Postoperative Telehealth Mindfulness Intervention After Spine Surgery

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VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Optimizing a Postoperative Telehealth Mindfulness Intervention to Improve Outcomes After Spine Surgery
Version Date:	05/02/2022
Principal Investigator:	Carrie Brintz, PhD

Consent to Participate in Research Study

Screening ID_____

The following is given to you to tell you about this research study being conducted at Vanderbilt University Medical Center. Please read this form with care and ask any questions you may have about this study.

If you have any questions as you read through this form, you may call or email the study coordinator, Amanda Priest (phone: 615-421-8336, email: mindful@vumc.org) or the principal investigator, Dr. Carrie Brintz (phone: 615-875-9885, email: carrie.brintz@vumc.org).

Key information about this study:

You are being asked to take part in this research study because you will have back surgery for a degenerative condition. There is evidence that how people manage stress, difficult feelings, and thoughts and beliefs about pain and other symptoms may affect recovery after back surgery. Research studies have shown that learning mindfulness skills can help reduce the interference of pain and stress in one's life. The purpose of this study is to find out if an intervention that teaches mindfulness skills to reduce stress reactivity, increase your confidence in managing your pain and medications after surgery, and improve your physical and emotional well-being is feasible, acceptable, and beneficial to patients recovering from spine surgery. You will also take part in standard medical care.

If you choose to participate and if you are eligible, you will complete a preoperative questionnaire, a postoperative questionnaire, 8 weekly sessions with a mindfulness therapist over telehealth (online using audio and video), a post-treatment questionnaire, and a 30-minute, post-treatment phone interview.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying that you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Detailed Information

Possible Risks or Discomforts:

We anticipate based on previous research of mindfulness training interventions that the study will pose minimal safety risk. There is the possibility that you may feel some discomfort when first learning mindfulness skills because you will be asked to notice your thoughts, feelings, and body sensations in ways that may be new to you. If this should occur, your mindfulness therapist will guide you through this. However, you are never required to participate in any skill that makes you uncomfortable. You may experience discomfort related to answering questionnaires about your pain and mood.

There is also the risk of loss of confidentiality. All efforts, within reason, will be made to keep your personal information in your research record confidential.

Good effects that might result from this study:

1. The benefits to science and humankind that might result from this study are that healthcare professionals will be able to better understand and treat patients after back surgery.

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2. The benefits you might get from being in this study are to learn more about your own recovery after back surgery. Also, taking part in this study may help you learn useful skills, increase your ability to manage pain and stress after surgery, and reduce your recovery time after surgery, although this cannot be guaranteed.

Procedures to be followed:

You will complete:

1. A short, 5- to 10-minute screening interview in person or over the phone with the research coordinator to confirm whether you are eligible for this study. A few of the questions may be sensitive, as they ask about mental health and substance use. Any responses that we save will be labelled with a screening ID and kept separate from information that could identify you in a secure file.

2. A preoperative questionnaire using a REDCap survey link that will be emailed to you after you complete this consent form and are determined to be eligible to participate. You may also complete the survey at the Vanderbilt Comprehensive Spine Center if you are at a clinic visit when you enroll in this study. If needed, you can complete the survey over the phone with the study coordinator. The survey will ask you questions about your pain and its interference in your life, pain medications you take, questions related to your mood, and how you think about and cope with pain

3. A postoperative questionnaire using a REDCap survey link that will be emailed to you 2 weeks after your surgery. You may also complete the survey at your postoperative clinic visit depending on the date of your visit, or over the phone.

4. Approximately 2 weeks after your surgery, you will begin the 8 weekly mindfulness sessions over Zoom (audio and video) delivered online by a trained mindfulness therapist. You will meet one-on-one with the therapist, with sessions lasting 1 hour and 15 minutes each (75 minutes), except for the first session which will last 1 hour and 30 minutes (90 minutes). You will have 10 weeks to complete the 8 sessions to allow for 1-2 possible missed weeks. If you do not have a device such as a computer or tablet that has both a microphone and a video camera, you will be given a tablet for use during the study. The sessions will be audio recorded for purposes of assuring the quality of the therapist's session delivery. The sessions will not be video recorded.

The sessions will involve learning mindfulness skills that may help you manage and cope with pain, stress, and difficult symptoms and feelings during your back surgery recovery. You will learn several different mindfulness skills such as 1) body scan meditation, a gradual moving of attention through the body, with awareness of breathing and other bodily sensations, 2) seated practices focused on awareness of breathing, bodily sensations, thoughts, and emotions, 3) gentle movement practices that can be completed sitting or standing and are intended to develop mindfulness during movement, and 4) ways to integrate mindful awareness into your daily activities and to respond to stress or discomfort in ways you find most helpful.

You will be provided with session handouts and guided audio-recordings of the skills and asked to practice between sessions and to track your practice. You will record your practice daily on paper and weekly via the Home Practice Record using a REDCap survey link that will be emailed to you every week prior to your next session.

5. A post-treatment questionnaire using a REDCap survey link that will be emailed to you after you complete the mindfulness sessions (around 3 months after your surgery). You may also complete the survey over the phone if needed.

6. A 30-minute, post-treatment phone interview that will be scheduled with a study staff member and audio recorded. We are interested to learn about your experience with the sessions and any suggestions you have to improve the post-surgical mindfulness program for future patients who participate.

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Payments for your time spent taking part in this study or expenses:

You will be paid $20 per questionnaire (Pre-operative Intake Assessment, 2-week Post-operative Baseline Assessment, & Post-treatment questionnaire up to $60) and $25 for completing the phone interview, for a possible total of $85. You will not be compensated for completing the weekly Home Practice Record.

Cost to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator with Sponsor input that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Carrie Brintz at (615) 875-2643 or a member of the study staff at (615) 421-8336

Reasons why you may be taken out of the study:

You may be withdrawn from the study if your medical or mental health condition changes so that staying in this study may risk your health or disqualify you for this research. The entire study could be stopped at any time if the safety of research participants is found to be at significant risk. If the study is stopped for any reason, you will be told that the study is being stopped. If you are taken out of the study, you will be told the reason why.

What will happen if you decide to stop being in this study?

If you decide to stop being in the study, you should tell the principal investigator, Dr. Carrie Brintz. Deciding to not be a part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

A description of this clinical trial will be available on www.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.

Confidentiality and Privacy:

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All efforts, within reason, will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Any information you provide to us, including audio recordings from your sessions and phone interview will be stored in a password-protected database and will only be accessed by the principal investigator and study staff. You will be given a study ID number that will go on your online questionnaires and interview forms. The information linking your identity to your study ID will be kept in a password protected document that only the study staff have access to. Within 7 years after the study is complete, the audio recordings will be erased and destroyed and any information that could link you to the study will be removed from this database and destroyed. Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Brintz and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Study Results:

Study results will not formally be shared with you.

Authorization to Use/Disclose 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 (including both Vanderbilt University Medical Center and others) 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. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your deidentified information with others outside of Vanderbilt University Medical Center. 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

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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.

If you decide not to take part in this research study, it will not affect your treatment, payment, or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Contact Information

If you should have any questions about this research study or possible injury, please feel free to contact Dr. Carrie Brintz at (615) 875-2643 or a member of the study staff at (615) 421-8336

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY:

I have read this informed consent form. All of my questions have been answered and I freely and voluntarily choose to participate.

◯ Yes
◯ No

Signature of person agreeing to be in this study:

_____

Date and Time:

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