Feasibility of Mindfulness Meditation Training and Home Practice in Persons with Spinal Cord Injury: A Pilot Study

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UTHealth
The University of Texas
Health Science Center at Houston

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: SCI Pain Study

Full Study Title: Feasibility of Mindfulness Meditation Training and Home Practice in Persons with Spinal Cord Injury: A Pilot Study

Study Sponsor: National Center for Complementary and Integrative Health

Principal Investigators: Radha Korupolu, MD, MS, Associate Professor, Physical Medicine and Rehab, UTHealth, and Chelsea Ratcliff, Ph.D. Assistant Professor, Sam Houston University.

Study Contact: Radha Korupolu, MD, MS, [redacted]
Chelsea Ratcliff, Ph.D., [redacted]
Research Coordinator: Shrasti Lohiya, MBBS, MPH, [redacted]

The purpose of this study is to find out if using an app is a feasible and acceptable treatment for chronic pain in persons with spinal cord injury. Participants will have a 50% chance of being asked to listen to 10 minutes of audio-guided meditations using an app each day for six weeks, and a 50% chance of being asked to listen or watch to 10 minutes of educational presentations about physical and emotional health (TED Talks related to sleep, mood, relationships, nutrition, chronic pain, and health behaviors) for six weeks. If you choose to participate in this study, you will be asked to complete three online surveys about your physical and mental health lasting 20-30 minutes (one when you first enter the study, one six weeks later, and another six weeks later). Additionally, you will be asked to complete brief (<10 minute) online surveys once a week during the first six weeks of your participation. The total amount of time you will be in this study is 12 weeks.

There are potential risks involved with this study that are described in this document. This study has minimal risks and discomforts. The risks are considered low. There may be potential benefits to you such as greater acceptance of pain, improved mood, and improved quality of life.

There are alternatives such as not choosing to participate in this research study.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth) or Memorial Hermann Healthcare System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?
The purpose of this study is to find out if using an app is a feasible and acceptable treatment for chronic pain

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in persons with spinal cord injury.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the study has ended, the website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?
You are being asked to take part in this research study because you have a spinal cord injury and chronic pain. This study is being conducted at TIRR Memorial Hermann and UT Health. About 60 people will take part in the study. This study will examine if using an app daily is something that individuals with spinal cord injury and chronic pain are interested in and willing to do.

Persistent pain is a problem for over two-thirds of individuals with spinal cord injury. Managing pain through medication is not always possible, making it important to find alternative methods for pain management. Both meditation and education about physical and mental health have been shown to help people manage their pain. However, few studies have examined the acceptability and feasibility of app-guided meditation or education among individuals with spinal cord injury.

What will happen if I take part in this study?
If you participate in this study, you will be emailed and texted a link to an online baseline or pre-intervention survey and will be asked to complete this 30-minute survey about your physical and mental health.

After you complete this online survey, you will be assigned to one of two conditions: a mindfulness meditation (MM) condition or a health education condition (HEP). If you participate in this study, you will have a 50% chance of being assigned to MM, and a 50% chance of being assigned to the H EP.

If you are assigned to MM, you will be asked to attend a 30-minute online video meeting with the study's research coordinator using Zoom or WebEx. In this meeting, the research coordinator will provide you with a unique code and assist you in downloading and using an app consisting of mindfulness meditation exercises. You will be asked to listen to audio-guided meditation exercises on the app for 10 minutes each day for the next six weeks. Additionally, you will be asked to document your app use in a log that the research coordinator will give you.

If you are assigned to HEP, you will be asked to attend a 30-minute online video meeting with the study's research coordinator using Zoom or Web-ex. In this meeting, the research coordinator will assist you in downloading and using the TED app. You will be asked to listen to 10 minutes of educational presentations about physical and mental health each day for the next six weeks. Additionally, you will be asked to document your app use in a log that the research coordinator will give you.

At the end of each week during the first six weeks of your participation, the research coordinator will email and text you a link to a brief (<10 minutes) online survey that asks about your pain, your mood, and how often you have used the apps that week. At the end of the six-week period, the research coordinator will email and text you a link to a 30-minute online post-intervention survey, which will be similar to pre-intervention with the addition of a few questions to assess your satisfaction with the assigned app. Six weeks later, the research coordinator will email and text you a link to another 30-minute online follow-up survey, which is similar to the pre-intervention survey. You may receive the post-study survey link (<5 minutes) through email or text. We will also ask the participants to export the data from the app at the end of the post-intervention, which creates an

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email from the participant's email address to the study email with an Excel file attached that documents the participant's app usage. The research coordinator (RC) will provide the participants with an instruction guide to assist them in exporting the app usage data.

How long will you be in the study?

If you agree to take part, your participation will last for 12 weeks. The first six weeks will involve completing brief (<10 minutes) online surveys once a week, and all participants will be asked to complete three online surveys about their physical and mental health lasting 20-30 minutes (one when the participant first enters the study, one six weeks later, and another six weeks later).

What choices do you have other than this study?

You may choose to not participate and select other options than being in this research study.

What are the risks of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

This study has minimal risks and discomforts. However, it is important to recognize that thinking about physical and mental health concerns while answering questionnaires can be uncomfortable for some people. The risks, however, are considered low. In light of this, a document with information on accessing mental health resources will be provided to all study participants. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

There may be some risks that the study doctors do not yet know about.

What are the benefits to taking part in this study?

The benefits of participating in this study may be: You may experience greater acceptance of pain, improved mood, increased health-related knowledge, and improved quality of life. However, it is possible that you may receive no benefit from participating in this study.

This study may help the study doctors learn things that may help other people in the future.

Can you stop taking part in this study?

You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Dr. Radha Korupolu at [redacted]

Your doctor or the sponsor can stop the study at any time. Your doctor or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available

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and could affect your willingness to stay in the study.

What happens if you are injured during the study?
If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment. You should report any such injury to Radha Korupolu, MD at [redacted]. You will not give up any of your legal rights by signing this

What are the costs of taking part in this study?
You will be paid for your time to take part in this study. You will be paid for completing the baseline assessment ($25 gift card value), post-intervention assessment ($25 gift card value), and six-week follow up assessment ($25 gift card value) ($25 x 3 = $75). You will also be reimbursed for completing short surveys at end of weeks 1-5 ($10 gift card value per assessment completed; 6 x $10=$60). Thus, you can earn up to $135 in gift card value ($75 + $60 = $135) for participating in this study. You will be mailed one gift card for the total amount earned during the course of the study at the end of your participation in the study.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed. If you sign this document, you give permission to UTHealth, or Memorial Hermann Healthcare System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes your medical record, such as your demographic information, medical history, pain scores, and evaluations performed as a part of the study.

Personal identifiers such as your name and medical record number will be removed from the information collected in this study. After we remove all identifiers, the information may be used for future research or shared with other researchers without your additional informed consent.

Please understand that research study data will be sent to the research collaborators at other Universities. The data that will be shared will not include your name but may include your initials, date of study visits, and date of study procedures.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth and/or Memorial Hermann Health System
- Institutional Review Board
- Companies engaged with the UTHealth for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this

research study. UTHealth and Memorial Hermann Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Dr. Radha Korupolu in writing at [redacted]. This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact the Dr. Radha Korupolu at [redacted] as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, and obtain information in addition to asking questions about the research.

Are you interested in being contacted for future research studies?
Please check the appropriate box to indicate your preference. If you are interested in participating in future studies, the research team will retain information that will identify you, such as your name, phone number, mailing address, and/or email address.

□ Yes, I am interested in being contacted for future research studies.

□ No, I am not interested in being contacted for future research studies.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted]

SIGNATURES:

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date Time
Printed Name of Person obtaining Informed consent		
Signature of the person obtaining consent		
Date Time		

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