STUDY TITLE: **Pain Self-Management Intervention to Reduce Pain & Improve MOUD Engagement in Primary Care: A Randomized Trial**

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RESEARCH CONSENT SUMMARY (KEY INFORMATION)

This study seeks to improve chronic pain in individuals who use opioids for treatment.

The research study is testing an intervention called Pain Self-Management (PSM). PSM is an educational program in which individuals with chronic pain work with a trained pain coach to explore strategies to effectively manage the daily problems that arise from chronic pain.

The intervention will take place over a period of 12 weeks (3 months). Participants randomized to the PSM group can earn up to $75 for completing the program. Participants in the usual care group will be paired with someone in the PSM group and will receive the same payment amount.

All participants will complete surveys every 3 months for a period of 9 months (total of 4 survey visits). Participants will receive compensation for each survey visit completed up to a $360 over 9 months.

There are risks associated with participating in the study, including breach of confidentiality and psychological distress caused by discussing difficult topics.

INTRODUCTION

Chronic pain is pain that lasts more than three months. It's a big problem for people who take prescription or non-prescription opioids or have opioid use disorder (OUD). This issue is often ignored in regular doctor visits. It's even harder for people in underserved communities, like Black and rural patients, who face more stigma and are less likely to see pain specialists. Fixing these issues is important for helping people use medications for OUD and improving their overall health.

Pain self-management (PSM) is a method that helps people manage their pain and improve their daily lives. But it hasn't been tested much in regular doctor settings or with people who use opioids. This study wants to see if PSM treatment can help these individuals manage their chronic pain better.

Who is being asked to take part in this study?

Up to 228 patients from participating clinics in Pennsylvania and West Virginia are being asked to take part in this study.

You are being asked to take part because you:

- Are at least 18 years old
- Experience chronic pain
- Use opioids for pain and/or have a diagnosis of opioid use disorder

What is the duration of participation in this study?

Your participation in this study may last up to 9 months.

RESEARCH ACTIVITIES

In this study, we are testing pain-self management (PSM). There will be two intervention arms. You will be assigned to one of these groups by chance, like drawing names out of a hat. Up to 114 patients will be included in each of the following groups:

1. Usual Care
2. Pain Self-Management

The intervention will take place between baseline (when you start the study) and your 3-month visit. All participants will complete 4 outcome assessment visits online or over the phone with a member of the study team. These will take place at baseline, Month 3 (the end of the intervention period), Month 6, and Month 9 (the end of your time with the study). *See Figure 1 below for visual representation of study flow.*

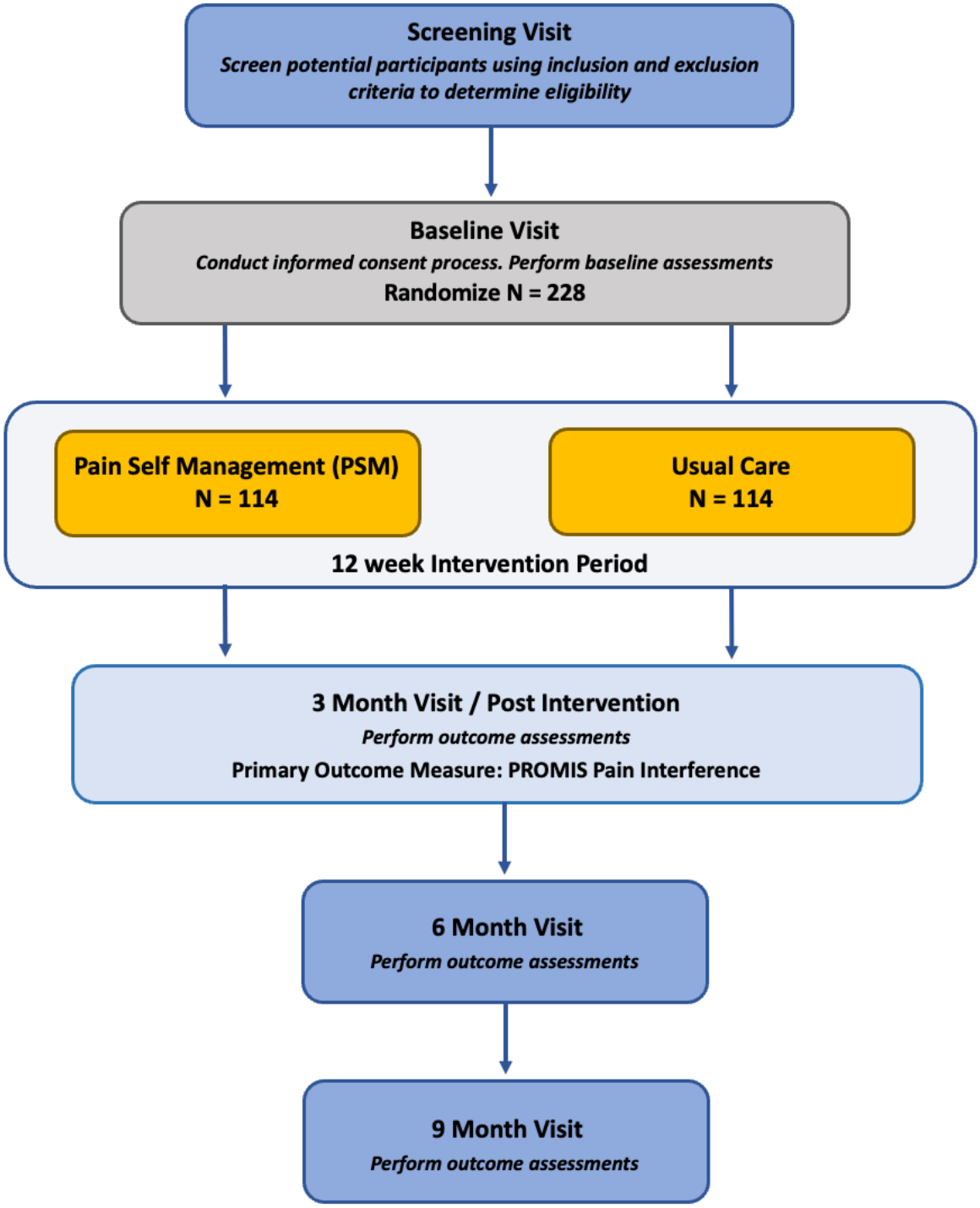
Usual Care

You will continue treatment as usual for chronic pain, which could include pain clinic visits, physical therapy, medication, seeing a counselor, psychiatrist, or psychologist.

Pain-Self Management (PSM)

This treatment will consist of 10 individual sessions delivered over a period of 12 weeks. Every 1-2 weeks, you will meet with a member of the study team for 60 minutes. After the first two sessions, you will be able to choose the order of topics for the 8 remaining sessions based off your level of interest.

Figure 1. Study Flow



STUDY RISKS

***Recording your personal information*:** There is a small chance of loss of confidentiality of your personal information. We take great care to minimize this chance by not recording your personal information (like your name) on study forms. All data collection will be handled by trained research staff. Your data will be linked to your record using an alphanumeric code to protect your privacy and reduce the risk of a breach of confidentiality. Access to protected health information (PHI) in the study database will be restricted. Study data will be collected and stored in a secure password protected database. In the event a paper form is used, it will be kept in a locked office or other secure space.

For this study, a unique identification number (Global Unique Identification, or GUID) will be created for you. This number will be used to connect (link) your research information from this study to other research studies that you may participate in that also use the GUID system. To receive this number, we will collect information about you: your first, middle, and last names at birth, your date of birth, name of the city/municipality where you were born, and gender at birth. Once the GUID is created, your personal information is deleted.

Text messages and emails may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study.

***Psychological distress*:** You may feel embarrassed answering some of the questions on the surveys, and although we encourage you to answer all of them, you may skip those which make you feel uncomfortable. In addition, our study team members will be trained in the recognition of signs of emotional distress and will be able to respond to you if a situation of emotional stress were to arise during the study activities.

STUDY BENEFITS

Participants may not receive any direct benefit from participating.

If you are assigned to the group with pain self-management (PSM), you may experience therapeutic benefits from the intervention, both in terms of reduced pain and improved pain-related function.

If you are assigned to the usual care group, we do not expect you to receive any direct benefit from study participation.

ALTERNATIVE TREATMENTS

If you decide not to participate in this study, you may continue to receive your regular clinical care according to the standard practices of your local clinic.

NEW INFORMATION

We will tell you about any new information that we learn that may cause you to change your mind about staying in the study.

CONFIDENTIALITY

People outside of our study team may need to access your information as a part of their typical job duties.

- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).
- Authorized representatives from the National Institutes of Health (the sponsor of this study), including, the HEAL Network and the IMPOWR Network.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

All research records will be maintained for at least 7 years following final reporting of this study in accordance with University of Pittsburgh and NIH policy. If data is shared with other investigators for use in future studies, it will always be done so in an aggregate, de-identified manner to protect you and your personal information.

There are circumstances when the investigators might have to release identifiable information due to state law or another circumstance. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

At some point during or after the study, your identifiers might be removed from the private

information. This de-identified information will be transferred to a secure database and may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent.

HIPAA (ACCESSING MEDICAL RECORDS)

As part of this research study, we are asking your permission to use your medical records to confirm your eligibility for the study and collect specific information. This permission does not expire. We will collect the following information: visit schedule, cancelled/missed appointments, prescription information, and data from urine drug screens. This medical record information, which includes your name, is available to members of the research team for an indefinite period.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the study sponsor, Federal regulatory agencies, the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study.

We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study including from your medical records once people outside UPMC or the University have viewed it.

You may also withdraw your permission to allow us to use and disclose health information from your medical records, but if you do, you will not be able to continue to participate in this study. To do so, you should provide the Principal Investigator, Erin L. Winstanley, with a written and dated notice of that decision. The research team will only use information collected from you or your records up to the date you withdraw.

FDA CLINICAL TRIAL REGISTRY [21 CFR 50.25]

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

COSTS

Neither you, nor your insurance provider will be charged for the cost of the procedures performed only for the purposes of this research study.

You and/or your insurer will be billed in the usual manner for your standard medical care (care you would receive even if you were not participating in this research study).

PAYMENTS

Outcome Assessment (Survey) Payments: You will be paid the following for each outcome assessment study visit that you complete: baseline ($50), post-intervention/3-month ($75), 6-month ($100), and 9-month ($125). There are 4 total visits, and you can receive $350 in total compensation for completing all study visits. You can also receive a bonus payment of $10 for completing the 3-month survey. That means you could earn up

to $360 altogether for completing the study.

Participant Compensation for Study Visits					
	Baseline	**3 Month Visit**	**6 Month Visit**	**9 Month Visit**	**Overall Total**
Base Compensation	$50	$75	$100	$125	**$350**
Bonus Compensation		$10			**$10**
Total Per Visit	**$50**	**$85**	**$100**	**$125**	**$360**

Intervention Payments: Each participant in the usual care group will be randomly paired with a participant in the PSM group. This pairing will happen continuously as new participants join the study. The process will be managed at each site, making sure participants from the same site are paired. We will use a computer program to do this random pairing.

- ***PSM Group Payments:*** If you are assigned to the PSM intervention group, you will earn $5 for each PSM session you complete. Additionally, you will receive a $15 bonus after completing the 6th session and a $10 bonus after the 10th session, totaling up to $75.
- ***Usual Care Group Payments:*** If you are assigned to the usual care group, you will be randomly paired with someone in the PSM group and will receive the same incentives. You will be paid on an ongoing basis as the participant to which you are paired completes the intervention sessions. You may receive no additional payment but up to $75 depending on the activities of the participant to which you are paired.

Participant Compensation for the Intervention Period											
Intervention Session	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Overall Total**
Base Compensation	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	**$50**
Bonus Compensation						$15				$10	**$25**
Total Per Visit	**$5**	**$5**	**$5**	**$5**	**$5**	**$20**	**$5**	**$5**	**$5**	**$15**	**$75**

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a “Form 1099 – Miscellaneous” with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for ‘backup withholding;’ thus you would only receive 76% of the expected payment.

COMPENSATION FOR INJURY

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

WITHDRAWAL FROM STUDY PARTICIPATION

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh or your current or future medical care at a UPMC hospital or affiliated health care provider.

Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor.

You can withdraw from this research study at any time. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team. Your decision to withdraw will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

CONSENT TO PARTICIPATE

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study and provide authorization to use and share my medical records. A copy of this consent form will be given to me.

_____ _____

Printed Name of Participant Date

_____

Signature of Participant

INVESTIGATOR CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions, concerns, or complaints as they arise. I further certify that no research component of this protocol was started until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date