Preventing Chronic Post-Surgical Pain and Prolonged Opioid Use: The Perioperative Pain Self-Management Program

NCT04979429

December 21, 2023

Participant Name: _____ Date:_____

Title of Study: Preventing Chronic Postsurgical Pain and Prolonged Opioid Use: The Perioperative Pain Self-management (PePS) Program

Principal Investigator: Diana Burgess (Site PI); Katie Hadlandsmyth and Hilary Mosher (MPIs)

VA Facility: Minneapolis VA

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA's Health Services Research and Development (HSR&D)Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study is about the effects of pre- and post-surgical telephone support calls on outcomes after orthopedic surgeries. These telephone calls make up the PePS (Perioperative Pain Self-management) Program. This study is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn whether the PePS program helps Veterans. I

If you agree to take part in this study, your involvement will last for 6 months following surgery. Participation includes completing questionnaires prior to surgery, three months and six months following surgery. The questionnaires should take about 35 minutes each to complete. You will also be asked to complete one brief (5 minute) phone call per week following surgery to provide information on post-operative medication use, for the first six weeks following surgery. In addition, you may be randomly assigned to receive the PePS program: including one telephone call prior to surgery and three following surgery. Each call will last approximately 30 minutes. If you are assigned to PePS you may also be invited to complete an optional interview (about 30 minutes) to give your opinion on the PePS program.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

1. To help future Veterans who are having orthopedic surgeries.
2. If assigned to the PePS program, you may find this helpful in recovering from your surgery.

For a complete description of benefits, refer to the Detailed Information section of this form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

1. You are not interested in participating.

For a complete description of risks, refer to the Detailed Consent.

FOR IRB USE ONLY

Minneapolis VA Health Care System IRB (Institutional Review Board)
Effective Date: December 21, 2023

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DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Diana Burgess, PhD at the Minneapolis VA and Katie Hadlandsmyth, PhD at the Iowa City VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, the study coordinator, Gloria Yang's contact information is: 612-629-7096.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a Veteran receiving treatment through the Minneapolis VA Health Care System who is having surgery for your knee, hip, or shoulder.

The purpose of this study is to evaluate the effects of the Perioperative Pain Self-management (PePS) program, which involves four phone calls to provide support in surgery recovery.

HOW LONG WILL I BE IN THE STUDY?

If you agree to take part in this study, your involvement will last for 6 months following surgery. Participation includes completing questionnaires prior to surgery, three months and six months following surgery. The questionnaires should take about 35 minutes each to complete. You will also be asked to complete one brief (5 minute) phone call per week following surgery to provide information on post-operative medication use, for the first six weeks following surgery. In addition, you may be randomly assigned to receive the PePS program: including one telephone call prior to surgery and three following surgery. Each call will last approximately 30 minutes. If you are assigned to PePS you may also be invited to complete an optional interview (about 30 minutes) to give your opinion on the PePS program.

The entire research study is expected to take approximately 4 years in total.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Questionnaire completion

You will be asked to complete questionnaires about your daily functioning, pain, mood, and quality of life. This will take about 35 minutes. You may skip any question you prefer not to answer. You will be asked to complete the same questionnaires again 3 and 6 months following surgery. If you are randomized to receive the PePS program telephone sessions, you may be invited to participate in a telephone interview (20-30 minutes minutes) asking for your feedback on the coping sessions. All questionnaires can be completed from home; either via a link sent over email or paper copies (per your preference). Data will be collected using University of Iowa Survey software and will not collect any directly identifiable information about you. You will also receive brief (5 minute) phone calls weekly for up to the first 6 weeks after surgery to collect information on what medications you are taking after surgery. A random number will allow us to link your data collected on this online system with your other study-related data stored on VA servers. If you choose to complete the questionnaires online, your random study identification number will be linked to the online questionnaires. All study identifiers are securely stored on VA servers only.

Perioperative Pain Self-Management (PePS) Program

You may be randomly assigned to receive standard treatment or standard treatment plus PePS (which includes 4 telephone calls). This means that whether you receive PePS will be determined purely by chance, like flipping a coin. If you receive PePS, you will be sent a packet of materials through the mail and receive one pre-operative phone session and three weekly postoperative phone sessions, beginning two weeks after surgery. The telephone sessions will include relaxation training, approaches to coping with surgical pain, goal-setting, and looking at how thoughts impact the experience of surgery and surgical pain.

Medical Record Review

The following details will be recorded from your medical record by a research study team member. Your unique medical record identifier, age, address and phone for contacting you, type of anesthesia on the day of surgery, and any postoperative complications. This data will be stored on VA servers.

Audio Recording

One aspect of this study involves making audio recordings of the PePS calls. These recordings are made so that the project leader can assure that the treatment being offered is correct and appropriate. These audio recordings will be made at the Minneapolis VA during treatment calls and only research team members will have access to these recordings and transcripts that are needed for quality control purposes.

Audio recordings are also made of the one-time interview which you may be offered to participate in following the PePS calls. These recordings are made so that we can assess the information you provide regarding your feedback on the treatment phone calls.

Recordings and transcripts will be stored on VA servers.

Safety

If at any point in the study researchers become concerned that you might kill yourself, we will utilize emergency services to ensure your safety.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you decide to participate you will be expected to complete surveys and questions about postoperative medication use as outlined above. You may also be expected to attend the 4 PePS telephone calls and an interview about the PePS sessions (detailed above).

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Questionnaires: You may feel uncomfortable answering questions related to your surgery, emotions, and behaviors. You may also experience some fatigue after answering many questions.

PePS Telephone Sessions: During the telephone sessions you may experience emotional discomfort when discussing issues such as problems with pain and function.

There is also a risk of loss of confidentiality of data.

In order to remedy the potential risks associated with questionnaire completion and the PePS telephone sessions, 1) you will be given the opportunity not to participate, 2) you may stop the study at any time, 3) you may ask questions of the investigator at any time, 4) you do not have to answer any questions that you do not want to answer or talk about any topics you choose not to discuss.

In order to remedy the potential risk of loss of confidentiality of data: Participants will be assigned a research number (or ID code). A master list of participants and their corresponding number will be maintained in the research office. This office will be locked and only accessible to the investigators. The list will be maintained on a computer server that requires an access code. Consent forms will be stored in a different file from the completed research instruments to protect the identity of the participants. Hardcopy data will be kept in a locked filing cabinet in the research office. Electronic data used for analysis purposes will be entered by code. The data will be encrypted and password protected.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

Previous research indicates that this type of telephone support can improve pain, functioning, and mood. Thus, we hope that participants in the study randomized into the telephone PePS sessions will receive some benefit.

We also hope that, in the future, other people might benefit from this study because of knowledge gained about this treatment for patients undergoing surgery.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participants will be assigned a research number (or ID code). A master list of participants and their corresponding number will be maintained in the research office. This office will be locked and only accessible to the investigators. The list will be maintained on a computer server that requires an access code. Consent forms will be stored in a different file from the completed research instruments to protect the identity of the participants. Hardcopy data will be kept in a locked filing cabinet in the research office. Electronic data used for analysis purposes will be entered by code. The data will be encrypted and password protected.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

Participants will be assigned a research number (or ID code). A master list of participants and their corresponding number will be maintained in the research office. This office will be locked and only accessible to the investigators. The list will be maintained on a computer server that requires an access code. Consent forms will be stored in a different file from the completed research instruments to protect the identity of the participants. Hardcopy data will be kept in a locked filing cabinet in the research office. Electronic data used for analysis purposes will be entered by code. The data will be encrypted and password protected.

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Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, telephone number, date of birth, information from your medical records such as medical history, and bank account routing information and SSN (for payment on completion of the study).

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Iowa City VA research site (the coordinating site of this multi-site study); the Data Safety and Monitoring Board;

Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Diana Burgess and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not have any costs for being in this research study.

You will be compensated up to $110 for participating in this study. All compensation will be sent on completing your participation in the study via direct deposit or VA debit card. If you withdraw from the study, your participation will be pro-rated as follows:

- Completion of preoperative assessments (once eligible to participate in study): $20
- Completion of 3-month post-operative assessment: $20
- Completion of 6-month post-operative assessment: $30
- Completion of weekly postoperative phone calls ($5 per call): up to $30
- Completion of the post-PePS qualitative interview if offered: $10

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with

study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because your condition has become worse or because in our judgment it would not be in your best interest for you to continue.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

For study-related questions please call Gloria Yang at 612-629-7096.

If you wish to verify the validity of the study and its authorized contacts, call the Patient Representative or contact the IRB office at (612) 629-7387.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Any new findings developed during the course of the research that may affect your willingness to continue participation will be provided to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A research team member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that

you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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