Study Title: Preventing Cardiometabolic Disease in HIV-Infected Latino Men through a Culturally-Tailored Health Promotion Intervention (HOLA)

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University of Miami

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Preventing Cardiometabolic Disease in HIV-Infected Latino Men through a Culturally-Tailored Health Promotion Intervention (HOLA)

Principal Investigator (PI): Daniel E. Jimenez, Ph.D.

Key Information: The following is a short summary of this study. It will help you decide if you want to take part or not. More detailed information is given later in this consent.

You are being asked to take part in a research study. Your participation is voluntary. This study is sponsored by the National Institutes of Health/National Institute on Minority Health and Health Disparities. This research study is being conducted by the University of Miami (UM) Miller School of Medicine.

The purpose of this study is to look at the best ways to prevent chronic diseases like diabetes, high blood pressure, and obesity in midlife and older Latino adults living with HIV. We expect that you will be in this study for seven months**.** You will be interviewed and asked to take part in walking groups.

There are some risks with taking part in the study. You might experience some discomfort in talking about your health and emotions or in answering some questions during the interviews. There may also be some risk involved in starting a new exercise program. However, we believe the risks related to this study are very low. We cannot promise any benefit from participating in this study. The information you provide will teach us the best ways to prevent chronic diseases like diabetes, high blood pressure, and obesity in midlife and older Latino adults living with HIV.

Your alternative to being in this research study is to not take part.

Detailed Information: The rest of the form gives more detailed information from that above.

You are being asked to take part in a research study. Your participation is voluntary. Please read the following and ask all the questions you need to be sure that you understand the study. At the end, we will ask you if you wish to take part in the study.

PURPOSE OF STUDY

The purpose of the study is to look at the best ways to prevent chronic diseases like diabetes, high blood pressure, and obesity in midlife and older Latino adults living with HIV. We want to know if we can run a health promotion program, led by a community health worker (CHW), made to help prevent diabetes, high blood pressure, and obesity. You are being asked to be in this study because you are a 50+ Latino, living with HIV, and may be at risk for getting chronic diseases.

PROCEDURES

If you agree to be in this study, you will be interviewed by a research assistant. Before starting the interview, we will ask you permission to look into your medical records to see cholesterol, blood sugar levels, fat found in your blood, the amount of the HIV virus in your blood, your height, and weight. During the research interview, we will ask you questions about: demographic information (e.g., gender, education, income, preferred language, country of origin, time in the US, etc.); your mood; your stress levels; your ability to walk; how much you exercise; your quality of life; your social support; stigma; and your satisfaction with the study. This interview will last about 60 minutes and will be conducted 3 times (before starting the study, 4, and 7 months after the first interview). You have the right to refuse to answer any question. We will also ask for your permission to access your medical records. The only health information that we will be looking at will be your cholesterol, blood sugar levels, fat found in your blood, the amount of the HIV virus in your blood, your height, and weight.

In the last two interviews, we will draw a small amount of blood from your arm (4 tablespoons or less) before you answer these questions. This blood will be used to look at your cholesterol, blood sugar levels, and fat found in your blood in order to understand the effect the program is having on these signs of diabetes, high blood pressure, and obesity.

After the first interview, you will be assigned to the Happy Older Latinos are Active (HOLA) program

HOLA is a health promotion program led by a CHW and consists of three parts:

(1) Two individual, 30-minute sessions with the CHW;
(2) A group walk (6 participants), led by a CHW. The group walks will take place in a local park, three times a week, and will last for 45 minutes for 16 weeks; and
(3) After each group walk, the CHW will ask each participant to make a pleasant events list. Participants are expected to do the pleasant events listed in between each walking session.

(4) After 16 weeks (about 4-5 months), you will get one booster walking session twice a month for three months.

About 18 participants will take part in the study.

RISKS

The risks related to this study are very low. We cannot be sure how your body will respond to the exercise used in this study. The research team will discuss possible problems and the chances that they will happen. Unknown problems may happen.

Psychological Stress: You may experience some discomfort in talking about your health and emotions or in answering some questions during the interviews. If you feel uncomfortable during the research interviews, you may skip any question you do not wish to answer. You may also stop the interview at any time. Some of the questions ask about depression and anxiety. If you score high on these questionnaires, we will work with you to connect you with treatment. The research assistant will contact your primary care physician (PCP) or a mental health professional, such as a psychologist, in order to set up an appointment. We will gladly answer any questions, concerns, or doubts that you may have about these risks and discomforts.

Risks/Side effects of exercise: You might feel muscle soreness, fall, or feel discomfort in your chest because of the exercise. We have many safety measures in place to avoid injury or harm. If you feel uncomfortable at any point during the group walk, please stop walking and let the CHW know that you are feeling uncomfortable. The CHW will then contact your PCP and ask for advice on what to do.

Blood draw: You might feel some discomfort in your arm from the blood draw. There might be some bruising as well. Infection, bleeding, and/or fainting are also possible, but not likely.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical exams or visits to your PCP.

BENEFITS

We cannot promise any benefit from participating in this study. The information you provide will teach us the best ways to prevent chronic diseases like diabetes, high blood pressure, and obesity in midlife and older Latino adults living with HIV.

COMPENSATION:

You will be paid $15 on the first visit, $25 on the second visit, and $35 on the third visit (for a total of $75).

COMPENSATION FOR STUDY-RELATED INJURY

The risks related to this study are very low, but if you get hurt, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay,

you will be expected to pay. Compensation for pain, expenses, lost wages, and other damages caused by injury are not routinely available.

CONFIDENTIALITY

All results will be confidential. All information will be held in a password-protected file on a secure computer. You will not be identified by name. To participate, you must agree not to reveal anything you learn from the walking groups or other activities.

Your personal identity will not be revealed in any publications or released with results. Study records may be kept indefinitely for analysis and follow up. Study information may be released to other researchers for scientific purposes, but only after removing your name and any other identifying information.

Your records are considered confidential to the extent permitted by law. However, study-related information will be shared with the National Institutes of Health (the sponsor of this study), and persons working with the Sponsor to oversee the study. This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. Your records and results will not be identified as pertaining to you in any publication without your expressed permission. The U.S Department of Health and Human Services (DHHS) may request to review and obtain copies of your records. Your records may also be reviewed for audit purposes by authorized University or other agents who will be bound by the same provisions of confidentiality.

Florida has laws for "mandatory reporting". These laws require that certain trained individuals tell the proper authorities any information shared with them about abuse of the elderly, abuse of mentally ill or disabled persons, child abuse, or child sexual abuse. In the event that the CHW, research assistant, or investigator learns of any threats you make to yourself or others, they are required, by law, to report this information to the proper authorities.

RIGHT TO DECLINE OR WITHDRAW:

You do not have to take part in this research study. Your decision to be in the study is completely voluntary. If you change your mind about participating, you can withdraw from the study at any time. Your decision to participate or not participate in this study will not affect the physical and mental health care you receive now or in the future in any way. You may be removed from the research study by the investigators if they believe that it is in your best interests. The Institutional Review Board (IRB), regulatory authorities, or the sponsor may also discontinue your participation in the study.

If you cancel your permission after you have started in the study, the study staff will stop collecting your information. Although they will stop collecting new information about you, they may need to use the information they have already collected. If you start the study and then you cancel your permission, you will not be able to continue to participate in the study.

CONTACT INFORMATION:

If, at any time, you have any questions about the study, or in the event of a study-related injury, please contact Dr. Daniel E. Jimenez (305-355-9063). If you have questions about your rights as a research participant, you may contact Human Subjects Research Office at the University of Miami, at (305) 243-3195.

CONSENT:

You will receive a copy of this signed informed consent form.

I have read this consent, which is printed in English (a language which I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study procedures, risks, and discomforts have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to give permission (consent) for me to take part in this study.

_____

Name of Participant

_____ _____

Signature of Participant **Date**

_____

Name of person obtaining consent

_____ _____

Signature of person obtaining consent **Date**

PERMISSION FOR FUTURE CONTACT

It is possible that we may conduct other studies related to chronic diseases in the future. May we contact you to be a possible participant in those studies?

The choice to let us contact you for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide to give us permission to contact you, please call the PI, Dr. Daniel E. Jimenez at (305) 355-9063. You can change your mind at any time.

YES _____ By initialing here I agree to allow the study staff to contact me for future studies.

NO _____ By initialing here I DO NOT agree to allow the study staff to contact me for future studies.

Photography, Video and Audio Recording Consent:
I hereby authorize the University of Miami, its partners, and media outlets to take still photographs, videotapes, and/or sound recordings of me and use in any manner said photographs, film, video or tape recordings, in whole or in part as follows *(Please read and check box next to appropriate permission statement):*

☐ ***For the purpose of teaching, research, scientific meetings and scientific publications, including professional journals or medical books*;**

☐ ***For research purposes only.***

☐ ***For promotional purposes.***

I agree that the University of Miami, its Trustees, officers, employees, faculty and agents will not be responsible for any claims arising in any way out of the taking and use as described above of such photographs and/or recordings. I understand that I will not have an opportunity to inspect and approve such photographs or recordings prior to their use.

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of Person Obtaining Consent

_____ _____
Person Obtaining Consent Date