

Pain Reduction Through Empowered Recovery (PRIME) Study

NCT05619510

IRB000341962

Informed Consent Form

2/16/2023

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Women in Pain Reduction and Improved Mood through Empowerment (PRIME)

Application No.: IRB00341962

Funded By: Cornell University Translational Research Institute for Pain in Later Life Center (**National Institute on Aging**).

Principal Investigator: Janiece Taylor, PhD, RN, FAAN
525 N. Wolfe St., Room N401
Baltimore, MD 21205
Office: 443- 287-4503

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to test an intervention called Women in Pain Reduction and Improved Mood through Empowerment (PRIME) that includes setting goals and working with a nurse in your home to target pain and mood symptoms.

Each participant will be randomly assigned to one of two groups. The first group will receive the intervention right away. The second group will have information taken twice and wait for about 4-6 months before receiving the intervention.

This study is being done to test a 12-week behavioral intervention targeting pain and mood symptoms for older women with disabilities. The intervention will involve two data collection visits that last 1-2 hours. You will be asked to wear a small patch (like a Band-Aid) that will be used to collect sweat. The patch is to help us understand some of the hormones or chemicals in your body and if they are related to your pain and if the intervention may help. You will also have 4 one-two hour long visits with a nurse in person at your home or a location most convenient for you. We also will offer a virtual option if

necessary for these home visits. You will be asked to participate in strategies that may help pain and your mood. There will also be 8 virtual sessions with 2-5 other participants in the study that will be led by a clinical psychologist. The clinical psychologist will be leading Acceptance Commitment Therapy with the group at a time that is most convenient for those in the group.

You may want to participate in this study because it may help you find strategies to alleviate symptoms associated with your pain, depressive symptoms, and/or difficulties with mobility or walking. You will also be helping us learn more information to help others who have pain, depression, or difficulty with their mobility or walking.

You may not want to participate in this study because of the time commitment required, and/or because of potential risks associated with being in the study that include discomfort or fatigue from providing saliva samples, fatigue from completing activities targeting pain, and /or because you may experience distress from discussing symptoms of depression or your mood.

2. Why is this research being done?

The goal of this pilot project is to test the feasibility of a behavioral activation intervention called Women in Pain Reduction and Improved Mood through Empowerment (PRIME) that uses goal setting, non-pharmacological (non-drug) tailored strategies, and virtual group sessions to target pain and depression among community dwelling older African American women who are frail or pre frail.

This research is being done to:

1. learn if this study Women in PRIME is realistic and the way we use it is helpful to the women intended.
2. evaluate differences in pain, depressive symptoms, and physical disability after participating in this study.
3. evaluate if there are changes in specific biomarkers or hormones in your sweat after participating in Women in PRIME. In this study, we will use a skin patch called a “sweat patch”, which is like a band-aid that participants wear for 3 days. Through this sweat patch, we can collect information on how your body works without having to draw blood.

Who can join this study?

Women may join who:

- 1) Report pain that keeps you from doing at least one activity you would like to do that has lasted longer than 3 months
- 2) Report symptoms of low mood or depression
- 3) Identify as a women
- 4) Live in the community
- 5) Are 50 years of age and older
- 6) Have difficulty with at least one activity of daily living (dressing, bathing, hygiene, transferring or climbing stairs).

How many people will be in this study?

A total of 30 women.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

1. A total of 15 women will be randomly assigned to the first intervention group. If you are assigned to this group, you will be in the first group to receive the intervention. The other 15 women will receive

the study intervention later. This will be determined randomly, like flipping a coin, to decide which group you start in.

2. The virtual component involves logging onto a computer or electronic device to have a video visit or asked questions over the phone. In person visits will include research team members visiting your home and wearing personal protective equipment (gloves, gowns and masks).
3. Before and after the intervention you will be asked to fill out a questionnaire.
4. We will also ask you to place a small adhesive patch (like a band-aid) on your stomach area or arm before and after the intervention.
 - You will be asked to wear the patch for 24 hours.
 - The patch collects microscopic amounts of sweat. We'll use a machine to analyze the sweat and to test for stress and inflammatory biomarkers
 - We will ask that you do not take a bath (shower is okay) or go swimming for that 24 hours with the patch.
5. The nurse visits will consist of in person visits or virtual visits (on the phone or by video) or with a nurse to work with you on goals surrounding pain, depressive symptoms, and other physical symptoms. The sessions with the nurse should not last longer than 2 hours at a time.
6. You will have 4 in person or virtual visits with the nurse over 4-6 weeks.
7. You will have 8 virtual group sessions with a clinical psychologist and 2-5 other participants in the study.
8. You will have a final visit by a study team member. The study team member will collect information on your physical ability, and ask you to complete questionnaires.
9. We will ask you to wear a patch on your skin again.
10. You may be asked to have a follow-up interview (via in person, phone, or via video) at 24 weeks (about 5 ½ months) to see what you thought of the study intervention and whether it was helpful.

Audio Recording

As part of this study, we may audio-record some of your intervention sessions and you may be asked to participate in a follow-up interview.

- If you agree to allow the tape recordings and then change your mind, you may ask us to destroy that recording. If the recording has had all identifiers removed, we may not be able to do this.
- We will only use these recordings for the purposes of this research.
- The audio recordings from the follow-up interviews only will be transcribed by an outside company that has agreed to keep all data confidential.

Please indicate your decision below by checking the appropriate statement:

I **agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use audio recordings of me for the purpose of this study.

I **do not agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use audio recordings of me for the purpose of this study.

Participant Signature

Date

Will research test results be shared with you?

This study involves research tests that may produce information that could be useful for your clinical care. We will share this information with you after the study is completed unless it is an emergency. We may have information about your hormones from your saliva, or symptoms of your pain and/or mood that may be important to share with you.

Reporting Requirements

The research team will comply with Maryland law and will tell the local or state authorities if they suspect abuse or neglect of a child or dependent adult.

How long will you be in the study?

You will be in this study about 1-1.5 years.

4. What happens to data and biospecimens that are collected in the study?

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Examples of biospecimens include blood, tissue, saliva, urine, bone marrow, cells, etc. The specific types of biospecimens that will be collected in this study are described in Section 3 of this document. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way. One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify, you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required. Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens are required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

Sweat Patches

You could have a reaction to the stickiness of the patch, like the stickiness of a band-aid, which could cause a little bit of irritation.

Interviews or questionnaires

You may get tired or bored when we are asking you questions, or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information

There is the risk that people outside this study may learn information about you.

6. Are there benefits to being in the study?

You may or may not benefit from being in this study. If you take part in the study, your information may help develop treatment for others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. Other options include discussing pain and mood symptoms with your primary health care provider.

You can stop the visits and quit the study at any time. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

You will be paid \$25 at the end of the study for your participation and will receive an additional \$10 if you are chosen for a post interview after the study. This can be delivered to you via no physical contact or mailed to you via gift card.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed \$600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- Leaving this study early will not affect your employment/education.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You receive a terminal diagnosis.
- Have two or more hospitalizations while you are enrolled in the study.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be maintained and how will the confidentiality of your data be protected?**HIPAA Authorization for Disclosure of Protected Health Information****What information is being collected, used, or shared?**

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire.

Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?

The risk of loss of confidentiality will be minimized by identifying all participants by code numbers, securing all data collected in locked files in the PI's office, and screening information to locked file cabinets with limited staff access. Only one master log of subject names, addresses, telephone numbers, and study identification assignment will be maintained in a password protected computer program. Data collection will be on computer tablets that are password protected. Audio recording of nurse visits will be routinely conducted for fidelity and quality control review. These recordings will be identified by numbers only and stored in files on computers of the project coordinator and Dr. Taylor who will provide fidelity oversight of the interventionists. Access to these computer files will be password protected; recordings will not contain respondent name or other personal identifying information and will not be transcribed. Recordings will be used only for quality control and training purposes and then destroyed (deleted from computers) within one year of trial completion.

13. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

14. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

Approved February 16, 2023

Date: February 16, 2023

Principal Investigator: Janiece L. Taylor, PhD, RN, FAAN

Application No.: IRB00341962

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study?

Call the principal investigator, Dr. Janiece Taylor at 443-287-4503. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

15. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say “no” to this/these optional component(s).

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES

Signature of Participant

Date

No

Signature of Participant

Date

16. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant

(Print Name)

Date/Time

Signature of Person Obtaining Consent

(Print Name)

Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).