

Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Lead Study Investigator: Nada Lukkahatai, PhD. RN
Master Informed Consent Approval Date: December 12, 2024
Site-Specific Information Approval Date:
Application No.: IRB00243141

Auricular Point Acupressure to Manage Chemotherapy Induced Neuropathy

NCT04920097

Version Date: December 12, 2024

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

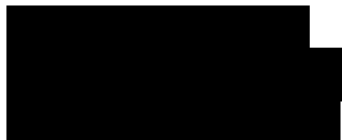
RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Auricular Point Acupressure to Manage Chemotherapy Induced Neuropathy (Master - ALL)

Application No.: IRB00243141

Funded By: National Cancer Institute

Lead Site Principal Investigator: Dr. Nada Lukkahatai



You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

This is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to examine the effectiveness of auricular point acupressure (APA) to reduce chemotherapy-induced neuropathy. APA is an acupuncture-like stimulation on the ear using small seeds.

Participants will be enrolled in the study for a total of 12 months. You will be responsible for attending 1 in person, 1 online intervention visits and 4 weekly online surveys, completing 3 monthly in person follow-up visits, 3 follow-up questionnaires over email and reporting your experiences during the intervention period using the APA app.

While there are no likely direct and immediate benefits, you may experience pain relief if the intervention works. There is minimal risk involved with participating in this research study. The risks involved with this study are outlined further in detail in the sections below. Participating in the study comes at no cost to you.

2. Why is this research being done?

This research is being done to determine the effectiveness of auricular point acupuncture (APA), an acupuncture-like stimulation without needles on the ear using small seeds, for treating chemotherapy-induced neuropathy.

Who can join this study?

People 18 years old or older with chemotherapy-induced neuropathy (CIN) or have pre-existing peripheral neuropathy that worsened after chemotherapy may join.

How many people will be in this study?

About 238 people are expected to take part in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Consent and Baseline:

During your first in-person visit, we will obtain informed consent, demographics information, and a sample of your blood. We will ask you to complete a study questionnaire, functional magnetic resonance imaging (fMRI), and quantitative sensory testing (QST). For QST, you will undergo several different tests so we can try to measure how you feel sensations like pain, cold, and heat.

Intervention:

You will then be randomly assigned (by chance, like drawing numbers from a hat) into one of the following groups: (1) In-person treatment and training and self-guided smartphone application to understand and administer APA (mAPA), (2) A virtual APA (vAPA): mAPA + plus a secure zoom session for APA coaching with questions and answers, (3) Wait-List Usual Care Control (UC). We will ask that you not seek outside medication or treatment to help with your pain. You may continue to use any medication or treatment that you had previously been using prior to starting the research study.

- (1) mAPA Group: Participants will come to the first study visit for outcome assessment, receive a training for participant or caregiver on ear seed placement, receive an app, and will be administered APA treatment during the first visit and one online zoom meeting for seed placement coaching and questions and answers on the second week. Participants will be asked to self-administer APA for 4 weeks.
- (2) virtual APA (vAPA): Participants will have the same study procedures in mAPA group but will not have an in person training and seed placement on the first study visit, instead receive an app with instruction for participant and/or caregiver on how to place the seed and a zoom session for APA coaching with questions and answers on the second week
- (3) Wait-List Usual Care Control (UC): After one month follow-up, the participants will be randomized into the mAPA or vAPA group.

Post-intervention

You will have four more in-person study visits after your intervention visits, in which you will repeat the same assessments as your baseline visit. One visit will occur after completion of the 4-week APA intervention, followed by monthly follow-ups for 3 months. Afterwards, you will receive a follow-up questionnaire through email at 6, 9 and 12 months.

The table below shows the schedule of study visits, including seed placement visits:

Study Visit Schedule	mAPA group	Virtual APA group	Waitlist Usual Care	
1 st visit (Day 1)	X	X	1 st visit (Day 1)	X
2 nd visit (Day 30)	X	X	2 nd visit (Day 30)	X
3 rd visit (D60)	X	X	3 rd visit (D60)	X
4 th visit (Day 90)	X	X	4 th visit (Day 90)	X
5 th visit (Day 120)	X	X	5 th visit (Day 120)	X
			6 th visit (Day 150)	X

Audio recordings:

As part of this research, we are requesting your permission to create and use audio recordings to help answer the research question. Any audio recordings will not be used for advertising or non-study related purposes.

You should know that:

- You may request that the audio recordings be stopped at any time.
- If you agree to allow the audio recordings and then change your mind, you may ask us to destroy that audio recording. If the audio recording has had all identifiers removed, we may not be able to do this.

Please indicate your decision below by checking the appropriate statement:

_____ I **agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use audio recordings of me for the purpose of this study.

_____ I **do not agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use audio recordings of me for the purpose of this study.

Participant Signature

Date

Description of Study Procedures:

Blood Sample: Your blood will be drawn at baseline, pre-intervention, and post-intervention, 1, 2 and 3 month follow-up. Each time, 15 ml (3 teaspoons) of blood will be drawn from a vein in your arm either by a registered nurse or laboratory technician. This process will take less than 10 minutes to complete. We will use the sample to test for biomarkers for inflammation that may indicate whether the APS was effective.

Questionnaires: You will also be asked to fill out several health questionnaires, which will ask you about your overall pain, pain interference, and demographic information.

APA: You will be instructed to download the app, review the videos and self-administer the APA to manage your pain weekly for four weeks. An APA kit (including the seeds and probe) will be provided to you without the cost.

fMRI: Magnetic Resonance Imaging (MRI) scans create images of the body using a strong magnet and radio waves. There is no radiation involved in an MRI exam. The MRI exams in this study will take about 30 minutes. You will have an fMRI at baseline, post-APA intervention, 1-month follow-up.

You may not take part in this study if you have any metal or device in your body which is not compatible with MRI. Examples include certain pacemakers, defibrillators, aneurysm clips, or other implanted electronic or metallic devices, shrapnel, or other metal.

If you have a history of metal in your head or eyes, you cannot take part in this study.

The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam.

Incidental Findings

As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an “incidental finding.”

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding from an imaging procedure.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

- An incidental finding may cause you to feel anxious.
- Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company's responsibility.

Will research test results be shared with you?

This study involves research tests that we do not expect will be useful for your clinical care. We will not share these results with you.

How long will you be in the study?

You will be in this study for 12 months. The intervention period will last 4 weeks and the follow-up period will last 11 months.

4. What happens to data and biospecimens that are collected in the study?

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

The researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at this institution and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We will do our best to protect and maintain your data/biospecimens in a safe way. One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups.

If data/biospecimens are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, additional consent from you may be required.

Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens is required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

Interviews or questionnaires

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Risks of Acupressure Procedure

The side effects of auricular acupressure are minimal. You could experience mild physical discomfort during the auricular acupressure. You do not have to press the tape if it makes you uncomfortable and can stop the intervention at any time. Although it is very rare, you may experience skin irritation or allergic reactions (e.g., redness, itching, swelling around the points) to the tapes and materials used in the APA, bruising and bleeding on the acupressure points due to excessive pressure and improper technique and falling of seeds into the ear canal. You must remove the tapes and seeds and seek medical attention for these rare risks.

Blood Draw

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Sensory Testing

There is a small chance that you might experience mild bruising from the pressure pain procedure. The cold water may produce discomfort, but the intensity used is not enough to cause harm and all tests may be stopped at any time.

Risk of fMRI

While no significant risks have been found from the use of MRI scans, you may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise.

Identifiable private information

There is the risk that information about you may become known to people outside this study.

Unknown risk

There may be side effects and discomforts that are not yet known.

6. Are there risks related to pregnancy?

While it is unlikely that APA would be harmful in pregnancy, the safety of using APA in pregnant women has not been established. Therefore, pregnant women will be excluded from the study.

7. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. It is possible that the intervention will provide some temporary benefit. It is also possible that there will be no benefit. If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

12. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

13. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at [REDACTED] with your questions or concerns.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

You may contact the lead principal investigator, Dr. Nada Lukkahatai, at 4 [REDACTED]. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at [REDACTED]

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department.

You may also contact the investigator for your study site listed in the second part of this consent form.

14. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say “no” to this/these optional component(s).

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES ☐ _____
Signature of Participant Date

No ☐ _____
Signature of Participant Date