IRB ID: IRB00226182 **Depression and Pain Perseverance Through Empowered Recovery Intervention** NCT04091347

Informed Consent

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Pilot Study of Depression and Pain Perseverance through Empowered Recovery (DAPPER) Intervention

Application No.: IRB00226182

Funded By: Robert Wood Johnson Medical Faculty Program and Johns Hopkins Older Adults Independence Center **(National Institute on Aging** P30AG021334).

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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 DAPPER - Depression and Pain Perseverance through Empowerment that includes setting goals and working with a nurse in your home to target pain and mood symptoms.

This study is being done to test a 12-week behavioral intervention targeting pain and mood symptoms for older African American women. The intervention will involve two data collection visits that last 1-2 hours, and 8 two hour long visits with a nurse virtually (over a computer or the phone). There is also an in-person option, this intervention will involve two data collection visits that last 1-2 hours, and 8 two hour long visits with a nurse in your home. You will be asked to participate in strategies that may help pain and your mood, provide samples of your saliva (spit), and may be asked to have a follow-up interview. The kit to collect your saliva will be delivered to your home and picked up from your home through no person contact.

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 DAPPER (Depression and Pain Perseverance through Empowerment and Recovery) that uses communication and non-pharmacological (non-drug) tailored strategies 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 more about how to best adapt a previous study called "Get Busy Get Better/Beat the Blues," to DAPPER to help older and middle aged African American women improve symptoms of pain and depression.
2. learn if this study DAPPER is realistic and the way we use it is helpful to the women intended.
3. evaluate differences in pain, depressive symptoms, and physical ability (frailty) after participating in this study.
4. evaluate if there are in changes in specific biomarkers or hormones in your saliva after participating in DAPPER.

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 African American/Black and female
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 64 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. DAPPER: 32 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 32 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 study will be done either virtually or in person. You will have the option to choose virtual or in person if you live in Maryland and it will be virtual if in another location. The virtual option 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. We will give you a kit to collect saliva samples at your first visit or we will drop off to your home via no contact if you are participating in virtual visits. You will be asked to collect your saliva in a tube and store it in a freezer until someone picks it up. A study team member will contact you and pick up your samples within 48 hours without physical contact with you. This may occur a second time if you are in the group who receives the intervention later.

4. The nurse visits will consist of virtual visits (on the phone or by video) or in person visits 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.
5. You will have 8 virtual or in person visits with the nurse over 12 weeks.
6. You will have a final visit virtually or in person by a study team member. The study team member will collect information on your physical ability, heart rate, and ask you to complete questionnaires.
7. We will ask you to repeat the saliva samples again. A study team member will contact you and pick them up within 48 hours (no contact).
8. 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.
9. We will call via phone or zoom you after completion of the study to ask your up to date contact information and ask if you would like to receive a report of the study findings. During this call we will also ask you questions about your time in the study and after completing the study.

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, and the portion of the post study phone call.

- 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?

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Biospecimens for this study include saliva.

If you join this study, 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 these efforts.

What testing or procedures may be done with your biospecimens?
Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes looking at some of your hormone levels that may be related to your health conditions.

How will your data and/or biospecimens be shared now and in the future?
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:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

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

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data, we limit the uses of the information and whether these data can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include cell gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators.

Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study.

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

Heart Rate Monitoring

If you choose to participate in the in-person option, placing your finger on the monitor will be painless. You may fatigue or get bored sitting and having the monitor on for five minutes while we ask you to remain fairly still.

Saliva Sample

Placing saliva in a small tube may cause you to experience dryness of the mouth and/or fatigue from the process of placing saliva in the tube.

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 $20 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.

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).