

W INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Pain Relief with Integrative Medicine (PRIME)?: Feasibility Trial of Acupuncture for Long COVID

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KEY STUDY INFORMATION

This research study will compare acupuncture treatment to your current treatment plan in treating pain symptoms from long COVID. We invite you to ask the research team questions. The contact information for the researcher in charge of the study is at the top of this page if you have questions later.

WHY ARE WE DOING THIS STUDY AND WHAT WILL I BE ASKED TO DO IF I PARTICIPATE?

Studies have shown that acupuncture can help relieve chronic pain symptoms. But, so far, acupuncture has not been widely offered for long COVID patients. We hope to learn whether acupuncture may help reduce long COVID symptoms such as pain. The goal of this study is to find out if the study design will work for treating patients with long COVID pain.

If you agree to participate:

- You will be randomly selected to receive either acupuncture or continue your current treatments. A computer will randomly assign you to one of the two groups. You will have an equal chance of being in either group.
- The acupuncture group will receive 8 weekly 1-hour acupuncture treatments at the UW Northgate Primary Care Clinic.
- You will receive four online surveys: at the beginning, middle, the end of the study, and 3-months after the study ends. You will be asked about your health, pain symptoms, and quality of life.
- We will ask if you would like to participate in an optional 1-hour interview. In this interview, we will ask questions about your experience in the study and how we might improve it. We will provide a \$50 gift card to thank you for your time and feedback.

WHY MIGHT I NOT WANT TO BE IN THIS STUDY?

You might not get acupuncture if you are randomly assigned to the non-acupuncture group. You may have to travel to the UW Northgate Primary Care for acupuncture treatments. Travel time and expenses may be a burden on you. Acupuncture is considered an experimental treatment for long COVID.

WHY MIGHT I WANT TO BE IN THIS STUDY?

If you are selected for the acupuncture treatment group, you will receive acupuncture free of cost. You can complete the surveys from your home on your phone, tablet, or computer. Your responses may help us learn about potential treatment options for others with long COVID.

At the end of the study, you will have a chance to win one of twenty \$100 gift cards. Each survey completed is an entry into the gift card drawing (up to 4 entries). We aim to enroll 80 participants in our study. This means that if you complete all four surveys, your chances of winning a gift card will be about 1 in 4. We will contact the winners of the gift card within one month of completing the study procedures.

The UW financial system requires us to input your name and mailing address to process the gift card. Your name and participation in this study will be visible to employees who handle financial transactions for the UW.

DO I HAVE TO TAKE PART IN THIS STUDY?

No. This study is completely optional. Your participation will not impact your care with the UW Medicine Long COVID Clinic. You can decide you want to take part in this study, it should be because you want to volunteer. You can choose to leave the study at any time. You may also seek out any other treatment options, including acupuncture, outside of this study.

WHAT IF I WANT MORE INFORMATION?

The rest of this document gives you more information about the study:

- What the study is about.
- What you will be asked to do during the study.
- The benefits and risks of this study.
- The benefits and risks of acupuncture treatment.
- How we will protect your privacy.

- Who to talk to if you have questions, problems, or concerns.

What is this study about?

This study is about treating pain for long COVID patients with acupuncture. You are being asked to participate because you are, or have been, a patient at the UW Medicine Long COVID Clinic.

What will I be asked to do?

You will be randomly assigned to either receive acupuncture or continue with your current treatment plan. If selected to receive acupuncture, you will travel to the UW Northgate Primary Care Clinic for 8 weeks. Each acupuncture treatment lasts 1 hour. Both groups can continue to receive their regular care as your doctor recommends.

You will be asked to lie on your back while the acupuncturist inserts needles in a few different places on your body. These needles will be kept in place for 15-30 minutes. You can let your acupuncturist know if you feel any discomfort and your acupuncturist will adjust the treatment. At the end of the session, the acupuncturist will place up to 10 very short needles (press needles) into your ear, arms, torso or legs and ask you to keep these press needles in place for up to 5 days. You can remove them at any time if you feel any discomfort.

Both groups will fill out four surveys. The surveys may take up to 30 minutes but you can save them to continue later.

PROCEDURES	Usual Care	Acupuncture
Survey #1	X	X
Scheduling acupuncture treatments		X
Weeks 1-8 – Attending acupuncture treatment sessions.		X
Weeks 1-8 – Continue to receive any treatments or care recommended and referred to you by your doctors.	X	X
Week 4 / Survey #2	X	X
Week 8 / Survey #3	X	X
Week 20 / Survey #4	X	X
Interviews – Interviews with the research coordinator where you will discuss the overall process and your feelings while participating in the study.	X	X

Do I have options outside of this study?

Document Date & Version

09.19.2023 posted

10.01.2023 implemented

Version 1.2

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If you choose not to participate in the research, the treatment or care available may include medication, supplements, physical therapy, massage therapy, or occupational therapy. The research team will discuss these options with you and provide information about the risks and benefits. You may also wish to discuss these options with your doctor.

What can I do if I want more information?

Talk to the study team. We are here to help you understand the study. Please ask us any questions you have, even about things that are not in this document. It is our responsibility to give you the information you need to decide and give you time to think about whether you want to sign up.

Talk to someone else. You may want to discuss your decision about whether to sign up with your family, friends, your regular doctor, or someone else. You can show them this document to help them talk about the study with you.

Talk to someone about your rights as a subject. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or report problems or complaints about the study, contact the UW Human Subjects Division at hsdinfo@uw.edu or 206.543.0098.

Additional potential benefits of the study.

To summarize the benefits described at the beginning of the consent form:

- The study will cover all the costs of the acupuncture treatment.
- Acupuncture treatments can potentially offer pain or symptom relief from ongoing long COVID symptoms.
- By completing each survey, you can earn an entry to win one of twenty \$100 gift cards.

Additional potential risks or side effects of the study.

In addition to the risks described at the beginning of the consent form, there are a few risks listed below. There is also the risk of a breach of confidentiality. Notify the study team if you experience any of these risks or side effects. They will be able to address any issues and adjust your treatment plan. There may be risks that we are not able to anticipate.

Potential risk or side effect	How we plan to address this risk
Discomfort from the acupuncture needle.	Your acupuncturist will discuss all possible side effects and discomforts you should be aware of during and after your session.
Infection or bleeding from the sites of the acupuncture needle	We have strict protocols in place to minimize the risk of infection as much as possible. A small amount (1-2 drops) of bleeding may occur at the acupuncture point. There is a higher risk of bleeding if you are on blood thinners.
Discomfort from the “press needles.”	Remove the press needle as soon as you feel any discomfort.
Embarrassment or concern in sharing sensitive personal information, including disclosure that falls under mandatory reporting.	When applicable, sensitive questions will include a “prefer not to answer” choice. The research coordinator may reach out to connect you to resources to best support your health. The research coordinator will be available during business hours (9-5pm M-F) by phone, SMS, or email to answer any questions about the assessment.

How will we protect the information I provide?

We will protect your confidentiality. We will store your name and other personal information separate from the study data. Access to your personal information will only be seen by certain members of the study team and anyone from the UW or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name. If we learn you intend to harm yourself or others, we must report that to the appropriate authorities.

If you receive acupuncture, the acupuncture treatment may be placed in your MyChart record. This means people outside the research such as health insurers, health care providers, and anyone you have permitted to access your records may be able to find out you participated in this study.

The research coordinator will use your initials during the interview. An audio recording will be transcribed. Any remaining identifiers may be removed once the transcription has been reviewed for accuracy and the audio recording destroyed.

We have a Certificate of Confidentiality from the U.S. federal National Institutes of Health (NIH) which allows us to protect identifiable research information that is stored in the U.S. from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish. Research information that is placed in your medical

record may not be protected by this Certificate. Ask a member of the study team for information about what research information will be placed in your medical record.

There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

The Certificate expires when the NIH funding for this study ends. Currently, this is January 31, 2027. Any data collected after expiration is not protected as described above. Data collected before expiration will continue to be protected.

What if I want to stop being in this study, or if the researcher decides you should no longer participate?

If you decide you want to stop being in this study, contact the research coordinator. You can withdraw at any time for any reason.

If you become pregnant during the study, acupuncture will no longer be advisable and we will withdraw you from the study.

Additionally, we will ask you to withdraw if you experience certain side effects, and you will no longer receive the treatment due to safety concerns.

How will we share your information?

Sharing your information. The National Institutes of Health (NIH) has developed data (information) banks that collect study data. The NIH will store your de-identified information in these data banks for other researchers to use in future studies on any topic. The researchers could be from government, academic, or commercial institutions.

We will store information from this study in a public unrestricted data repository that anyone can use. This public information will not include your name or other information that could identify you. You will not receive any results from allowing your data to be placed in the NIH data banks.

You can withdraw your consent within one year of taking part in the study if you do not want your data in the NIH data banks. You will not be able to remove your information after it is sent to the NIH data banks. There will be no consequences for withdrawing consent. However, data that has already been sent cannot be retrieved.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you. If we do so, the information may then be used for future research studies or given to another investigator without getting added permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether we need to get additional permission from you.

Other information

Being in this study is voluntary. This means that you can refuse to sign up. It also means that if you do sign up, you can decide to stop being in the study at any time without penalty.

We are receiving financial support from the National Center For Complementary and Integrative Medicine (NCCIH).

If you have been injured or otherwise harmed by participating in this study, contact a member of the research team at 206-616-3961.

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

We will email a copy of the consent form to you at the email address that you provide. It will be a “PDF” document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer does not already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher(s) listed in this consent form.

Subject’s statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form. I give permission to the researchers to use my medical records as described in this form.

Printed name of subject

Signature of subject

Date

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