Telehealth Mindfulness After Spine Surgery

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Consent

VUMC Institutional Review Board

Informed Consent Document for Research

Study Title:

Postoperative Behavioral Interventions for Lumbar Spine Surgery Recovery: Pilot Randomized Controlled Trial

Version Date:

08/11/2023

PI:

Carrie E. Brintz, PhD

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. Your questions will be answered. Also, you will be given a copy of this consent form. If you have any questions, you may contact the study coordinator, Amanda Priest (phone: (615) 200-8524, email: amanda.priest@vumc.org) or the Principal Investigator, Dr. Carrie Brintz (phone: 615-875-9885, email: carrie.brintz@vumc.org).

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to take part in this research study because you will have back surgery for a lumbar degenerative condition. There is evidence that how people manage stressful feelings and thoughts about pain and activity may affect recovery after back surgery. The purpose of this study is to learn if patients will benefit from education and skills to self-manage pain, stressful feelings, and activity while they recover from back surgery. If you decide to take part in this study, you will be involved for 6 months after your back surgery. Before you begin the study, you will be asked to sign this consent form. You will also take part in standard medical care.

If you choose to participate, a study coordinator will ask you questions to determine if you are eligible for the study. If you are eligible, you will then complete a set of online questionnaires before you have surgery and again at about 2 weeks after your surgery. The online questionnaires will ask you about your pain, physical function, mood, stress, and pain medications. About 2 weeks after you have back surgery, you will be randomly assigned by chance to receive one of two behavioral treatments. Both treatments will involve weekly online sessions with a study coach for 8 weeks after you have surgery. You will also take part in standard medical care. You will then be asked to complete a set of online questionnaires about 3 months after surgery, and about 6 months after surgery. If able to return to clinic, you will also be asked to complete a sensory pain task before surgery, about 2 weeks after surgery, about 3 months after surgery, and about 6 months after surgery.

The benefits to science and humankind that result from this study are that medical professionals will be able to better understand and treat patients after back surgery. The benefits you might get from being in this study are to learn more about your recovery after surgery. Also, taking part in this study may help you learn useful skills for self-managing pain, stress or other symptoms after surgery, although this cannot be guaranteed.

You will be paid for your time as part of this study. You can receive up to $260 for participating in the study. You will receive $50 for your participation in the sessions where the pain testing procedures are completed (up to 4 sessions for $200 total). If you are unable to return to the clinic for these pain testing procedures, we may be able to come to your home. If we do the pain testing in your home, you will only be compensated $30 for the session. You will also receive a $15 check for completing the questionnaires at the preoperative time, 2 weeks after surgery, 3 months after surgery, and 6 months after surgery (up to 4 surveys for $60). We may ask for your Social Security number before you are compensated for taking part in this study.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you will have back surgery for a lumbar degenerative condition. The purpose of this study is to learn if patients will benefit from education and skills to self-manage pain, stressful thoughts and feelings, and activity while they recover from back surgery.

We would like to enroll 72 participants in this study.

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. Information that you provide for this research study will be kept separate from your Vanderbilt electronic health record.

Side effects and risks that you can expect if you take part in this study:

You may find completing questionnaires regarding your pain and psychological state to be mildly distressing, tiring, or boring.

You may experience mild distress from talking to the treatment coach about pain or stress and from learning skills in which you may notice your thoughts, feelings and body sensations in ways that are new to you. You are never required to participate in any skill that makes you uncomfortable.

You will likely experience some discomfort from the sensory pain testing procedures that are conducted during the study. The discomfort is expected to be mild-to-moderate and short-lived, and you will have total control over the duration of each pain stimuli. Previous research indicates that these tasks are safe and are not expected to produce any lasting pain or damage to you.

There is the risk that information about you may become known to others outside this study. The study staff will try to keep this from happening by using a code instead of your name on your information.

Risks that are not known:

It is possible that there may be physical and mental risks that we do not know about at this time. Tell your study coach or the study staff right away if you have any new physical or mental health problems.

Good effects that might result from this study:

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

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 for self-managing pain, stress or other symptoms after surgery, although this cannot be guaranteed.

Procedures to be followed and approximate duration of the study:

If you decide to take part in this study, then the time you are in the study will last for 6 months after your surgery. Before you begin the study, you will be asked to sign this consent form.

Eligibility screening

A brief interview lasting around 5-10 minutes with a study staff member to confirm if you are eligible to participate. Some of the questions may be sensitive, as they ask about mental health and substance use.

Preoperative Assessment Period

Before surgery, the following research related procedures are performed:

You will be asked to complete an online questionnaire asking about your pain levels, pain medications, mood, stress and physical function (approximately 15-20 minutes to complete).

We will also examine your medical record to learn some specific details about your surgery, medical history, and your medication list.

If you are already at the clinic or able to return to the clinic, you will be asked to complete two sensory pain tasks administered by a study staff member taking approximately 30 minutes. If you are unable to return to the clinic, we may be able to complete these tasks in your home. The sensory pain task is designed to measure your natural pain responses. The pain task involves brief, mild-to-moderate pain and you will control the duration of the task and end the procedures whenever you wish.

In the first pain task, you will be asked to squeeze a hand-grip exerciser every second for 2 minutes while wearing an uninflated blood pressure cuff. The blood pressure cuff will then be inflated, you will indicate when you feel pain, and the test will stop when you can no longer tolerate the pain. Another test will require a staff member to apply 3 different plastic pencil like objects, with 3 different grams of force to the finger. This will be done repetitively and you will indicate your pain levels during the task. It is important that you know that even though each procedure may produce some level of pain, you will be able to end the procedure at any time with no consequences. The pain they produce is brief and none of these procedures are expected to produce any lasting pain or damage.

Baseline Assessment Period

About two weeks after back surgery, the following research related procedures are performed:

You will be asked to complete an online questionnaire asking about your pain levels, pain medications, mood, stress and physical function (approximately 15-20 minutes).

We will also examine your medical record to learn some specific details about your surgery, medical history, and your medication list.

If you are able to return to the clinic, you will complete the same two sensory pain tasks that you completed prior to surgery taking approximately 30 minutes. If you are unable to return to the clinic, we may be able to complete these tasks in your home.

Randomization

There are two treatment groups in this study. You will be assigned to one of these two groups by chance, like flipping a coin. The treatment will start around 2 to 3 weeks after surgery. Participants in both groups will receive 8, weekly telehealth sessions from a study coach.

Treatment Period

You will meet one-on-one with the treatment coach once per week for 8 weeks using a device that has internet connection, a microphone, and a video camera. You can do the sessions from home or another location. If you do not have an electronic device that has both a microphone and a video camera, you will be given a tablet for use during the study. If you are given a tablet, you will receive packaging in which to return the tablet by shipping after you complete the treatment sessions, at no cost to you. You can also return it in person if you return to the clinic for a study visit. The weekly treatment sessions with the study coach will be audio recorded for purposes of assuring the quality of the interventionist's session delivery and data collection. The sessions will not be video recorded.

You will be asked to complete a short online questionnaire about 3 weeks after starting the treatment and again at the end of the treatment to evaluate your experience during the treatment sessions (approximately 3 minutes to complete).

Each of the two treatments will involve learning different types of education and behavioral skills for self-managing post-surgical pain, stressful thoughts and feelings, and activity with the goal of improving your back surgery recovery. Depending on which treatment you are assigned to, you may be assigned home practices to try to complete on most days of the week between sessions. You will be asked to report how much home practice you complete in a weekly online survey taking approximately 5 minutes to complete.

3-months Postsurgical Assessment Period

About 3 months after back surgery, the following research related procedures are performed:

You will be asked to complete an online questionnaire asking about your pain, medications, mood, stress, physical function and treatment satisfaction (approximately 15-20 minutes).

We will also examine your medical record to learn some specific details about your surgery, medical history, and your medication list.

If you are able to return to the clinic, you will complete the same two sensory pain tasks taking approximately 30 minutes. If you are unable to return to the clinic, we may be able to complete these tasks in your home.

6-months Postsurgical Assessment

About 6 months after back surgery, the following research related procedures are performed:

You will be asked to complete an online questionnaire asking about your pain levels, pain medications, mood, stress and physical function (approximately 15-20 minutes). Once this assessment is completed, your participation in the study will end.

We will also examine your medical record to learn some specific details about your surgery, medical history, and your medication list.

If you are able to return to the clinic, you will complete the same two sensory pain tasks taking approximately 30 minutes. If you are unable to return to the clinic, we may be able to complete these tasks in your home.

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

You can receive up to $260 for participating in the study. You will receive $50 for your participation in the sessions where the pain testing procedures are completed (up to 4 sessions for $200 total). If you are unable to return to the clinic for these pain testing procedures, we may be able to come to your home and complete the pain tasks. If we do the pain testing in your home, you will only be compensated $30 for the session. You will also receive a $15 check for completing the questionnaires at the preoperative time, 2 weeks after surgery, 3 months after surgery, and 6 months after surgery (up to 4 surveys for $60 total).

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs 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 or sponsor 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 the Principal Investigator Carrie Brintz at 615-875-9885 or a member of the study staff 615-421-8336. In the case of a medical or psychiatric emergency, please call 911 or go to your nearest emergency room.

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

Reasons why you may be taken out of this study:

You may be withdrawn from the study if your medical or psychiatric condition changes so that staying in this study may risk your health or disqualify you from 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, your [illegible]

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

Taking part in this study is completely voluntary. You are free to choose not to take part in the study or to stop taking part at any time without any penalty or loss of benefits to which you otherwise would be entitled. You do not need to give a reason. If you decide to stop being part of the study, you should tell the Principal Investigator, Dr. Carrie Brintz or a member of the study staff. Deciding to not be 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:

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.

All information you provide to us will be stored in a password-protected database. You will be given a study ID number that will go on your online questionnaires, audio recordings and interview forms. The information linking your identity to your study ID will be kept in a password protected document. 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.

Privacy:

Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name. This information may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:

Study results will not formally be shared with you. You may contact the Principal Investigator Carrie Brintz to learn where study results have been reported or published after the study has ended.

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 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 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 or a study staff member 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.

You have the right to see and copy the private health information we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

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.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

	Consent Form Signatures	
1)	Signature of patient/volunteer: Please sign electronically if you agree to participate in this study.	_____
2)	Date:	_____
3)	Participant Name:	_____
4)	Consent obtained by:	_____
5)	Consented by:	_____
6)	Date and TIme:	_____