Informed Consent/Authorization for Participation in Research

Title of Research Study: Opioid-Sparing Effects of Nurse-Delivered Hypnosis During Breast Cancer Surgery

Study Number: 2022-0959

Principal Investigator: Dr. Lorenzo Cohen

Co- Principal Investigator: Dr. Elizabeth Rebello

_____ _____
Participant's Name Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in this research study because you have breast cancer and are scheduled to have a lumpectomy, including excisional biopsy, and/or sentinel node biopsy.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Surgery is a necessary treatment for breast cancer, but patients may experience side effects from the general anesthesia and opioids given during and after surgery.

Hypnosedation is an alternative to general anesthesia that places patients under conscious sedation where they remain awake and numbed during surgery. It involves the use of words and images to help patients relax and to affect their thoughts about what is happening during surgery.

The goal of this clinical research study is to learn about the effectiveness of hypnosedation alone given before and during surgery on reducing opioid use after surgery compared to standard general anesthesia given alone or with hypnosedation.

This is an investigational study. Hypnosedation is a standard relaxation method. It is considered investigational to compare the effects of these sedation techniques on opioid use after surgery.

How long will the research last and what will I need to do?

You are expected to be in this research study for up to 90 days after your surgery.

You will be randomly assigned to receive either standard general anesthesia alone during surgery, hypnosedation before surgery plus standard general anesthesia during surgery, or hypnosedation before and during surgery. You will also answer questionnaires (such as about your symptoms, anxiety, and expectations) and complete tests to check your cognitive function (such as thinking, remembering, and attention).

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

You may feel uncomfortable during the hypnosedation. If this occurs, you may choose to stop the procedure at any time. Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Hypnosedation may reduce your anxiety, pain, and other symptoms as well as your opioid use during and after surgery. It may allow you to avoid general anesthesia. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of taking part in the study, you may choose to receive standard general anesthesia during your surgery outside of this study. This alternative option has risks and benefits that may be the same or different than those in this research study. The study doctor can discuss this alternative option, including it risks and benefits, with you.

In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the study doctor, Dr. Lorenzo Cohen, at 713-745-4260; the co-study chair, Dr. Elizabeth Rebello, at 713-792-6090; or the study manager, Jewel Ochoa, at 713-563-4008.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

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

How many people will be in this study?

It is expected about 225 people will be enrolled in this research study. All will take part at MD Anderson.

What happens if I agree to be in this research?

Baseline Assessments

If you agree to take part in this study, you will complete the following baseline assessments:

- You will be asked to verbally rate your anxiety, pain, nausea, and fatigue on a scale of 0 to 10.
- You will answer questionnaires about your general anxiety, severity of pain, cancer-related symptoms, tendency to dwell on or avoid thoughts about stressors, openness to experiencing emotional and cognitive changes, ability to tolerate uncomfortable situations, and expectations about hypnosedation. During this study, questionnaires may take between 15-30 minutes total to complete at each timepoint.
- You will complete a series of computer-based tests called the BrainCheck to check your cognitive function (such as thinking, remembering, and attention). It will take about 15-20 minutes to complete. The tests will check your ability to:
    - Process visual information
    - Pay attention
    - Organize, plan, and carry out a set of tasks in an efficient manner (called executive function)
    - Control your response to distractions
    - Remember and recall information

  Your BrainCheck test performance will be scored under your study participant number and stored in the BrainCheck cloud storage facility. Your name or other identifying information will not be linked to your score in the BrainCheck cloud.
- You will complete 3 tests to measure how you respond to different pain sensations. The tests will take between 10-15 minutes to complete.
    - During the first test, a device will be used to apply increasing, pointed pressure to your skin, and you will be asked to tell the study staff when you feel pain and how much pain on a scale of 0 to 10. Two parts of your body will be tested: on your thigh and a spot near where the surgical wound dressing is expected to be.
    - During the second test, researchers will measure the sensations you feel by using a soft cotton swab to touch 2 different areas of your skin (on your forearm and a spot near the surgical wound dressing is or is expected to be).
    - During the third test, an area of skin on your forearm will be touched by a device or object for a few seconds that has a controlled temperature of about 115-120 degrees Fahrenheit. You will feel warmth or heat, but it should not be burning or scalding. The study team will ask you to rate your discomfort on a scale from 0 to 10 based on the temperature of the device. This third test will only be done at the start of the study and not repeated again.

Study Groups

After completing the baseline assessments, you will be randomly assigned (as in the roll of a dice) to 1 of 3 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will have an equal chance (33/33/33) of being assigned to any group:

- If you are assigned to **Group 1**, you will receive hypnosedation before and during surgery as well as local anesthesia and pain/nausea medications during surgery.
- If you are assigned to **Group 2**, you will receive hypnosedation before surgery and standard general anesthesia during surgery.
- If you are assigned to **Group 3**, you will receive standard general anesthesia alone. You will not receive hypnosedation.

The study doctor will tell you which group you are assigned to. You will sign a separate consent form for the surgery.

Surgery

Groups 1 and 2

Hypnosedation is a standard relaxation method. The hypnosedation technique may help to lower anxiety and pain levels during surgery. During hypnosedation, a hypnotherapist (a nurse trained in mind-body techniques) will use words and images to help you relax to affect your thoughts about what is happening during surgery.

At least 24 hours before your surgery, you will have a session with a trained hypnotherapist where you will share an image of a place and time of calm, relaxation, or safety. For example, this may be a vacation experience, childhood memory, or place of relaxation. This image will be used and expanded on during the hypnosedation procedure. During this session, you will be exposed to hypnosedation for 10 minutes.

On the day of surgery, hypnosedation will be started in the pre-operative holding area and will last 20 minutes.

If you are in Group 1, hypnosedation will be restarted after arriving in the operating room and will continue for the whole time of surgery. You will be put under conscious sedation, meaning you will be awake during hypnosedation and surgery but will have received a numbing drug and other drugs to control pain and nausea. Your pain and discomfort will be closely monitored, and you may switch to receive general anesthesia at your request or if the anesthesiologist thinks it is needed. You may request to receive general anesthesia at any time.

If you are in Group 2, you will receive standard general anesthesia and medications to control your pain after arriving in the operating room. You will be asleep during the surgery and will not receive additional hypnosedation.

Group 3

You will receive standard general anesthesia and medications during surgery to control your pain. You will be asleep during the surgery and will not receive hypnosedation.

Study Assessments

When you are moved from the pre-operative holding area to the operating room, you will be asked to verbally rate your anxiety, pain, and nausea on a scale of 0 to 10.

After surgery, you will be moved to the post-anesthesia care unit. **Every 15 minutes you are in the post-anesthesia care unit until you are discharged**, you will be asked to verbally rate your anxiety, pain, and nausea on a scale of 0 to 10. The study staff will also record if you vomit.

At the time you are discharged, you will:

- Verbally rate your anxiety, pain, and nausea on a scale of 0 to 10.
- Answer a questionnaire about your satisfaction with the surgery and/or hypnosedation (if you receive it).

Then, on **Days 1, 3, 5, and 7 (+/- 1 or 2 days) after your surgery**:

- You will be asked to verbally rate your anxiety, pain, nausea, and/or fatigue on a scale of 0 to 10. The study staff will also ask you if you have vomited.
- On Days 1 and 7, you will answer the questionnaires about your cancer-related symptoms and severity of pain.

On **Days 14 (+/- 5) and 90 (+/- 15) after your surgery**:

- You will be asked to verbally rate your anxiety, pain, and nausea on a scale of 0 to 10. The study staff will also ask you if you have vomited.
- You will answer the questionnaires about your cancer-related symptoms, severity of pain, and work productivity. On Day 14, you will also answer the questionnaire about your satisfaction with the surgery and/or hypnosedation (if you receive it).
- You will repeat the same 2 tests that were done at baseline to measure how much pain or discomfort your body can handle.
- You will repeat the BrainCheck tests.

On **Days 1-14**, you will be provided with a research medication diary to track your daily medication use. You should bring your pill bottles and leftover doses to the clinic on Day 14 and then later on Day 90. The study will review the diary and conduct pill counts for the use of all study medications.

After your completion of the study, you will be asked to participate in an exit interview where you will be asked questions about your experience of the study. The interview will be conducted over the phone or in-person and will be audio recorded and transcribed (typed). The exit interview is optional, and you may choose not to take part in it even if you participated in the whole study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study team about any symptoms or side effects you have, follow study directions, and come to all study appointments (or contacting the study team to reschedule).

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can then decide if you need to have any visits or tests to check on your health.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

You may feel uncomfortable during the **hypnosedation**. If this occurs, you may choose to stop the procedure at any time.

Questionnaires and interviews may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire and/or interview, you are encouraged to contact your doctor or the study chair.

You may become **distressed** during this study. If you are feeling distressed or if the questionnaire answers show that you are distressed, the study staff will notify your primary physician and/or nurse.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

Hypnosedation will be performed at no cost to you. You and/or your insurance provider will be responsible for the cost of surgery.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

As compensation for your time and effort, you will receive $50 in the form of a gift card.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food

and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson, the National Institutes of Health, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if your comfort or health is risked by remaining on study, if your surgery is changed to include any other procedure that increases the time in the operating room, or if your questionnaire responses show that you are not likely to respond to hypnosedation.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Lorenzo Cohen, at 713-745-4260), study co-chair (Dr. Elizabeth Rebello, at 713-792-6090), or the study manager (Jewel Ochoa, at 713-563-4008)

You will not be reimbursed for expenses or compensated financially by MD Anderson or the National Institutes of Health for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by the National Institutes of Health.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Part of your care may be provided outside of MD Anderson by your home doctor(s).

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

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson

- National Institutes of Health, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
- BrainCheck, who will store your BrainCheck performance score in their cloud storage facility
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

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

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

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

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

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

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

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

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT