead, MRI uses a large magnet in a tunnel-like machine to produce images.

During the MRI scan, you will lie on a table that will move you into the tunnel for about one hour. During this time, the movement of your head will be limited so that the MRI can record images of your brain and how it is functioning. We will ask you to lie as still as possible without moving.

For a portion of the hour during the MRI scan you will be asked to think of nothing in particular. At other times, you will look at a screen positioned in front of you and press a button next to your hand to perform tasks examining brain responses. You will have the chance to practice the tasks you will complete in the scanner, and you will be able to talk with the researchers performing the tests.

Before your MRI scan, you will provide a urine sample to determine whether you have consumed any controlled substances that could affect your cognitive function. You will also provide a saliva sample to determine whether you have consumed any alcohol, which could affect your ability to perform the tests. If the MRI technologist requests a urine pregnancy test, you must complete it.

Diary
You will be asked to record your activities in a weekly diary during the eight weeks of the intervention and at each of the three study assessments. The activities we will ask you to record in your diary include MBSR or HEP homework you completed and any activities you did similar to what is in MBSR and HEP. It will take you about 5 minutes each week to complete the diary. You can complete the diary electronically via a secure link provided through email to a program called REDCap, or you may choose to keep a paper diary provided by the study.

Intervention – Visits 3 through 11
Following the two-part baseline assessment, you will be randomly assigned to either MBSR or HEP.

Mindfulness-Based Stress Reduction (MBSR)
If you are assigned to the MBSR group, you will be asked to complete an eight-week program where you report for a two and a half-hour class each week and one seven-hour retreat that will occur near the end of the eight weeks. These sessions will be completed at the New York University. An expert who is trained in MBSR will lead each session. In these sessions, you will complete activities such as sitting and walking meditation, gentle yoga, body scan, instruction in mindfulness, and group discussion. You will be asked to complete 45 minutes of homework on other days during the eight-week period. Some of this homework may be audio guided, which you can access on the Internet or with a CD.

Health Enhancement Program (HEP)
If you are assigned to the HEP group, you will be asked to complete an eight-week program where you report for a two and a half-hour class each week and one seven-hour retreat that will occur near the end of the eight weeks. These sessions will be completed at New York University. One or more experts in the topic areas will lead each session. In these sessions, you will complete activities such as physical activity and functional movement, music therapy, nutrition education, and group discussion. Physical activity will include moderate-intensity walking and stretching; functional movement will include balance, stability, and agility exercises; music therapy will include music making, song writing, and imagery; and nutrition education will include recommended nutritional intake and how to improve your diet. You will be asked to complete 45 minutes of homework on other days during the eight-week period. Some of this homework may be audio guided, which you can access on the Internet or with a CD.

Short-term Follow-up Assessment – Visit 12
You will complete a short-term follow-up assessment within three weeks after you finish either MBSR or HEP. This follow-up assessment will occur about three months after your baseline assessment. It will be similar to the baseline assessment and will include surveys and MRI. You will be asked to provide a sample of blood (about 1 tablespoon, 15 ml) at this visit. It will not include cognitive testing done at the baseline assessment. This session should take about 2 and a half hours.

Long-term Follow-up Assessment – Visit 13
You will complete a long-term follow-up assessment about three months after you finish either MBSR or HEP. This follow-up assessment will occur about six months after your baseline assessment. It will be

similar to the baseline assessment and will include surveys and cognitive testing. You will be asked to provide a sample of blood (about 1 tablespoon, 15 ml) at this visit. It will not include the MRI done at the baseline and short-term follow-up assessments. This session should take about 2 and a half hours.

5. What are the possible risks or discomforts?

Risks of Study
The known possible risks of this research study are described below. The research may involve risks that are currently unforeseeable.

Risks of Study Measures
It is possible that you may become frustrated or tired during some of the cognitive tests and surveys. If you feel frustrated or tired, please let us know. You will be offered breaks, and you do not have to complete questions that you do not want to answer.

Some questions will ask about depression. We may provide you with resources or a referral for mental health consultation, depending on your responses to these questions. If you answer that you might harm yourself or others, we are obligated to notify an emergency department.

Risks of MBSR or HEP
MBSR and HEP include some physical activities. Risks of completing physical activities can include injury to joints or muscles, soreness, and fatigue. Falling is an infrequent risk, and this risk will be lessened by the close monitoring of group leaders. Very rare risks associated with physical activities include the possibility of having a heart attack or serious heart rhythm problem that could require hospitalization. Although the gentle and moderate physical activity you will do in MBSR or HEP is safe for most people, it is generally recommended that you talk to your healthcare provider before you start any type of physical activity program. If the study staff have concerns about your health during your participation in these physical activities, you will be asked to stop until you can talk with your healthcare provider. If we think your health is in immediate danger, we will notify an emergency provider.

Some of the group activities include discussion, which may make you uncomfortable. It is possible that you may become frustrated or tired during the completion of group activities. You will be offered breaks, and you do not have to participate in any group activities that you choose not to.

Risks of Blood Draws
Bruising, bleeding, or soreness may occur as a result of the needle sticks to obtain blood from your vein. Rarely, fainting or infection may occur. Study personnel who draw blood will use precautions to reduce the risk of infection and will take steps to minimize discomfort.

Risks of Genomic Research
The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of confidentiality. We will protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password protected database. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. A current 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.

To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record, and will not be shared with you or your medical providers. We will keep your genomic data separate on secure servers, separate from your personal information. However, it is possible that a breach of confidentiality could occur that may put sensitive genomic information about you at risk. Taking part in a genetic study may also have a negative impact on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

Magnetic Resonance Imaging (MRI)
MRI uses a strong magnetic field to create images of the body. There are no known risks or adverse effects resulting directly from exposure to MRI. However, there are risks associated with any strong magnetic field. These risks are detailed in this section.

One possible risk is burns to the skin. There is an increased risk of burns from devices that conduct electrical energy. These devices can include metallic objects, pulse oximeters, EKG leads, or skin tattoos. These devices can be either in or on the patient in order for a skin burn to occur. The FDA has found that 70% of all reported injuries from MRIs were burns to the skin. To reduce this risk, all patients who are scanned in this study must complete thorough screening to ensure that no conductive materials are present in or on the patient's body.

Subjects who have a pacemaker or metal objects in their body such as shrapnel or metal in the eye should not have the scan performed. You will be asked questions about any metallic, electronic, or magnetic objects in your body, and you will be asked to change out of any clothes that have metallic, electronic, or magnetic parts. Many objects in the body are safe for MRI, so this screening is to determine whether those objects would be safe. If you have any question about metal implants or metal fragments in the body, you should inform study staff or the MRI technologist before entering the magnet room.

Another possible risk is that a metal object could be pulled into the scanner and hit you. You could be physically injured as a result. To reduce this risk, everyone near the magnet will remove all metal from their clothing or pockets when in the scanning environment. The door to the scan room will remain closed during the exam for your safety.

Fear of Confined Spaces: Some people may feel confined and experience anxiety in the MRI scanner, which is called claustrophobia. If you are unable to tolerate being in the scanner, you can squeeze a ball we will give you to stop the scan immediately at any time.

Fatigue: You might become frustrated or fatigued during the scan. We will ask how you are feeling and offer breaks between each test during the scan.

Noise Levels: The MRI scanner produces tapping and banging sounds during operation, which may reach very loud levels. To minimize any discomfort from this noise, you will be given disposable earplugs to reduce the noise levels but will still allow voice communication with the scanner operator.

MRI system failure (quench): In extremely rare cases, a magnet can lose its magnetism, in which case cooling fluids may be released noisily through escape valves and may collect in gas form in the scan room. The gas is not harmful in itself as long as fresh air is available. In this very remote event, you will immediately be brought out of the magnet room.

Neurostimulation and heating: Some subjects may experience muscle twitches or tingling sensations and/or a slight increase in body temperature during some types of scan activity. These experiences are very unlikely under current MRI guidelines.

Risks to Privacy and Breach of Confidentiality
All study investigators are trained in privacy policies and procedures, and sign confidentiality agreements.

You will be assigned a unique ID number for data collected during the study. All study data including blood draws will be identified by this code, which will not contain your name or other identifying information. Only the principal investigator and limited research staff under his supervision will be able to link this ID number to the personal identifiable information collected during screening and enrollment. Hardcopies of your personal identifiable information will be stored in a locked file cabinet in a locked room at New York University. However, even with these safeguards, there is a possibility that the confidentiality of your study data could be breached and become generally known.

You will not be identified by name in any publication of the research results.

6. What if new information becomes available?

During the course of this study we may find new information that could be important to you. This new information might cause you to change your mind about being in the study. We will notify you as soon as possible if new information becomes available.

We will not provide you with your personal results from this research study, because the imaging and genomic results cannot yet be interpreted or applied in a clinically relevant manner. However, if your personal results become clinically relevant in the future, that information may be provided to you.

We will be able to view images of your brain during the scanning session, and we might incidentally detect something unusual on your MRI scans. However, the MRI scans in this study are done to answer research questions and are not the type used to reveal medical conditions. You should not participate in this study as a substitute for diagnostic MRI scans that you want done, because abnormalities may not be noticed by our research staff. In the unlikely event that we detect an abnormality in your scan, the technologist will refer your scan without your name to a specialist. You will be contacted by study staff should the consulting specialist recommend further examination.

The genetic research in this study is done to answer research questions and is not the type used to reveal medical conditions. You should not participate in this study as a substitute for diagnostic genetic testing that you want done.

7. What are the possible benefits of the study?

You may not benefit personally from being in this study. You might experience reduced stress and improvements in your health by participating in MBSR or HEP. We hope that findings from this study lead to better understanding in the future about whether and how MBSR and HEP may improve cognitive function in women with breast cancer taking aromatase inhibitors.

8. What other choices do I have if I do not participate?

You do not have to participate in this study to receive all necessary standard medical care. You may discuss alternatives with your personal physician.

9. Will I be paid for being in this study?

You will be paid $50 after completing each of the two parts of the baseline assessment for a total of $100 for the two-part baseline assessment (TP0). You will be paid $75 after completing the short-term follow-up assessment (TP1) and another $75 after completing the long-term follow-up assessment (TP2). Therefore, if you complete the study, your total compensation would be $250. You will not receive payment for any of the MBSR or HEP intervention study visits.

You will receive reimbursement for public transit or parking at NYU for each of the study assessment visits. Parking fines will not be reimbursed. Reimbursements for public transit or parking at NYU may be provided for the MBSR or HEP visits.

If you are not allowed to participate in an assessment after you sign this informed consent form (for example, because study staff or the MRI technologist determines that you would not be safe in the MRI machine), you will receive $10 and reimbursement for public transit or parking at NYU. If you complete a portion of the MRI scan but must stop before completion of the scan (due to claustrophobia, for example), you will receive $25 and reimbursement or a voucher for public transit or parking.

Your tissue or biological sample may lead, in the future, to new inventions or products. If investigators develop new inventions or products from the research use of your tissue or biological sample, there are currently no plans to share with you any money or other rewards that may result from the development of these inventions or products.

10. Will I have to pay for anything?

Neither you nor your insurance provider will be charged for the costs of any of the procedures performed for the purpose of this research study. You will be charged, in the standard manner, for any procedures performed for your routine medical care.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of these costs.

There are no plans for NYU College of Nursing, School of Medicine, or Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the study before it ends?

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care, or your eligibility for health care benefits.

This study is expected to end after all participants have completed all study visits and all information has been collected. Your participation may be ended at any time by your healthcare provider, the principal investigator, or the study sponsor without your consent if:

- It is necessary for your health or safety.
- You have not followed study instructions.
- The study has been stopped.
- There is a change in your eligibility for the study (for example, your treatment changes).

Might I be contacted after I have completed my participation in this study?
We might contact you after you have completed this study to share the aggregate results of the study, if we need more information from you for this study, or if we have other studies in which you may be interested in participating.

13. How will my information be protected?

NYU Langone Health, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to

give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

What information about me may be used or shared with others?
The following information may be used or shared in connection with this research:

- Information in your medical record and research record, including, for example, results from your physical examinations, laboratory tests, procedures, questionnaires and diaries.

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

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

Why is my information being used?
Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

Who may use and share information about me?
The following individuals may use, share or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: National Institute of Nursing Research (NINR), which is part of the National Institutes of Health (NIH)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites
- University of California, Davis DNA Technologies & Expression Analysis Cores, or other outside laboratories or companies we might use to collect genomic data

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

14. Optional permission for future use

NYU Langone Health would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYU Langone Health or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYU Langone Health will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYU Langone Health or its research partners. _____ Subject Initials

15. Samples Stored for Future Use

As part of this study we plan to do research on the DNA in your blood samples. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child. We cannot, at this time, tell you exactly which biomarkers, genes, or gene products will be tested as part of this study.

We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes may be analyzed and used by researchers to study links to many diseases or conditions. However, we will not do true genetic testing as part of this analysis.

Where will my blood sample be stored?

Blood samples will be stored in freezers in the Bluestone Center and Aouizerat Laboratory in the College of Dentistry under the control of the principal investigator and laboratory staff who work with him. Your blood samples and any material derived from them will be maintained indefinitely until they are used completely. These blood samples may be shipped outside NYU to other universities or companies for processing and data collection.

How long may my samples be stored?
Your permission to store your samples for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to store my samples?
Yes, you may withdraw or take back your permission to store your samples at any time. If you withdraw your permission, we will not be able to take back information obtained from the samples that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

16. Optional Permission for Broad Future Use of Data and Stored Samples

With your permission, data in your research record and your samples may be used broadly for other future research, even after this study has finished. Examples of how your data and samples may be used include, but are not limited to:

- Coded study data, including your genomic data, will be sent to and maintained indefinitely in NIH databases for approved use by other researchers. These databases may include the Gene Expression Omnibus (GEO), the database of Genotypes and Phenotypes (dbGaP), or similar.
- Coded blood samples and data derived from them may be provided to qualified secondary investigators, who are investigators who are not directly involved in the conduct of this study, at the discretion of the principal investigator. These secondary investigators could study biomarkers, genes, and gene products related to any information collected in this study.
- Any other coded study data may be provided to qualified secondary investigators. These secondary investigators could use these data for research purposes related to any information collected in this study.

If we send your study data or material to a different facility or qualified secondary investigator, none of your personal identifying information will accompany it. Only your study ID would be used.

How long may my data and samples be used or shared?
Your optional permission to use or share your data and samples for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my data/samples?
Yes, you may withdraw or take back your permission to use and share your data/samples at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

☐ Checking this box indicates my permission to store, use, and share my data and samples from this study broadly for future research.

_____
Subject Initials

17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you

have any questions about your rights as a research subject, you should speak with the principal investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available online at 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 study results. You can search this website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date