**Protocol Title**: Hypnosis to Reduce Aromatase Inhibitor (AI) Associated Musculoskeletal Pain and to Improve AI Adherence: An RCT to Explore Efficacy and Cost Effects

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## TITLE OF RESEARCH STUDY:

Title: Hypnosis to reduce aromatase inhibitor (AI)-associated musculoskeletal pain and to improve AI adherence: An RCT to explore clinical efficacy and cost effects.

## PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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## WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

## PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to investigate how to help women who are taking aromatase inhibitors (AIs) as part of their breast cancer treatment to manage musculoskeletal pain associated with those AIs. Previous research has suggested that: 1) many women taking AIs experience some musculoskeletal pain, often described as joint pain or stiffness; 2) because of that pain, many women do not take their AIs as prescribed (e.g., skip doses, stop taking the medicine); and, 3) there is no current "gold standard" treatment for AI-related pain. However, past research has shown that hypnosis is helpful in managing other types of pain, including pain in women with breast cancer. Hypnosis is like focused concentration with relaxing words and imagery. This study is the first to examine at whether hypnosis can help women manage AI-related musculoskeletal pain, and whether

by reducing pain, hypnosis can help women to take their AI medication as prescribed.

You may qualify to take part in this research study because you have been prescribed AIs as part of your breast cancer treatment, and because you are experiencing some pain or discomfort as a result. Taking pain relievers like NSAIDS, acetaminophen, or aspirin will not interfere with your study participation. However, if you take narcotics regularly or have taken corticosteroids in the past four weeks, you will not be eligible to enroll in the study.

Funds for conducting this research are provided by the National Institute of Health (NIH) and the National Center for Complementary and Integrative Health (NCCIH).

## LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last approximately one year from the time of consent.

The number of people expected to take part in this research study at Mount Sinai Hospital is 200.

## DESCRIPTION OF WHAT'S INVOLVED:

You will be screened by the study team to see if you are eligible. If you continue to be eligible after being screened, and agree to participate in this research study, the following information describes what may be involved.

You will be asked to complete a brief baseline survey. This survey will ask about demographics and medical history (your age, race, ethnicity, and pain management approaches), your symptoms and side-effects (such as pain), your thoughts, feelings, opinions about hypnosis and cancer, your experiences taking AIs, and your expenses related to cancer treatment. This packet should take no more than 15-20 minutes to complete.

Then, you will be randomly assigned to one of two groups: the Hypnosis Group or the non-hypnosis, Attention Control group. The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctors will choose what study treatment you get. You will have an equal chance of being given each study treatment.

**Hypnosis-Live Group**

If you are assigned to the Hypnosis Group, you will meet with a study psychologist for three hypnosis sessions at Mount Sinai. Session 1 will be approximately 40 minutes, and sessions 2 and 3 will be approximately 30 minutes. These sessions will be scheduled at your convenience. The first hypnosis session will involve education about hypnosis, participation in a one-on-one hypnosis session, and training in self-hypnosis, so that you can begin to learn how to use hypnosis on your own. You will be asked to practice hypnosis on your own when you experience musculoskeletal pain. You will also be given an audio recording of a hypnosis session.

The second hypnosis session will take place approximately one week after the first hypnosis session. This second session will include a discussion of your hypnosis practice over the past week, a second hypnosis session, and a plan for hypnosis practice over the next month. We will also schedule your

third and last hypnosis session.

The third hypnosis session will take place approximately one month after the second session. In this third and final session, you will discuss the last month's hypnosis practice, review what you have learned, participate in a final hypnosis session, and complete training in self-hypnosis.

You will also be asked some brief questions about how you are feeling at the beginning and end of each of the three hypnosis sessions.

Between sessions 1 and 2, and between sessions 2 and 3, the study staff will briefly contact you to remind you to practice self-hypnosis.

**Attention Control Group**

If you are assigned to the Attention Control Group, you will meet with a study psychologist for three sessions at Mount Sinai. The first session will be approximately 40 minutes. Sessions 2 and 3 will be approximately 30 minutes. During these sessions, the study psychologist will speak with you about your thoughts and feelings about your cancer and aromatase inhibitors.

You will also be asked some brief questions about how you are feeling at the beginning and end of each of the three sessions.

If you are assigned to this group, and if you are still interested in having a hypnosis session at the end of your participation in the study (12 months after consent), you will be offered the opportunity for a hypnosis session at no charge.

**Regardless of which group you are assigned to (Hypnosis group or the non-Hypnosis/Attention Control group)**

You will be given an eCAP pill bottle that will hold your AI medication. The eCAP bottle records every time your pill bottle is used. We will ask you to bring in the eCAP pill bottle (with the cap on it) to all of your follow-up study visits. At each study visit, we will download the data from the eCAP. This will let us know how often you have taken your medication, and will help us to understand the difficulties associated with taking AIs as prescribed.

After the completion of all intervention sessions, you will be asked to meet with study staff members to fill out brief follow-up surveys at four timepoints: 3 months, 6 months, 9 months, and 12 months after your baseline visit. These meetings will take place at a time that is convenient for you (for example, on the same day that you have other medical appointments at Mount Sinai). These surveys should take no more than 10-15 minutes to complete. The surveys will ask questions about your symptoms and side-effects (such as pain), your thoughts, feelings, opinions about hypnosis and cancer, your experiences taking AIs, and your expenses related to treatment. At each of these time points, you will also be asked to bring in the eCAP pill bottle so that we may collect and download the data.

All research activities will take place at Mount Sinai. Our staff will contact you to schedule your study visits and to remind you to bring the eCAP to each visit. We will ask you for your preferred mode of communication (e.g., e-mail, phone call, or text), and your preferred time to be reached, and will use that information to guide our contact efforts.

After you finish the twelve-month questionnaire packet, your participation in the study will be complete.

No medical advice will be given during this study. If you have any questions about your aromatase inhibitors or pain, we will recommend that you consult with your treating physician.

Your medical care will be the same whether you participate in the study or not. In no way will your medical care be altered because of the study.

Part of the research involves medical record review. Accordingly, by consenting to take part in this study, we will also be reviewing your medical chart so that we can learn about your medical experience. We would like to capture information like the type of treatment you had for your breast cancer (if any) prior to receiving your aromatase inhibitor prescription, other medical conditions, and other medications you take. Your personal medical information, like everything else in the study, will be kept confidential. That is, your information will only be identified with a number and not your name.

We would like your permission to audio-record your meetings with your study psychologist. The purpose of this recording is to ensure that the study psychologists are doing things the same way for all participants in the study. These tapes will remain confidential. That is, your information will only be identified with a number and not your name. Once the study is completed, the Principal Investigator, Dr. Guy H. Montgomery, will have the recordings deleted. Until that time, the recordings will be stored in a secure, password protected file on the Mount Sinai server. Only the researchers working with Dr. Montgomery will be able to listen to the recordings. You will still be eligible to participate in the study, even if you choose not to have your sessions recorded.

To find out your wishes about being audio-recorded during the study, please to let us know by initialing below:

_____ I CONSENT TO BEING AUDIO-RECORDED DURING THE STUDY SESSIONS

_____ I DO NOT CONSENT TO BEING AUDIO-RECORDED

In the future, we might plan additional research projects related to this one. We would like to know whether you would agree to let us call you in the future to discuss additional research studies. Please initial one of the statements below to let us know whether you agree to be telephoned by us in the future to discuss additional research projects.

_____ I CONSENT TO FUTURE PHONE CONTACTS

_____ I DO NOT CONSENT TO FUTURE PHONE CONTACTS

## YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: completing surveys at baseline, answering questions before and after each intervention session, and completing surveys at 3, 6, 9, and 12 months after baseline; using the “eCAP” system; and, participating in three sessions with a study psychologist.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this research study will not lead to extra costs to you. You will not be reimbursed for your travel or time that may be required for study visits.

If you agree to take part in this research study, we will pay you $20 (in the form of a gift card) for completing your baseline survey, and for surveys at 3, 6, 9, and 12 months. These gift cards are for your time and effort. If you complete all of these five surveys, you will receive a total of $100 in gift cards.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

## POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that you will experience fewer or less intense side effects associated with aromatase inhibitors, and that you may adhere better to your aromatase inhibitor schedule. In addition, you may benefit from the knowledge that your involvement in the study may help other future patients facing the possibility of pain associated with aromatase inhibitors. Possible benefits to others include a greater scientific understanding of interventions that may help reduce AI-related pain and improve AI-related adherence.

## REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The study will not affect the rest of your medical care in any way. Following hypnosis, there is a chance you may notice a sense of relaxation and associated mild drowsiness. Any drowsiness experienced typically subsides quickly (within 5 minutes) and has no lasting effects.

We are asking people taking part in the study to answer some personal questions about their thoughts, feelings, opinions and daily habits. Most people have little or no problem with these surveys. However, some people may find doing them to be frustrating, upsetting, or in some other way a problem. Of course, you may choose to skip questions. The surveys you complete for the study will not have your name on them or any other identifying information. Once you complete them, the study team will keep them confidential. If you decide that you need to discuss any issues which upset you about the study, you may contact the principal investigator, Dr. Guy Montgomery at (212) 659-5521.

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk.

There are no legal, social, or economic risks of study participation.

## OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Regardless of which study intervention you may be assigned to receive, hypnosis is available outside of the research context, and patients do not have to participate in the study to receive hypnosis. The choice is totally up to you.

Instead of being in this research study, your choices may include: pain medications (e.g., pain relievers such as aspirin, NSAIDS, or acetaminophen), talk therapy approaches (e.g., cognitive-behavioral therapy, mindfulness), and other complementary techniques (e.g., massage, yoga). We always recommend that you discuss possible options with your physician.

## IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

## ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent

## CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number 212-659-5531.

If you experience an emergency during your participation in this research, call 911 or go to the emergency room.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

## DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

## MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be disclosed (shared) with others?</u>

As part of this research project, the research team will collect your name, address, telephone/fax numbers, e-mail address, birthdate, breast cancer treatment dates, and medical record number.

The researchers will also get information from your medical record at The Mount Sinai Hospital.

During the study the researchers will gather information by:

- reviewing your medical chart to learn about your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- completing the procedures and questionnaires explained in the description section of this consent
- audio-recording study sessions

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Center for Complementary and Integrative Health of the National Institutes of Health.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, and the Office of Human Subjects Protection (OHRP) of the Department of Health

and Human Services will be granted direct access to your medical records for verification of the research procedures and data. OHRP is authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result of a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

## Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

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## Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

**DO NOT SIGN THIS FORM AFTER THIS DATE →**

| | |
|---|---|
| Signature of subject | Date |
| Printed name of subject | Time |

## Person Explaining Study and Obtaining Consent

| | |
|---|---|
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | Time |

***Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):***

*My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.*

| | |
|---|---|
| *Signature of witness to consent process* | *Date* |
| *Printed name of person witnessing consent process* | Time |