RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Pilot Testing A Theory-Driven Self-Management Intervention for Chronic Musculoskeletal Pain**

(Master)

Application No.: **IRB00290512**

Principal Investigator: **Chao Hsing Yeh, Ph.D.**
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You are being asked to take part in a research study. 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) phone app on chronic musculoskeletal pain (CMP) outcomes. APA is an acupuncture-like stimulation on the ear using small seeds.

Participants will be enrolled in the study for a total of 4 months or 6 months, depending on the assigned intervention group. You will be responsible for attending one study visit (either in person or virtually, depending on the assigned study groups), completing 4 follow-up visits for up to 3 months, 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 acupressure (APA), an acupuncture-like stimulation without needles on the ear using small seeds, as treatment for chronic musculoskeletal pain.

Who can join this study?
People 18 years old or older with chronic musculoskeletal pain.

How many people will be in this study?
About 90 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:
Consent will be obtained by email. After consent form signed, we will ask you to complete study questionnaires. Then, you will be assigned to one of the three study interventions:

Intervention:
You will then be randomly assigned into one of the following groups: (1) Self-guided app (S-mAPA), (2) In-Person Training + app (IP-mAPA), (3) Usual Care Control (UC). You may choose Self-guided app (mAPA) group if you are not able to come in for the In-person training when you are assigned to this group.

The intervention will be 4 weeks. During the intervention, 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) If you are assigned to the self-guided app (S-mAPA), you will receive an app and will self-administer APA at home weekly for four weeks. You will the opportunity to receive in-person or zoom section APA training after you complete the 3 month follow-up.
2) If you are assigned to the in-Person Training + app (IP-mAPA), you will have one in-person study visit for APA training, receive an app, and self-administer APA at home weekly for four weeks.
3) If you are assigned to the usual Care Control (UC), you will continue to do whatever you are doing but will receive pain self-care information. You will be re-randomized into S-mAPA or IP-mASA group after you complete one-month follow-up. You may choose Self-guided app (mAPA) group if you are not able to come in for the In-person training when you are assigned to this group.

Post-intervention
You will have four more study visits after 4-weeks of intervention, 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 three monthly follow-ups.

Audio video recordings:
As part of this research, we are requesting your permission to create and use audio/video recordings to help answer the research question. The audio/video recordings will occur during the virtual sessions. Any audio/video recordings will not be used for advertising or non-study related purposes.

You should know that:
- You may request that the audio/video 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/vidoe 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/video recordings of me for the purpose of this study.

_____ _____
Participant Signature Date

Description of Study Procedures:

Questionnaires: You will 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.

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 4 months which includes five study visits (in-person or virtual, depending on the assigned study group). The intervention period will last 4 weeks and the follow-up period will last 3 months. If you are assigned in the Usual Care group, you will be re-randomized into APA group after you complete one month follow up, thus you will be in the study for 5 months.

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

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

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

Sharing data is part of research and may increase what we can learn from this study. Often, data 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 may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

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

We (Johns Hopkins) will do our best to protect and maintain your data in a safe way. One of the ways we protect data 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 sharing agreements and review by oversight groups within Johns Hopkins.

If data 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, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data 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 sharing could change over time, and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data 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.

Identifiable private information

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

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 (based on your self-reported data) 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 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. 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

SITE SPECIFIC CONSENT INFORMATION

Site Name: Johns Hopkins School of Nursing

Study Title: Pilot Testing A Theory-Driven Self-Management Intervention for Chronic Musculoskeletal Pain

JHM IRB Application Number: IRB00290512

Site Principal Investigator: Dr. Chao Hsing Yeh

Site Principal Investigator Contact Information:
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Other Study Contact(s):

Introduction:

This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Payment for Study Participation:

All participants will receive free parking (if you come in for in-person training) and can receive up to $130 for completing all study visits and EMA ($20 for each study assessment visit, including baseline, post-intervention, 1, 2 and 3 monthly follow-ups and $30 for EMA).

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

Compensation for Research-Related Injury:

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

Site IRB Contact Information:

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. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

For questions about the study, call the principal investigator, Dr. Chao Hsing Yeh at 667-208-7637. 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 410-502-2092.

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.

Additional information about your local site:

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.

How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Confidentiality will be maintained by assigning participants a study number and numerically coding all data. One copy file linking the code number with identifying information will be kept in a separate locked file with direct access available to the PI and project staff only. All records and research data will be kept in locked filing cabinets or computers. Only summaries of group data will be reported in any publications or presentations, with no identification of individuals.

Signature Lines:

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).