Cover Page for ClinicalTrials.gov

Document:
Informed Consent Form

Official Study Title:
Empowering the Management of Pain-Obesity-Weight through Enhanced Reward

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NCT04851587

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UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Empowering the Management of Pain-Obesity-Weight through Enhanced Reward (EMPOWER)

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Emily J. Bartley, Ph.D., Assistant Professor, (352) 273-8934
Principal Investigator: Megan A. McVay, Ph.D., Assistant Professor, (352) 294-7029
Clinical Research Coordinator: Kasey Page, B.S. (352) 273-8798

4. Who is paying for this Research Study?

The sponsor of this study is the National Institute on Aging.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) **In general, what is the purpose of the research, how long will you be involved?** The purpose of this study is to test a program to help you better manage your pain and to lose weight. You are being asked to be in this research study because you are between the ages of 45 and 80 years old. You also have musculoskeletal pain and your BMI is greater than 25 kg/m^2. You will be in this study for approximately 8 months.

b) **What is involved with your participation, and what are the procedures to be followed in the research?** We will ask you about your recent health experiences and get a list of your current medications. Based on your responses, you may not be eligible to participate in the study. If you decide to participate, you will be assigned to a group program focused on pain management and weight loss. You will be asked to attend 8 core, in-person (or via UF PHI Zoom) sessions, held every other week. There will also be 8 additional in-person (or via UF PHI Zoom) intervention sessions that are optional. There will be 3 in-person assessment sessions, at baseline, 4 months, and 8 months. There will also be 8 sessions completed over the phone. You are free to withdraw from the study at any time.

c) **What are the likely risks or discomforts to you**? During the study, you will be asked to do a series of activity tests and questionnaires. The activity tests may make you feel discomfort. You can stop these tests at any time. You may be uncomfortable answering some of the questions on the surveys. You are free not to answer those questions.

d) **What are the likely benefits to you or to others from the research?** You may or may not benefit from taking part in this research study. The potential benefit is that you may lose weight and have improvement in your low back pain.

e) **What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?** You may choose to not participate.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Your normal clinical care will not be affected by your participation in this study.

7. What will be done only because you are in this Research Study?

You have already completed a brief telephone screening to see if you are eligible and interested in participation. You will also be asked to complete the following steps during study visits.

Procedures for Assessments at Baseline, Month 4, and Month 8 Visits:

- The Informed Consent will be reviewed with you at the Baseline visit to make certain that you understand everything that is involved in the study.
- A health assessment will be completed which includes you sharing information on your health and current medications. We will also measure your blood pressure and record your height and weight.
- You will be asked to complete several questionnaires about your physical and emotional health, pain symptoms, how you cope with pain and stress, mood (e.g., whether you feel down or nervous), and how you feel and think about things (including pain). Some of the questionnaires will ask how you are feeling right now or in the recent past, while others ask how you generally feel. You do not have to answer any questions that you do not want to.
- A physical performance test will be conducted which will involve you making brief movements including balance tests, sitting and standing from a chair, and a short walking test.
- A physician on this study will review your medical records to make sure you can engage in the exercise that is recommended in this study.
- You will also be asked to report on all the food and drinks you have had for 3 days around the time of these visits.

Procedures for In-Person (or Zoom) Intervention Visits:

- **Pain/Weight Management Intervention.** If you decide to take part in this study, you will be assigned to an 8-group session core intervention where you will learn ways to manage pain and lose weight. There will also be 8 optional intervention sessions, for a total of 16 possible group sessions. This program will build skills that center on increasing positive emotions, setting goals, stress management, healthy eating, and physical activities. Group sessions will happen every other week in a group of 6 to 8 people and someone with training in pain/weight management would lead the group. As part of the intervention, we will ask you to rate your pain, mood, and physical activities at home using an Apple Smartwatch. Due to COVID-19, in-person group visits may be delivered online via PHI Zoom video calls. All participants wanting to attend in-person intervention sessions will be required to provide proof of COVID-19 vaccination.
- We would like your permission to audio-record these intervention sessions. The purpose of these recordings will be to evaluate the study personnel and make certain that they are delivering the intervention appropriately. This review

process is a necessary part of the research study as it will ensure that you receive the same intervention that other study participants are receiving.

Procedures for Phone Visits:

- Phone visits will occur every other week and will last about 30 minutes.
- Phone visits will focus on setting new activity goals, evaluating past goal progress, and problem-solving challenges to meeting goals.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Your name, contact information, and tests related to your participation
- Medical history as self-reported
- Current medications
- Responses to questionnaires and home activities
- Your social security number for compensation purposes

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals, or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.

- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state, and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Your participation in this research study will be 4 to 8 months. This study will require 8 core, in-person or Zoom visits plus 8 optional in-person or Zoom visits, 2 or 3 (if applicable) assessment visits, and 8 telephone visits.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We expect a total of 60 participants to take part in this research study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

- The activity tests during in-person visits may produce discomfort and you can stop these procedures at any time.
- You may experience some distress from completing the questionnaires due to the sensitive nature of the items. You do not have to answer any questions if you do not wish to. We will take all necessary steps to minimize discomfort and you can omit any questions that you do not wish to answer. If your answers to any of the questions suggest that you are feeling down or nervous, we may recommend you seek treatment to help with your mood and give you information about where you can get this type of treatment.

Other possible risks to you may include:

It is generally unsafe for women who are pregnant to engage in weight loss efforts, and it is an exclusion criterion in our study. Participants will be withdrawn from the study if they become pregnant.

Another potential risk is from increasing physical activity, which you may choose to do as part of this study. This risk is no different than participating in other types of

walking programs. Muscle soreness and joint irritation are the most common risks associated with participation in physical activity.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

13a. What are the potential benefits to you for taking part in this Research Study?

You could potentially benefit by participating in this research study by getting an inside look at research and having the opportunity to participate in a new treatment for chronic pain and weight loss. Participants who complete the intervention may show

improvement in pain and weight management. This knowledge may improve quality of life, reduce weight-related health problems, and reduce pain in the target population.

13b. How could others possibly benefit from this Research Study?

Data obtained from the current study can advance treatment strategies for pain and weight management and may have larger implications for other medical populations with chronic pain and obesity.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

The other option to taking part in this study is not participating. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- You have had an unexpected negative reaction to the study, have failed to follow instructions, you are found not to meet eligibility criteria, or because the entire study has been stopped. In addition, if the investigator believes that continuing in the study could cause problems for you or for the study, you can be withdrawn.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No. It will not cost you anything to take part in this study.

17. Will you be paid for taking part in this Research Study?

You will be compensated for your participation in this research study. You will receive $15 for each intervention visit and $30 for each in-person assessment visit for a total maximum payment of $330. In addition, for participants traveling more than 25 miles each way to complete study visits, we will reimburse some travel expenses at up to the federal mileage rate. You will receive partial payment if you do not complete the entire study.

If you are paid more than $199 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on the amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the principal investigator.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider may be provided without charge. These healthcare

providers include physicians, physician assistants, nurse practitioners, dentists, or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.
The Principal Investigator (PI) of this study, _____, or *[his/her]* successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):
____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):
____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____
Signature Date