# Emergency Department Acupuncture for Acute Musculoskeletal Pain Management

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NCT04290741

Informed Consent Form v 1.50 (01/04/2023)

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
Emergency Department Acupuncture for Musculoskeletal Pain Management

**CONCISE SUMMARY**

The purpose of this study is to measure how well acupuncture (the insertion of very thin needles through your skin at strategic points on your body) improves pain and function, as well as its feasibility, acceptability, and safety in the Emergency Department (ED).

If you agree to participate in this study, you will have an initial assessment with a pain threshold test, study questionnaires, and optional blood draw. You will be randomly assigned to receive either one of two types of acupuncture or no acupuncture. Acupuncture will be performed by a North Carolina Licensed Acupuncturist while in the ED. One hour after your group assignment you will complete a second pain threshold test, study questionnaires, and optional blood draw. After your ED visit, if you are assigned to acupuncture you will attend acupuncture at an outpatient clinic twice a week for 4 weeks. You will be asked to complete questionnaires at 2 and 4 weeks after your ED visit. If you are assigned no acupuncture, you will be asked not to receive any acupuncture for 4 weeks after your ED visit, and you will only complete the questionnaires. Your data and samples collected for this study may be stored and shared for future research.

Risks associated with acupuncture include pain at the site of needle insertion, bruising, and bleeding. There are risks related to loss of confidentiality, but every effort will be made to safeguard your information.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you presented to the Emergency Department with a musculoskeletal pain (pain that affects the muscles, bones, and/or tissues that connect them).

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or staff if you are taking part in another research study.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**
If you decide to participate, Dr. Stephanie Eucker will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed. This study is sponsored by the Duke Endowment and the Substance Abuse and Mental Health Services Administration (SAMHSA).

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**WHY IS THIS STUDY BEING DONE?**
Musculoskeletal pain is one of the most common reasons for doctors' office and emergency department visits. Painful episodes can lead to significant disability and ongoing disruption of daily functioning.

Acupuncture involves the insertion of very thin needles through your skin at strategic points on your body. It is not well-understood how acupuncture works, but there is some evidence that it is safe and cost-effective in outpatient settings for management of acute and chronic pain, particularly of the back, neck, and shoulder. Acupuncture is most often used to treat pain and anxiety in the clinic setting, but has not routinely been used in the ED.

The goal of this study is to measure how well acupuncture relieves pain and improves function, as well as its feasibility, acceptability, and safety in the ED.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 750 people will take part in this study at Duke.

**WHAT IS INVOLVED IN THE STUDY?**
If you agree to be in this study, you will be asked to sign and date this consent form. If you sign this form electronically, you will be asked to provide your email address so that a copy of it can be emailed to you. By providing your email address for use in the consent process, you are at potential risk for a loss of confidentiality because email is not a secure means of communication.

You will undergo an Initial Assessment that includes the following:

- Pressure Pain Threshold test. This is a non-invasive test that uses a device that applies pressure to your body (shoulder muscle) to measure the amount of pressure that causes mild pain.
- Blood draw for biomarker measurements that is optional (approximately 3-4 teaspoons)
- Completion of questionnaires

You will be randomly assigned, like drawing numbers from a hat, to one of three groups listed below. You have an equal chance of being assigned to each group and a 2 out of 3 chance of getting acupuncture.

- Ear (auricular) acupuncture – placement of needles in up to 10 sites total in both ears
- Peripheral acupuncture – placement of needles in up to 30 specific sites in the head, neck, arms from the shoulders to the hands, and legs from the knees to the feet
- Control – no acupuncture

The acupuncture treatments will be performed in an Emergency Department examination room by a North Carolina Licensed Acupuncturist. Acupuncture consists of inserting single use, sterile, acupuncture needles, measuring 0.16-0.22mm in thickness (about the thickness of a hair) and varying in length from 1.5-5cm (0.5-2 inches). The skin will be cleansed prior to needle insertion, and needles will be placed utilizing clean needle technique. Needle insertion depth will vary between 0.5 cm (0.2 inches) and 4.5 cm (1.8 inches) (through the skin and sometimes muscle layers only), depending on the area of

treatment. Needles will be retained for up to 30 minutes. Auricular acupuncture needles are much smaller, 0.15 cm (0.06 inches) in length (only through the skin), attached to a bandaid adhesive so they can be retained for up to 4 days. All needles can be removed earlier at your request. All acupuncture performed adheres to the guidelines of Clean Needle Technique as required by North Carolina law.

Regardless of which group you are assigned to, you will also receive the usual care for musculoskeletal pain, including medications and other non-medication pain treatments such as ice/heat at the discretion your ED doctor.

You will receive the usual care for acute pain management as determined by your ED doctor.
If you are assigned to the control group you will not receive acupuncture. If you are assigned to one of the acupuncture groups, you will receive acupuncture in the ED. The session will last approximately 15-30 minutes.

One hour after you have been assigned to a treatment group you will be asked to complete a brief questionnaire, a pressure pain threshold test, and have an optional second blood draw (3-4 teaspoons) for research for future biomarker analysis.

Blood collection for biomarkers in this study is optional. Biomarkers are substances in the body that can be indicators of a disease. You do not have to allow for research blood draws to participate in this study. If you agree to blood collection, samples will be taken during and one hour after completion of the initial assessment in the ED.

Please initial below indicating whether or not you agree to research blood draws.

_____ Yes, I agree to undergo a blood draw for research purposes.

_____ No, I do not want to undergo a blood draw for research purposes.

If you are assigned to an acupuncture group, we will provide you with information and free access to group-based acupuncture in the outpatient Integrative Medicine clinic for the next 4 weeks. There will be two sessions per week, and each session will last approximately 30 minutes. You will be asked to provide your phone number and email address to schedule your acupuncture visits. Your name and contact information will be entered into an online scheduling program, Microsoft Bookings. This program will be used to schedule your acupuncture appointments and send appointment reminders.

If you are assigned to the control group, you will not receive acupuncture in the ED. Regardless of which group you are in, we ask that you not receive acupuncture or dry needling from other sources (including from your physical therapist or chiropractor) for 4 weeks after you sign this consent form. Current research supports that acupuncture will still be effective in treating pain after that time, should you choose to seek acupuncture treatment after participation in the study.

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Regardless of which group you are assigned to, you will be asked to complete questionnaires about your pain, pain management, and quality of life at 2 and 4 weeks after your ED visit. You will receive emails at these time points with a link to the study questionnaires. If you have not completed these within a few days of receiving the email you may be contacted by a member of the study team via text message and/or phone to ensure you are able to access the link. If you have trouble with the link or prefer to answer by phone the questionnaires may be completed via phone.

You may be asked to complete an interview via phone. Interviews will be conducted by a member of the study team. We will ask you questions about your experience with the study and research study materials. This interview will last approximately 15 to 30 minutes. The interviews will be recorded. Recordings may contain your name and age. Your interview will be transcribed within 2 to 3 months and any identifying information will be deleted. Recordings will be stored until the data analysis for this study is complete, approximately 2 years, at which time they will be deleted. Recordings and transcriptions of interviews will be stored in a secure folder that only the study team has access to.

**HOW LONG WILL I BE IN THIS STUDY?**
If you agree to be in this study, your participation will last approximately 4 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

**WHAT ARE THE RISKS OF THE STUDY?**
Acupuncture may occasionally result in slight bruising, pain at the site of needle insertion, and bleeding, dizziness, and numbness or tingling near the needling sites that may last a few days.
Infection, excess bleeding, or fainting are also possible, although unlikely.

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

There is also a risk of loss of confidentiality of your private information. Every effort will be made to protect your information, but this cannot be guaranteed. By providing your email address you are at potential risk for a loss of confidentiality because email is not a secure means of communication.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
There may be direct medical benefits to you for participating in this study. If you are assigned to an acupuncture group, you may have decreased pain but that cannot be guaranteed. A potential benefit of this study is to gain knowledge that may lead to improved pain management in the ED in the future. If you are randomized to the no acupuncture group there is no expected benefit above standard of care.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. By providing your email address for use in the consent process, you are at risk for a loss of confidentiality because

email is not a secure means of communication. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. Your date of birth, dates related to your ED visit, acupuncture visits, and any tests or procedures you have had will be collected for this study. Your name, phone number, and email address will be shared with Microsoft Bookings. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be shared if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record for at least six years after the study is completed.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some recipients who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**WHAT ARE THE COSTS TO YOU?**
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. The amount of your out-of-pocket expense will depend on your insurance plan.

Services and procedures that are done solely for research purposes will be paid for by the study. This includes the cost of both inpatient and outpatient acupuncture and costs related to blood draws (if applicable). Please talk with the PI/study team about the specific services and procedures that will be paid for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

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**WHAT ABOUT COMPENSATION?**
You will receive a $30 Amazon gift card after you complete the 4-week follow up survey. Gift cards may be sent via email or text message after the surveys have been completed.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a direct result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Eucker at 919-684-5537 during regular business hours and at 919-684-8111 after hours and on weekends and holidays and ask that she be paged.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that has already been collected will be maintained.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke. If you do decide to withdraw from the research study, we ask that you contact Dr. Eucker in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC Box 3096, Durham, NC, 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your study doctor may decide to take you off this study if she determines that it is no longer in your best interest to continue.

If you agree to allow your blood to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. Eucker in writing and let her know you are withdrawing your permission for your identifiable blood samples to be used for future research. Her mailing address is listed above. At that time, we will ask you to indicate in writing if you want the unused identifiable blood destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Your samples and data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your

identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://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.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Eucker at 919-684-5537 during regular business hours and at 919-684-8111 after hours and on weekends and holidays and ask that she be paged.

For questions about your rights as a research participant, to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

**STATEMENT OF CONSENT**
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

| _____ | _____ | _____ |
|---|---|---|
| Signature of Subject | Date | Time |
| _____ | _____ | _____ |
| Signature of Witness (if applicable) | Date | Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |