UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. 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.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

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

A Pilot Feasibility Study of a Gratitude Journaling Intervention to enhance Well-being and Exercise Readiness in Older African American Female Breast Cancer Survivors

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

Principal Investigator: Lakeshia Cousin, Ph.D., APRN
Phone number: 352-273-6318

4. Who is paying for this Research Study?

The sponsor of this study is the University of Florida Cancer Center.

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?

This pilot study will assess the feasibility of a gratitude intervention to promote physical activity, and well-being and positively impact biomarkers of health among older African American breast cancer survivors. The intervention will also include a goal-setting component to promote exercise readiness and examine the cultural phenomena of the Superwoman schema, a set of cultural norms that encourages silence around psychological distress and the prioritizing of care for others over care for self. This increased stress leads to weight gain, inflammation, and a higher risk of metabolic syndrome among Black women.

b) What is involved with your participation, and what are the procedures to be followed in the research?

The study will involve journaling (gratitude or general memory) at least twice a week for eight weeks. There will be two in-person appointments at UF Research Center in Gainesville, FL, for the duration of the 8-week study. Appointments include two small blood tests to measure inflammation at the beginning and end of the study.

c) What are the likely risks or discomforts to you?

Although generally safe, blood-draw collection procedures can confer limited risks, including that a participant will experience pain or discomfort. To minimize discomfort, we will make no more than two attempts per time point to obtain blood samples. The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

d) What are the likely benefits to you or to others from the research?

We believe that the expected benefits of participation outweigh the potential risks. Participants will benefit from exposure to the motivational techniques to promote gratitude, exercise readiness, and goal setting. We also hope that knowledge gained from the study will provide new information regarding culturally relevant factors that can improve metabolic health among African American breast cancer survivors. Ultimately, such knowledge could enhance the well-being of African American cancer survivors.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

There are no alternative procedures or courses of treatment associated with this study.

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)?

This study is will not impact your normal clinical care routine.

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

This study involves an 8-week gratitude journaling intervention. We will screen you first for eligibility and verbal consent before enrollment in the study. The first appointment involves a collection of a small blood sample to analyze your baseline biomarkers of health before you begin the study. We will examine your levels of inflammation before the study begins and at the end during your second appointment. The following inflammatory biomarkers will be examined: growth differentiation factor 15 (GDF15), a stress-responsive cytokine, and additional markers of inflammation (C-reactive protein [CRP], interleukin-6 [IL-6]. Then, you will complete a demographic and medical history form and a survey regarding gratitude, spiritual well-being, psychological distress, exercise readiness, and mental and health behaviors. A second appointment will be scheduled at this time. For the second appointment, another small blood collection will be drawn to examine inflammation and stress, and another round of the same psychological surveys will be given a second time. You will also return the journal so we can verify completion at journaling at least twice a week.

Once this research study is completed, the information or biospecimens 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. How long will you be in this Research Study?

Eight weeks.

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

32 African American Breast Cancer Survivors.

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

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

This study may include additional risks that include writing about possible memories of psychological distress and mental and health behaviors. This may cause undue stress to certain participants.

Other possible risks may include participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another 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.

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

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 or listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this Research Study?

Potential benefits of taking part in this research study include helping researchers understand how journaling activities may boost gratitude long-term over time to enhance spiritual well-being, lower psychological distress, improve readiness to exercise, and lower inflammation. .

11b. How could others possibly benefit from this study?

Enhancing knowledge of positive psychology, such as gratitude, can impact others by helping to reduce stress and improve physical and mental health.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

If you do not want to participate in this study, there are resources available to promote the practice of gratitude and journaling.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you decide to withdraw, no additional information will be used or collected.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- Participant not following study procedures or maybe deliberately providing false information.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

This study is free to participants who qualify.

15. Will you be paid for taking part in this study?

Qualified participants will be compensated a $50 gift card for the first study visit and a $50 gift card after the completion of the study at the end of eight weeks. .

16. What if you are injured because of the 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 will 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 the Principal Investigator 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 study.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible

for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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 privacy will be protected:

Signature of Person Obtaining Consent 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 privacy will be protected. 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. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting Date