

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

PRINCIPAL INVESTIGATOR: Erin L. Winstanley, PhD
Professor of Medicine
Division of General Internal Medicine
School of Medicine
University of Pittsburgh
Email: elw194@pitt.edu /// Phone: 412-624-1607

LOCAL PRINCIPAL INVESTIGATOR: Courtney Pilkerton, MD/PhD
Vice Chair of Research, Assistant Professor
WVU Family Medicine
Email: cpilkerton@hsc.wvu.edu
Phone: 304-285-7455

SOURCE OF SUPPORT: National Institute on Drug Abuse (NIDA)
Grant Number: RM1DA055311

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. 189 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.*

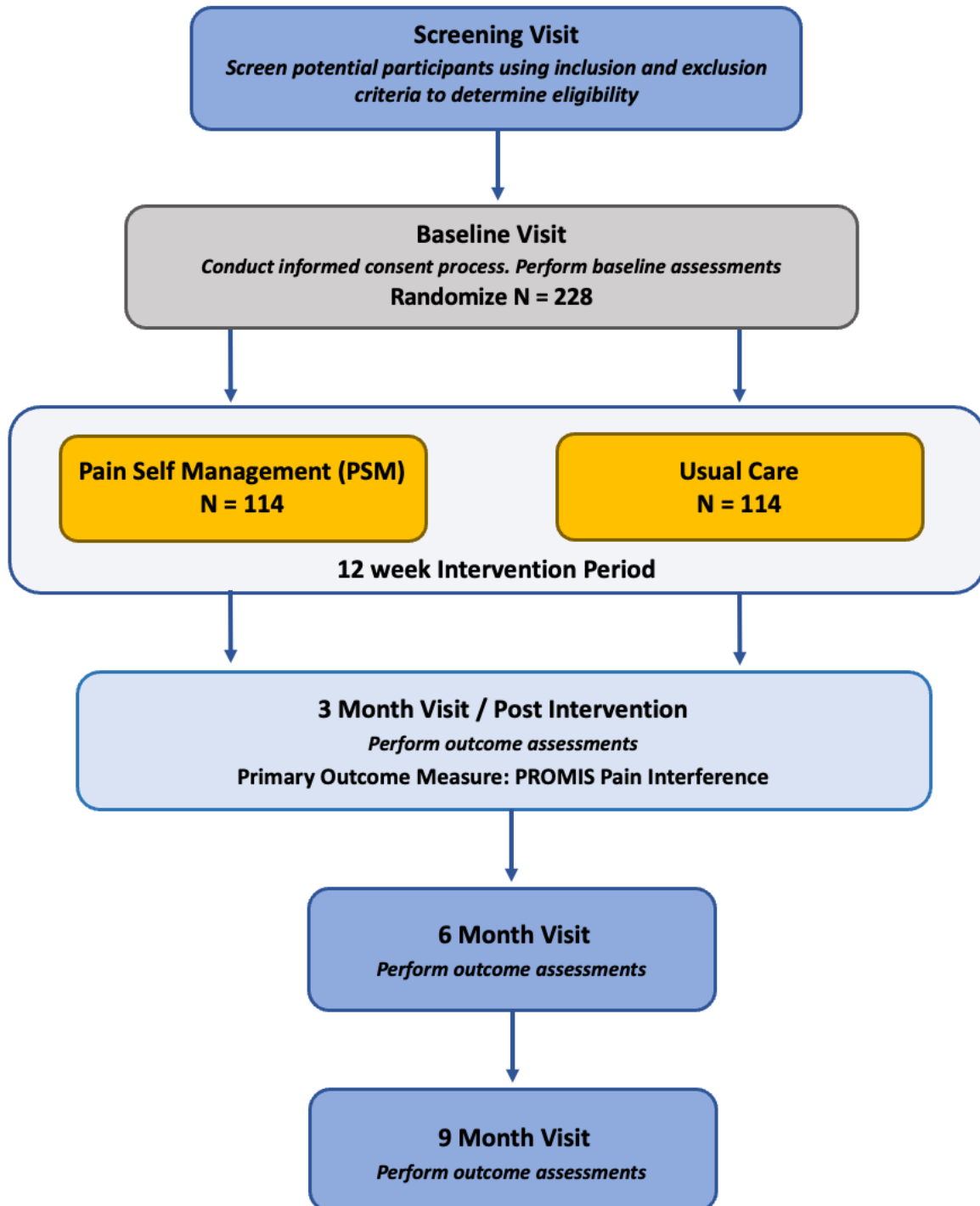
Usual Care

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 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 West Virginia 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.

Persons/Organizations Providing the Information:

- Participant – Data is from the participant

Persons/Organizations Receiving the Information:

- The research site(s) carrying out this study. UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS), and other affiliate sites, including the research and medical staff at the site(s).
- Health care providers who provide services to you as part of this research study.
- Laboratories and others that view your health information as part of this study in agreement with the study protocol.
- If applicable, required for FDA regulated research The U.S. Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA) and other groups that have the right to use the information as required by law.
- Authorized representatives of the University of Pittsburgh Office of Research Protections for the purpose of monitoring the conduct of this study.
- The members and staff of the Institutional Review Board that oversees this research study.
- The West Virginia University Office of Human Research Protections and the West Virginia University Office of Sponsored Programs.
- WVCTSI Clinical Trials Unit

The Following Information Will Be Used:

This information could include new or existing information about you, such as history and physicals, clinic visit notes, nursing and staff notes, laboratory results, demographic data, and study forms.

The Information is Being Disclosed for the Following Reasons:

Add applicable information and delete any information that does not apply.

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as; reviewing the safety or effectiveness of the study drug and other products or therapies, conducting performance reviews of the study drug, evaluating other products or therapies for patients, developing a

better understanding of the disease, or improving the design of future clinical trials.

You may cancel this HIPAA Authorization at any time by writing to the Principal Investigator.

All cancellations must be in writing to the Principal Investigator at the address listed on the first page of this form.

If you cancel this Authorization, any information that has been collected for the research study to date cannot be withdrawn. Once information is disclosed, according to this Authorization, the recipient may re-disclose it, and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the research study until the Sponsor has completed all work related to the study. At that time, you may ask to see the information related to your participation and request corrections to the information.

This Authorization will expire at the end of the research study unless you cancel it before that time.

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 West Virginia University have viewed it.

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

For information regarding the method of payment, contact the Principal Investigator.

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study is considered taxable income and must be reported to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are \$600 or more in a calendar year.

If you are a WVU employee or a WVU student-employee, you are required to report the total amount of compensation received for your participation in a research study to the WVU Tax Services Office upon receipt of payment.

Your data, health information, research results, specimens, genomic data, or any and other information related to this research or used in this research study may contribute to a discovery or treatment. In some instances, your data, your health information, your research results, your specimens, the discoveries or treatments, or any other information related to this research study (even if identifiers are removed) may be of commercial value. The information may be sold, patented, or licensed by the Principal Investigator and West Virginia University for use in other research or the development of new products. You will not retain any property rights, and you will not be eligible to share in any monetary or commercial profit that the Principal Investigators, West Virginia University, or their agents may realize.

COMPENSATION FOR INJURY

WVU does not maintain funding to pay for treatment if you are injured or become sick from participation in this research study.

If you are injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment from WVU to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the Principal Investigator, **Courtney Pilkerton, MD, PhD** at **304-285-7455** if you are injured or for further information.

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 West Virginia University or your current or future medical care at a West Virginia University 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 West Virginia University .

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