# The pain intervention via video optimization trial (PIVOT)

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University of North Carolina at Chapel Hill Verbal Consent to Participate in a Research Study Adult Participants

Consent Form Version Date: V.3 1/3/2024
IRB Study # 22-1551
Title of Study: The pain intervention via video optimization trial (PIVOT)

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Funding Source and/or Sponsor: Centers for Disease Control and Prevention (CDC)

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Summary: The purpose of this study is to compare two different ways of helping people recover from musculoskeletal pain. Study participants will be randomly placed into one of two groups. Participants in each group will receive the following care: Group 1 – receive usual care following their visit in the emergency room or urgent care, plus watch an educational video (~13 minutes in length) at home; Group 2 –receive the care usually given in the emergency room or urgent care. We will compare the two groups based on pain scores. The goal is to understand the effect of the video on recovery from pain. If you participate, your part in the study will last 3 months. We will conduct a baseline interview over the phone, lasting approximately 25 minutes, a few days after your acute care visit. We will then conduct two follow-up phone interviews about your pain and health, at 1 month and 3 months after your initial interview (each lasting about 20 minutes). This will give us information about whether the video helps patients manage pain over time. Minor risks from being in this study may include embarrassment or discomfort answering surveys about personal information as well as a risk of medication side effects or discomfort associated with recovering from your pain.

**What are some general things you should know about research studies?**

You are being asked to take part in a research study. Joining the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time. You will be sent a copy of this consent form.

**What is the purpose of this study?**
This research study was developed in response to the current opioid epidemic which is impacting millions of Americans and their families. The purpose of this study is to test an educational video for emergency department and urgent care patients with musculoskeletal pain, specifically addressing pain management and the risks of and risk factors for long-term opioid use. The primary goal of this study is to test the ability of the video to prevent long-term pain and opioid use through a randomized trial of emergency department and urgent care patients with musculoskeletal pain. This will be the first clinical trial of a patient-centered intervention designed for the primary prevention of long-term pain and opioid use.

You are being asked to be in the study because you are an adult 18 years or older and were seen in a UNC emergency room or OrthoNow clinic for musculoskeletal pain.

**Are there any reasons you should not be in this study?**
You should not be in this study if you are pregnant, a prisoner, unable to understand English, or do not have a phone.

**How many people will take part in this study?**
There will be approximately 250 people in this research study.

**How long will your part in this study last?**
Your participation in this study will last approximately 3 months.

**What will happen if you take part in the study?**
After you provide consent and HIPAA, you will be randomly assigned to one of two arms (intervention or usual care). If you are assigned to the intervention group, you will be provided with a link to an educational video (~13 minutes long) to watch at home, in addition to usual care. If you are assigned to the usual care arm, you will only receive guideline-based care, education, and advice on recovery promoting behaviors provided from your emergency or urgent care provider. After receiving the intervention or usual care, follow-up assessments will be conducted by a research assistant on the project who will be blinded to the treatment group to which you were assigned. The follow-up assessments will occur over the phone at 1 and 3 months. These follow-up calls will be scheduled using phone, e-mail, and/or text.

**During this phone call**

**Initial interview:**
After your consent, you will complete a 25-minute interview with a research assistant. This will involve answering questions about the pain you are experiencing and your health history.

**Group Assignment:**
After the initial interview, you will be assigned to one of two groups. You will receive your assignment randomly, like flipping a coin. One group of patients watches a 13-minute educational video. The second group will receive care as they normally would in the ER/OrthoNow.

**Follow-up Phone Calls:**
After the ER/OrthoNow visit, you will receive two telephone calls over the next three months. Someone from our study staff will call you to do these follow-up interviews. We will ask you questions about your pain and health. The phone calls will occur 1 and 3 months after the date of your ER/OrthoNow visit.

Each of these calls will take about 20 minutes. During these calls, you will talk about how you are feeling, your recovery, and any medications you are taking.

At any time during the study, you may choose to not answer a question for any reason. If you have questions at any point during the study, you may contact the study staff member listed on this consent form. You may also contact Dr. Michelle Meyer, who is the researcher responsible for patient safety in this study.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be that you learn new information about medical and non-medical pain management.

**What are the possible risks or discomforts involved from being in this study?**
Minor risks from being in this study may include embarrassment or discomfort answering surveys about personal information as well as a risk of medication side effects or pain associated with recovering from your pain.

**What if we learn about new findings or information during the study?**
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

If you are assigned to the control group (usual care) and wish to view the educational video, you may notify the research assistant. At the close of the study (completion of the last enrolled participant's final study interview), we will send you the video link via email upon your request.

**How will information about you be protected?**
Every effort will be made to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. The information we collect about you will be stored in REDCap, a research database at UNC that is password protected, and only the research team will have access to this information. You will also be assigned a code number to further protect your privacy.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as

quality control or safety.

The study team would like to message you by text messaging your phone or sending an e-mail, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following cell phone number/email to send communication: e-mail: _____ , cellphone #:_____

_____ No, I do not consent to receive un-protected communication from the study team.

**What is a Certificate of Confidentiality?**

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

**What will happen if you are injured by this research?**
There is minimal risk for injury by this research. However, all research involves a chance that something bad might happen to you. This may include the risk of personal injury. Despite all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions or because the entire study has been stopped.

**Will you receive anything for being in this study?**
You will be receiving digital gift cards for taking part in this study. You will receive $50 for initiating your participation in this study, and $25 for each follow-up phone interview you complete at 1 and 3 months. The digital gift cards will be sent to you after each visit. You would receive a total of $100 for completing all the visits.

**Will it cost you anything to be in this study?**
It will not cost you anything to be in this study.

**Who is sponsoring this study?**
This research is funded by the Centers for Disease Control and Prevention. This means that the research team is being paid by the sponsor for doing the study. The researchers do not have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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 website at any time.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you have questions about anything I just said?

**Participant's Agreement**:

Do you agree to take part in the study?

Yes

No

If Yes:

_____
Printed Name of Research Participant/Date

_____
Signature of Research Team Member Obtaining Consent/Date

_____
Printed Name of Research Team Member Obtaining Consent/Date