Verbal Informed Consent for Clinical Research

Study title for participants: The Effect of Acupuncture on Cancer-Related Cognitive Difficulties

Official study title for internet search on http://www.ClinicalTrials.gov: Effect and Mechanism of Acupuncture for Cancer-related Cognitive Difficulties (ENHANCE)

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Directions for the consenting professional:
- You can attempt to contact the potential participant **only 3 times**.
- Do not leave a voicemail message unless you have received IRB approval to do so.

Introduction

Hello, may I speak with (potential participant's name)?

If NO:
- **Do not** leave your name or number to call back. Say that you will call back another time and ask for a good time to reach the potential participant.

If YES:
- Continue with discussion.

My name is (consenting professional), and I am calling from the Integrative Medicine Service at Memorial Sloan Kettering Cancer Center. I am contacting you about our research study, The Effect of Acupuncture on Cancer-Related Cognitive Difficulties (ENHANCE). We are asking you to take part in this study because you are a breast cancer survivor who suffers from cognitive (mental) difficulties caused by cancer treatment. Cognitive difficulties can involve problems with memory, concentration, executive function (planning, prioritizing, emotional control), and/or psychomotor skills (performing everyday physical activities like walking upstairs or getting out of bed). In addition, you have difficulty with falling and staying asleep (insomnia).

Researchers are trying to learn if acupuncture can improve cognitive difficulties in breast cancer survivors who have both cancer-related cognitive difficulties and insomnia.

Would this be a good time to speak with you about this study? Our conversation will take about 30 minutes.

If NO:
- Ask when a better time might be to call and record his/her availability.
- If the potential participant is not interested in hearing more: Thank the potential participant for his/her time and end the call.

If YES:

- Continue with discussion.

Overview of the Consent Discussion

During this call, I will explain the study and its risks and benefits, and we will discuss any questions you have. After that, I will ask if you would like to take part in the study. It is important to know that a research study is completely voluntary. You can choose whether to take part, and you can change your mind at any time. Whatever choice you make, your medical care will not be affected. Please take your time to make your decision. If you have questions at any time, please feel free to ask me for more information.

Before continuing:

- After our conversation, we will mail you a study information sheet that includes key information about this study.

Study Information

The purpose of this study is to test whether acupuncture can improve cognitive difficulties and insomnia in survivors of *breast cancer*. Researchers will compare the effects of real acupuncture with those of placebo acupuncture and wait-list acupuncture. This study will also look at insomnia's link to cognitive difficulties.

Acupuncture is a medical technique that involves insertion of very thin needles into specific areas on the body with the goal of promoting health and well-being. It has been widely used to treat pain, but researchers think acupuncture can also improve the cognitive difficulties and insomnia that many cancer survivors report following chemotherapy and other cancer treatments. There is also some evidence that fixing sleep problems can improve some cognitive functions, such as memory and concentration. This study should provide researchers with useful information about acupuncture's effects on both cognitive function and insomnia. The study may also give researchers better insight into the connection between insomnia and cognitive difficulties.

If you decide to take part in this study you will be in the study for 26 weeks. You will receive one of the following treatments:

- Treatments of either real acupuncture or placebo acupuncture over 10 weeks. Placebo acupuncture is performed with the same needles as real acupuncture, but these needles are applied using different techniques to different places on the body than real acupuncture.
- Wait-list acupuncture—real acupuncture that happens after a 26-week period of waiting

All study participants (receiving real acupuncture, placebo acupuncture, or wait-list acupuncture) will complete study questionnaires and/or have cognitive testing at Weeks 0, 4, 10, 14 and 26. After the Week 26 visit, your participation in this study will end. If you are assigned to receive placebo acupuncture or wait-list acupuncture, you will have the option of receiving up to 10 real acupuncture treatments within the six months after the study finishes.

This study has 3 groups:

- Participants in Group 1 will receive real acupuncture.

- Participants in Group 2 will receive placebo acupuncture. Again, placebo acupuncture is performed with the same needles as real acupuncture, but these needles are applied using different techniques to different places on the body than real acupuncture. After the study is over, participants in Group 2 will have the option of receiving up to 10 real acupuncture treatments within six months of completing the study.
- Participants in Group 3 will receive wait-list acupuncture—real acupuncture that happens after a 26-week period of waiting. During those 26 weeks of waiting, participants will receive standard medical care as prescribed by their oncologists/primary care doctors or no treatment. After the study is over, participants in Group 3 will have the option of receiving up to 10 real acupuncture treatments within six months of completing the study

A computer will assign you by chance, like pulling names from a hat, to one of the study groups. This process is called randomization, and it is done by chance because no one knows if one treatment group is better or worse than the other. Two out of every 4 participants will be in the real acupuncture group, 1 out of every 4 participants will be in the placebo acupuncture group, and 1 out of every 4 participants will be in the wait-list acupuncture group. This is a blinded study, so neither you nor the study doctor or study staff will know whether you are receiving real acupuncture or placebo acupuncture. Only the acupuncturist will know to which acupuncture group you are assigned.

Before you begin the main part of the study, the study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in this study. If you join the study, you will have more exams, tests, and procedures so that the study team can continue to look out for your safety and health.

During the study, Participants in Group 1 and 2 will receive 10 treatments of acupuncture (real or placebo) over the course of 10 weeks with 1 treatment per week. Each acupuncture session will take about 30-45 minutes to complete. A licensed MSK acupuncturist will perform the sessions. Acupuncture is classified and regulated as a medical device by the FDA.

After waiting for 26 weeks, participants in Group 3 have the option to receive 10 treatments of real acupuncture over the course of 10 weeks with 1 treatment per week. Each acupuncture session will take about 30-45 minutes to complete. A licensed MSK acupuncturist will perform the sessions. The sessions will be free-of-charge and part of your standard-of-care treatment rather than part of the study.

You will also receive a sleep diary so that you can write down your sleep patterns, sleep quality, and sleep medications for 7 straight days during Weeks 0 and 10 of the study. You will return your diaries after you've completed each week's entry. The study team will give you a new diary for each week.

<u>Exams, Tests, and/or Procedures</u>
You will have the following tests and procedures during the main study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- You will complete questionnaires about cognitive difficulties and insomnia before treatment on Week 0 and after your treatment sessions on Weeks 4 and 10. The questionnaires will ask questions about your physical and mental health, your sleep quality, and your quality of life. You will complete these questionnaires electronically on a computer in the clinic or in your home. If you do not own a computer or are unable to complete the questionnaires on a computer, you will answer the questions for a member of the study team over the phone while you are at home. Completing these forms will take about 15-45 minutes.
- If you are assigned to receive real or placebo acupuncture, you will also complete questionnaires about your expectations for the effects of acupuncture (on Weeks 0, 4, and 10), and about which treatment you think you were receiving (on Week 4). You will complete these questionnaires electronically on a computer in the clinic or in your home. If you do not own a computer or are unable to complete the questionnaires on a computer, you will answer the questions for a member of the study team over the phone while you are at home. Completing these forms will take about 10 minutes.
- You will participate in cognitive testing on Weeks 0, and 10. These tests will provide information about your cognitive function, including your ability to pay attention and focus, remember and learn things, calculate numbers, and process information. On Weeks 0 and 10, you will complete around 30 minutes of cognitive tests on a video call with a researcher. *During the video call visits, there is a period of time we call a "delay." This delay takes 20 minutes, and you will fill out some of your questionnaires and several other cognitive tests during this time. This is included in the time estimates above.* In addition, on Weeks 0 and 10 you will complete another set of cognitive tests (around 45 minutes) on your own using a computer.
- Collection of blood (around 2-4 teaspoons each time) for research purposes on Week 0 to test a biomarker in the brain called Brain-Derived Neurotrophic Factor (BDNF). Researchers are trying to see if acupuncture has an effect on the amount of BDNF in your blood. A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. Instead of the blood sample, you may choose to have a saliva sample on Week 0.

Researchers will use the information from tests on the blood/saliva sample to try to learn more about BDNF and other biomarkers that may relate to your cognitive function, sleep, or other aspects of health.

The sample may also be used for genetic research. We may study your samples to improve our understanding of the way changes in genes can affect your cognitive abilities, sleep, or other aspects of health. Genes are the "blueprints" for our bodies. Sometimes genes may have changes that occur during your lifetime that can affect the way a gene works. These changes may affect cognitive abilities, sleep, or other aspects of health.

After your samples have been analyzed, if any part of them is left over, the material will be banked for use in future research.

The samples will be stored for an indefinite period of time for use in future research. Your sample(s), including your DNA, may be used or stored for as long as they are useful for research purposes.

A Federal law, 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. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or if you are a member of the military, or receive your health care through TRICARE, the Federal Employees Health Benefits Program, the Veterans Health Administration, or the Indian Health Service.

The results of blood/saliva sample would be used only for research, and not to guide your medical care.

The patient chooses to have the saliva sample instead of the blood sample on Week 0.

❑ Yes ❑ No

Follow-up visits:
After your last treatment session, the study team and study doctor will follow your condition and watch you for any side effects for the next 16 weeks. You will complete questionnaires during Weeks 14 and 26. On Week 26, you will complete about 30 minutes of cognitive tests on a video call with a researcher and about 45 minutes of cognitive tests on your own using a computer. *During the video call visits, there is a period of time we call a "delay." This delay takes 20 minutes, and you will fill out some of your questionnaires and other cognitive tests during this time. This is included in the time estimates above.* After this visit, your participation in this study will end.

Neither you nor your doctor will receive the results of any tests done for research purposes during this study.

About 270 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

Do you have any questions about this study so far?

Risks and Benefits

There are both risks and benefits to taking part in this study. If you choose to take part in this study, there is a risk that you may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office, and you may be asked sensitive or private questions that you do not usually discuss.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of acupuncture:

Common, some may be serious
• Small bruises around the acupuncture sites • Minor bleeding around the acupuncture sites • Minor pain or an unfamiliar feeling at the acupuncture sites

Occasional, some may be serious
• Allergic reaction causing hives • Drowsiness • Restlessness • Anxiety or nervousness • Dizziness or fainting • Nausea and vomiting

Rare, and serious
• Skin infection • Organ injury

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

If you choose to provide blood/saliva samples, there may be a risk in finding out new genetic information about yourself. New health information about inherited traits that might affect you or your family (blood relatives) could be found during this optional study.

You may ask the study team (lead researcher and research staff) any questions you may have about risks.

Taking part in this study may not benefit you directly, but what we learn from this research may help the study doctors learn things that may help other people with cognitive difficulties and insomnia in the future.

Alternatives to Participation

Some treatments used for cancer can cause long-term side effects, such as cognitive difficulties. The usual approach for patients with cognitive difficulties who are not in a study is to make lifestyle changes such as exercise or receive cognitive rehabilitation (various types of therapy to restore normal cognitive function or help people deal with cognitive problems). In some cases, your doctor may recommend medications to help with your symptoms.

If you decide not to take part in this study, you may choose to you may choose to have the usual approach described above**,** You may choose to take part in a different research study, if one is available**,** you may choose to receive acupuncture outside of this study**,** or you may choose not to be treated for cognitive difficulties**.**

Ending Participation

You can decide to stop participating in this study at any time. If you decide to stop, let the study team know as soon as possible. We will not be able to withdraw information about you that has already been used or shared with others.

The study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The lead researcher may remove you from the study if it is no longer in your best interest or you do not follow the study rules.

Conflict of Interest

This study is sponsored by Memorial Sloan Kettering Cancer Center. The study is funded by the National Institutes of Health (NIH). No conflicts of interest have been identified for either the institution or the investigator(s) in this study.

Costs of Participation

There will be no cost to you for taking part in this study. You will not be charged for the acupuncture treatment (real or placebo), and other procedures and tests will be provided to you at no charge while you are taking part in the study. If you are in Group 3, you will be offered free acupuncture for your participation in this study after the 26-week waiting period.

You and/or your health plan/insurance company will have to pay for all the other costs of treating your cognitive difficulties while you are in this study, including the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.
If you participate in this study, you will receive $50 after completing your Week 26 visit.

Your biospecimens (blood) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

Optional Studies

This part of the consent form describes optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The doctors leading this research hope that the results of these studies will help other people with cancer in the future.

The results of these studies will not be added to your medical records, and you and/or your study doctor will not be informed of the test results.

You will not be billed for these optional studies. You can still take part in the main study even if you do not participate in some or all of the optional studies. If you sign up for but cannot complete any of the optional studies for any reason, you can still take part in the main study.

A member of the study team will give all participants (including participants in Groups 1, 2, and 3) the option to wear a watch-like device on the wrist for two different one-week periods. The first period will be from Week 0 to Week 1, and the second period will be from Week 9 to Week 10. This device will automatically track your sleep patterns. If you choose to take part in this optional study, researchers will encourage you to wear the device as often as possible during the one-week periods to collect accurate information about your sleep.

The patient chooses to wear the optional watch-like device to track sleep.

❑ Yes ❑ No

A member of the study team will also give all participants the option to provide additional blood samples under specified testing conditions. If you choose to take part in this optional study, you will be asked to have a blood sample taken at Week 0 and Week 10, rather than only at Week 0. About 2-4 tablespoons of blood will be collected from a vein in your arm at Week 0 and Week 10. In addition, you will be asked to fast overnight for at least 12 hours prior to providing the blood sample. You will also be asked to provide the blood samples between 8:00 AM and 10:00 AM.

The results of the blood sample would be used only for research, and not to guide your medical care. You do not need to have this blood sample to take part in the main study.

Your medical care will not be affected, no matter what you decide to do.

The patient chooses to have the optional additional blood samples under the specified conditions.

❑ Yes ❑ No

Do you have any questions?

Privacy and Security Information

Your privacy is very important to us, so I would like to end by explaining who will have access to your information and how your information will be used.

In the future, any information that identifies you or your biospecimens may be removed. Your data and/or biospecimens may be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything

else that could identify you will not be used. It is possible that your de identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

MSK must get your permission before using or sharing your protected health information for research purposes. Your protected health information includes your medical and research records, which could include HIV-related or genetic information, and any health information or clinical data associated with your biospecimens.

The main reasons for using or sharing your information are to do the study, to check your health status, and to find out the research results. We also want to make sure the research meets legal and institutional requirements.

Your protected health information may be shared with and used by the following:

- The study's lead researcher and the research team
- People and offices that deal with research oversight, quality assurance, and/or billing, if applicable.
- MSK and the sponsor's research collaborators, business partners, subcontractors and agent(s) working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study.
    - Once your data is shared, it may not be as well protected as it is at MSK.
    - Your information may also be shared with federal and state agencies, and other domestic or foreign government bodies including:
        - the Office for Human Research Protections of the US Department of Health and Human Services
        - the National Cancer Institute /National Institutes of Health

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Your information may be given out, if required by law. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

If you agree to take part in this study, you give us permission to share your protected health information. If you do not agree to let us share your information, you will not be able to take part in this study. However, it will not affect your ongoing medical treatment or healthcare coverage.

Contact Information

You can talk to the study team about any questions or concerns that you may have about this study. You may also contact the lead researcher, Dr. Jun Mao at 646-888-0866. More information about this study may be available at ClinicalTrials.gov.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if

you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Agreement to Participate

Based on our discussion, do you voluntarily agree to participate in this study?

If NO:

- Thank the participant for his/her time. Do not complete the below participant and consenting professional information. Add a note to the medical record/research file indicating that he/she declined to participate.

If YES:

- Continue.

Thank you so much for your time and for agreeing to participate in this study.

Participant Information	
Participant Name	
MRN/Study ID	

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		