Informed Consent Document

Study Title: Strategies to Improve Pain and Enjoy Life (STRIPE)

NCT: NCT03743402

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Consent Form: ***The Strategies to Improve Pain and Enjoy Life (STRIPE) Study***

Researchers

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What is this study about?

The Strategies to Improve Pain and Enjoy Life (STRIPE) Study is a phone-based research study to see if weekly sessions of pain self-management skills training helps participants reduce chronic pain and improve quality of life. Additionally, we will offer participants support for trying to taper their opioid dose, if they choose to do that. Half of the study subjects will be offered the training and optional support for tapering, and half will not. At the end of the study we will compare both groups to see if the training helped. You will continue to receive usual care from your Kaiser Permanente medical providers regardless of which group you are randomized to. We are asking if you want to be a part of this research study.

What are you asking me to do?

We are asking you to do three things:

- **Complete three surveys**. We will ask you to complete one survey now, one 6 months from now and one 12 months from now. The survey asks questions about your physical health (including pain), mental health, and daily functioning. Some of the questions are on sensitive topics such as depression, anxiety, and substance use. By substances we mean medicines or other drugs that are illegal according to federal law, were used without a prescription, or were used in ways that are not indicated. This includes, marijuana, and opioids that are obtained by prescription or elsewhere. The first survey will take about 30 minutes to complete and the 6 and 12-month surveys will take about 20 minutes to complete. You can take the survey on the web or on the telephone. You can skip any questions you don't want to answer.

- **Let us collect some information from your Kaiser Foundation Health Plan of Washington (KP Washington) medical record about health care provided to you from** 2016-2022. This helps us understand how your survey answers relate to your health care. We will also use a computer to collect information on the health services you use—including doctor visits, lab tests, medications, and trips to the hospital, your and disease history. The information we collect will include sensitive topics like mental health disorders, drug and alcohol use. We may look at the notes written by your doctor in your medical record if you are in the pain self-management skills training group (see below).

- **Let us randomly assign you into either the pain self-management skills training group or the usual care group.** You will be assigned by chance (like flipping a coin) into either the pain self-management skills training group or the usual care group.

    - If you are in the **usual care group**, you will not receive pain self-management training, but you will continue to receive your usual care to manage your pain, your pain related medications and your overall care from your KP Washington primary care provider.
    - If you are in the **pain self-management skills training group** you will meet with the study research interventionist on the telephone 18 times over a year to receive pain self-management skills training. The research interventionist is a licensed medical provider (like a physician's assistant or a nurse) who is trained to teach people these skills. In addition, Dr. Sullivan at the University of Washington, will be consulting with and providing oversight of the research interventionist. Each session will last 30-60 minutes. See the last page for a description of the session, duration and frequency. Trainings will include topics such as: relaxation techniques, improving sleep, coping strategies and dealing with pain flare ups.
        - If you agree, we will record your telephone session for the research interventionist's quality assurance purposes only. You can still participate even if you don't agree to having your session audio recorded.
        - If you would like to try to taper your opioid dosage, the research interventionist will contact your KP primary care team who are responsible for your medical care. The research interventionist will notify your provider to inform them that you wish to taper your opioid(s). The research interventionist will recommend a plan for slowly tapering your opioid dose to your KP Washington primary care team. The research interventionist may also recommend your primary care team make other medication changes to support you in the taper. These changes may include adjusting dosage of other current medications and/or adding medications to alleviate symptoms experienced during the taper.
        - If you decide to try to taper your opioid dosage, we will coordinate these medication changes with your primary care provider. However, we strongly recommend you make monthly appointments with your primary care provider during the optional taper. As a reminder, if you choose to try the optional taper, any non-used opioids should be disposed of properly.
        - You can still participate in the study even if you decide not to taper your opioid medication dosage.

Opioid therapy management is complex and we will need to withdraw you from the study if you receive buprenorphine (Suboxone) treatment for opioid use disorder or become pregnant while enrolled in the study. If you are withdrawn from the study you will stop receiving pain self-management training, any optional tapering support, surveys, and we will not contact you for further participation.

- Anything you discuss with the research interventionist may become a permanent part of your medical record.
- We may do a follow-up research study in the future. If we do, we may contact you to ask you to participate but agreeing to be in this study does not mean that you have to agree to the follow-up study.

Will being in this study help me?

This study may help you personally if you are randomized to the intervention arm of the trial and receive training in pain self-management and support for an optional taper of opioid dose. However, we cannot guarantee that you will be helped. If you are randomized to the usual care arm of the trial, the study may not help you personally, but results of this study may improve care in the future for all patients.

Are there any costs associated with being in this study?

If you decide to taper your opioid medication, the recommended (not required) office visits with your doctor and medication costs including standard office visit co-pays, co-insurance, and deductibles that are part of your medical insurance coverage will be your responsibility.

Will I be paid?

You will receive $20 when you complete the first survey, $40 when you complete the 6-month survey. and $50 when you complete the 12-month survey.

Can anything bad happen to me from being in this study?

<u>If you are in the pain self-management skills training group</u>

- If you are in the pain self-management skills training group and decide to try tapering your opioid dosage, there are potential risks associated with tapering.
    - Your pain may increase with opioid taper. If pain increases, it tends to be a small increase. We can recommend medications to your primary care provider to possibly lessen the pain, however, your primary care provider is responsible for your medical care and they may prescribe what they determine is most appropriate.
    - You may experience mood changes or a worsening of depression and/or anxiety.
    - It is rare with gradual tapering but possible that you may experience opioid withdrawal. Symptoms of withdrawal include, but are not limited to: nausea, anxiety, insomnia, pain and indigestion. The opioid taper is designed to be gradual enough to prevent most opioid withdrawal symptoms, but it is possible that you will experience some withdrawal. We can recommend medications to alleviate the symptoms of withdrawal to your provider for symptoms as needed. These medications and other medications you may be

prescribed by your primary care provider may have risks, including allergic reaction.

Your primary care provider will be informed of your decision about being in the study. If you are randomized to the intervention arm of pain-self management training and decide to try to taper your opioid dose, the research interventionist will communicate that decision with your primary care provider using Epic Telephone Encounters. This information/communication is recorded in your medical record. Any information related to your participation in this study may be communicated to your provider and recorded in your medical record. This type of information includes, but is not limited to: the study name, the names of the researchers, study contact phone numbers, expected start and end dates for your time in the study, any symptoms related to pain, opioids or opioid tapering, progress of taper, and medication dosing recommendations.

- If for any reason during the taper, pain becomes challenging and you make the decision to reverse the taper, be aware that you are at higher risk for overdosing. During the taper, you may lose some tolerance to opioids. Abruptly increasing your dose puts you at risk for overdosing. For this reason, we remind you to dispose of any non-used opioids properly.

- Being in this study does not guarantee improvement – you may not feel better at the end, regardless of whether you receive pain self-management skills training.

  We will ask you if we can record your telephone visits with the research interventionist. These recordings will be shared with study investigators at the University of Washington. The purpose of these recordings is to provide the research interventionist with feedback on her performance. The audio recordings, like your other study information, will be stored in accordance to the confidentiality measures described below (see "How will you protect my confidentiality?"). The audio recordings might contain identifiable information. All audio recordings will be destroyed on or before December 31, 2026.
- Part of the training involves learning and practicing progressive muscle relaxation, a widely used and effective strategy in reducing pain. Although this skill, when performed properly, does not cause bodily injury or damage, some patients find that it temporarily increases pain. The research interventionist will work with you to reduce the chance it will increase your pain, and if it does, on ways to modify it so that it does not increase your pain again. Your practice of this skill is optional.
- Research staff have the right to stop your participation in the study at any time if your actions cause them to do so. Reasons for stopping you from being in the study include inappropriate conduct towards staff, receipt of buprenorphine to treat opioid use disorder, pregnancy, or if you develop another condition that would make your continued participation unsafe.

<u>If you are in either study group (usual care or pain-self management skills training)</u>

- We offer an option for unencrypted email to be used for study-related logistics. When using unencrypted email, we cannot guarantee the security of the email. If you choose email for communications related to study-logistics, we will use e-mail to remind you when study activities are due and send you a link for completing

surveys online. We cannot use the study email for any discussion of health issues. We will never ask you to provide health information using unencrypted email and we ask you not to send private and/or confidential information in this way. Your email address will not be shared with anyone outside of the study and will only be used for study-related purposes. You may choose to decline the use of email entirely, in which case you will be offered to conduct these activities by phone.

- You might feel uncomfortable answering some study questions. Some questions might seem too personal, embarrassing, upset you or cause other emotional distress You may skip any questions you don't want to answer.

- It's possible that someone other than the researchers could find out you were in the study or see your private information. We have many protections in place to safeguard your identity and health information.

How will you protect my confidentiality?
This study is being done by researchers at KP Washington and the University of Washington. All KP Washington and University of Washington researchers sign a confidentiality pledge that requires them to keep your information private.

We will take the following steps to keep your information confidential and to protect your identity:

- We will use a code number on all study forms and audio recordings instead of your name.
- We will store your personal information in a secure, locked location at a KP Washington facility where only a limited number of authorized individuals will have access to it.
- Audio files will be transferred to the University of Washington for quality assurance testing using KP Washington's Secure File Transfer Site. At the University of Washington, these files will be stored on a password protected computer that meets all University of Washington Medicine and University of Washington regulations and policies. Additionally, the UW has security controls in place to prevent unauthorized access.
- When we present information from this study or publish it in a medical journal, we will not include your name or any other information that could identify you.

We plan to keep your study information as described in this form until December 31, 2026. At that time, we will destroy any study records that include your name or other information that points to you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

We do not plan to contact you by e-mail unless you give us your email address and to take your surveys on the web. Information shared by e-mail is not considered secure. We cannot guarantee the privacy of e-mail, and we will be careful to limit the amount of personal information included in messages we send you.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

Research data in my medical record

If you are in the pain self-management group, we will communicate with your provider using Telephone Encounters. When we communicate with your provider using Telephone Encounters it becomes a part of your medical record and it is no longer protected by research regulations. Anything that you share with the study including, but not limited to: suicidal ideation, opioid misuse, and illegal behavior may be shared with your provider and recorded in your medical record. Once study information is recorded in your medical record, it cannot be removed.

How does HIPAA apply to this study?

Your health information is protected by a federal privacy law called HIPAA. KP Washington must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By agreeing to participate in this research, you are giving KP Washington permission to allow the researchers to collect, use, and share the following information with Investigators at the University of Washington:

1. Your survey answers.
2. Your medical record information as described above (See “What are you asking me to do?”)
3. Information about your pain self-management visits (if you are assigned to that group)
4. Audio recording of your pain self-management visits (if you are assigned to that group and you agree to be audio recorded)
5. Your Epic medical chart

It is possible that staff from KP Washington and the funding agency may look at our study records for oversight. We will not share the information we collect for this study with anyone else except as allowed by law.

The HIPAA privacy law does not always apply to those who are given protected health information. Once KP Washington has given out health information, the person who receives it may re-disclose it. Privacy laws may no longer protect the information.

In order to be in the study, you must agree to this use of your health information. This permission for the researchers to obtain your health information ends on December 31, 2026.

Do I have to be in this study?

No, being in this study is up to you. You are free to say no now or to leave the study at any time later. Either way, there will be no penalty. If you decide not to have your phone survey or telephone visits audio recorded you can still participate. If you decide not to receive unencrypted emails you can still participate. Your decision won't affect the health care you receive or benefits that you are entitled to.

What happens if I say yes, but change my mind later?

You may change your mind any time about letting us use your information for this study. If you change your mind, you may take back your consent by writing to:

Denise Boudreau, PhD
Senior Scientific Investigator
Kaiser Permanente Washington Health Research Institute
1730 Minor Ave, Suite 1600
Seattle, WA 98101

If you take back your consent, it will not affect your health care or benefits at KP Washington. We may still use the study information we collected before we received the

letter taking back your consent. But we will destroy any record of your name or other information that could identify you.

Who do I call if I have questions?

- If you have questions or concerns about the study, please call the project manager, Matthew Seymour, at **206-287-2159**
- If you have questions about your rights as a research participant, please call the KP Washington Human Subjects Review Office at 206-287-2919.

Description of Pain Self-Management Telephone Sessions

Session number	Week	Session content	Time
1	1	Overview of intervention and session	60 minutes
2	2	Relaxation techniques	30 minutes
3	3	Pain management education.	30 minutes
4	4	Motivational interviewing, withdrawal education, video and introduction of the idea of an opioid dosage taper	45 minutes
5	5	Sleep education	30 minutes
6	6	Review of coping skills covered in sessions 2-4	30 minutes
7	8	Activity pacing education	30 minutes
8	10	Coping with pain flare-ups	30 minutes
9	12	4-muscle group tense-release progressive muscle relaxation instruction	30 minutes
10	14	4-muscle group progressive muscle relaxation without tensing instruction	30 minutes
11	18	Coping self-statements instruction	30 minutes
12	22	Distraction coping skill instruction	
13	26	Body scan technique instruction	30 minutes
14	30	Mini-relaxations instruction	
15	34	Mini-relaxation application to daily life	30 minutes
16	38	Pleasurable activity instruction and review of coping skills learned in this program	30 minutes
17	42	Review of pain coping skills learned in this program	30 minutes
18	46	Skills summary and final plan for maintaining gains	30 minutes