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Duke University Health System

Consent to Participate in a Research Study
ADULT Consent
Integration of Mindfulness and Acupuncture after Spine Surgery
Pro00114814

CONTACT INFORMATION

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KEY INFORMATION SUMMARY

This project is a study of the *Integrated Mindfulness and Acupuncture (I-MASS) intervention (*I-MASS) intervention in patients undergoing spine surgery.

The I-MASS intervention is designed to reduce pain and the need for pain medication following surgery. Participants will be randomized (placed into a group by chance) to either receive I-MASS, which consists of mindfulness training using an app on your phone or tablet and auricular acupuncture (needles are placed in the ear) plus education OR education alone.
We will measure outcomes such as pain interference, physical function, pain intensity, sleep disturbance, quality of life, psychological distress, continued postsurgical pain development, opioid use, emergency department visits, and hospital readmissions after spine surgery.

There are minor risks associated with acupuncture such as soreness, bruising and infection that will be discussed with you prior to the acupuncture. There is also a risk of loss of confidentiality with participating in any research.

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

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about 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 and will be reviewed with you by the study team.
Please tell the study investigator or study staff if you are taking part in another research study.

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Drs. Trevor Lentz, PT, PhD and Christine Goertz, DC, PhD will conduct the study. The study is funded by National Health Institute (NIH), who will pay Duke University to perform this research. These funds may reimburse part of Dr. Lentz and Dr. Goertz's salary.

Who will be my doctor on this study?
If you decide to participate, Dr. Lentz will conduct the study. He will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

Why is this study being done?
The purpose of this study is to see if I-MASS is reasonable option for patients undergoing spine surgery.

This study will help to determine whether I-MASS is associated with improvements in pain interference, physical function, pain intensity, sleep disturbance, quality of life, psychological distress, persistent postsurgical pain development, opioid use, emergency department visits, and hospital readmissions after spine surgery.

Up to 55 people will take part in this clinical trial at Duke

What is involved in the study?
You will be randomized to one of two study arms: 1) the I-MASS intervention plus Enhanced Education or 2) Enhanced Education. Your chance of receiving either would be like the flip of a coin. After signing this consent form, you will receive an email with a copy of your consent as well as your randomization group and how to access the Pattern Health App. Both groups will complete surveys via the Pattern Health app.

You will be asked to download the Pattern Health app to your mobile device. Once downloaded, you will be asked to agree to the terms and conditions of the app and will provide the following information about yourself: First Name, Last Name, Email Address, Date of Birth, Phone Number, and Gender.

If you are randomized to the Integrated Mindfulness and Acupuncture (I-MASS) intervention:
This study will include pre-surgical and post-surgical data collection.

I-MASS begins with one introductory telephone call by a mindfulness coach PRIOR to surgery. This call will introduce you to mindfulness, discuss the benefits of combining mindfulness with acupuncture, discuss how to access educational content (described below), and lead a brief (~10 min) mindfulness exercise (if necessary).

Next, you will complete 4 self-directed training modules through the Pattern Health app, (1 prior to surgery, 3 following surgery).

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Each module is anticipated to last one week and includes a short (4–5 min) introductory video, daily sessions comprised of a 6–8 min guided mediation, and interactive suggestions for how to apply mindfulness within your daily routine (~10-12 min total per daily session).

Information included in the modules includes: awareness of breathing, a core meditation technique that begins to cultivate skills of mindful, non-reactive observation (Module 1); awareness of body systems that are working well or less well as a way to continue to cultivate skills of observing, describing and non-judgmental attention (Module 2); awareness of emotion and mindful acceptance, designed to acknowledge difficult emotions and cultivate feelings of kindness and compassion towards oneself and others (Module 3); and broadening awareness of senses of sound designed to be an external context to cultivate skills of observing one's experience, letting go and practicing non-judgmental awareness (Module 4).

Acupuncture: The technique used in this study is called Auricular Acupuncture, or ear acupuncture. This technique involves inserting tiny needles in specific areas of the outer ear to target points believed to influence pain. The needles will be left in place in your ear. The needles are very small and have an adhesive backing, like a band aid and can be removed easily. Your acupuncturist will instruct you on how to do this and for how long the needles can stay in place, which can be for as long as 4 days. If you are unable to tolerate ear acupuncture, acupuncturists will also have the option of using more traditional body acupuncture.

The initial acupuncture session will occur prior to surgery (ideally within 3 days of surgery depending on your availability).

You will receive up to 7 acupuncture visits after surgery, with the first ideally occurring within 3 days after surgery, depending on participant availability and mobility (you must be able to travel to acupuncture clinic and transfer to a fixed height treatment table).

Acupuncture sessions will last up to 30 minutes and occur at one of our acupuncture clinic locations in the Raleigh-Durham area. These are not Duke-affiliated clinics. *You can choose the site that is most convenient for you*. All acupuncture sessions (up to 8 total) will be scheduled with the licensed study acupuncturist and you will incur no costs for these visits.

Enhanced education: Both groups will receive enhanced education on pre-surgical planning and post-surgical care which is intended to complement the education materials provided as part of standard pre- and post-surgical care at DUHS.

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Educational topics include learning how to lift and sit when experiencing pain, proper precautions following surgery, how to ease back into daily activities following surgery, and ways to self-manage pain.

All educational content is delivered through the Pattern Health app. You will receive notifications in the app when new educational material is available; and will have on-demand access to this educational material through the Pattern Health app anytime during their time in the study.

We will ask you, regardless of study arm, to complete questionnaires: Prior to surgery, 2 weeks, 6 weeks, and 3 months following surgery. Questionnaires will take 15-20 minutes to complete and will measure characteristics like pain interference, physical function, pain intensity, sleep disturbance, quality of life, and psychological distress.

We will ask you to provide information on the pain levels and opioid use daily for the first two weeks following surgery.

At 3 months, we will also ask questions about the your experiences in the program. All questionnaires will be completed in the Pattern Health app.

Participation in this study will not affect your standard postoperative care and does not prevent you from receiving any treatments recommended by your health care provider, including pain medications.

How long will I be in this study?
You will be in this study for approximately 4 months; 1 month prior to surgery and 3 months post-operatively.

You can stop participating at any time without penalty. However, if you decide to stop participating in the study, please contact the PI on the trial or one of the Research Coordinators.

What are the risks of the study?
While acupuncture is generally considered safe when performed by a competent, licensed practitioner using sterile needles, there are potential risks associated with the acupuncture treatment:

Bleeding, Bruising, and Soreness: You may experience soreness, minor bleeding, or bruising at the sites where the needles are inserted.

Infection: There is a minimal risk of infection, provided that single-use, disposable needles are used (as will be used in this study).

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Risks specific to mobile apps:
Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device. We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. Some people or groups 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.

Are there benefits to taking part in the study?
If you agree to take part in this study, there may be direct medical benefit to you if the I-MASS intervention and/or enhanced education help you to manage your pain. However, this cannot be guaranteed.

We hope that in the future the information learned from this study will benefit other people with your condition.

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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. 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. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

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

If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers or results are made public. The removal of this information allows your data to be used without anyone knowing which person in the study it comes from.

Some people or groups 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 confidential. If you decide to share your 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.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

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There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?
You will receive up to $120 for your expenses related to your participation (completion of questionnaires in the Pattern Health app prior to surgery, 2 weeks post-op, 6 weeks, and 3 months following surgery). You will only be paid for the surveys you complete. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

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 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 Trevor Lentz, PT, PhD at 919-668-7495 during regular business hours.

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What if I want to withdraw from the study?
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 concern 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 have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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, we ask that you contact Dr. Trevor Lentz, PT, PhD in writing and let him know that you are withdrawing from the study. His email address is: *Trevor.Lentz@Duke.edu*

The study investigator may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Reasons why this might occur include significant worsening of your pain or condition as a result of receiving acupuncture or practicing mindfulness. The sponsor or regulatory agencies may stop this study at any time. If this occurs, you will be notified.

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 should 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. Lentz at 919-668-7495 during regular business hours.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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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 Participant	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time