Title of Study: Preventing Cognitive Decline in HIV-infected Latinos through a Culturally Tailored Health Promotion Intervention (HOLA)

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Sponsor: National Institute on Minority Health and Health Disparities and the National Institute on Aging

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Permission to Take Part in a Human Research Study-- SBS

University of Miami

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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Key Information: The following is a short summary of this study, and it will help you decide whether to take part in this study. More detailed information is given later in this form.

You are being asked to take part in a research study. Doing so is voluntary. The purpose of this study is to look at the best ways to prevent cognitive decline (loss of memory and/ or functioning) in midlife and older Latino adults living with HIV.

We expect that you will be in this study for 16 weeks**.** You will be interviewed, complete two blood draws at the beginning and end of the program and asked to take part in walking groups.

The risks associated with participation in the study are minimal. This study involves questionnaires and blood draws and walking exercises that may cause minor discomfort. No direct benefit can be promised to you for being in this study. The information you provide will help researchers learn ways to prevent cognitive decline in midlife and older Latino adults living with HIV.

You are one of 30 participants asked to take part in this study at the University of Miami.

The remainder of this form contains a more complete description of this study. Please

read this description carefully. You can ask any questions you need to help decide whether to join this study.

Detailed Information

You are being asked to take part in a research study. Your participation is voluntary. Whatever you decide, you will not be penalized or lose any benefits. 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 THE STUDY

The purpose of this study is to look at the best ways to prevent cognitive decline (loss of memory and/or functioning) 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 cognitive decline (loss of memory and/or functioning). You are being asked to be in this study because you are Latino, 50 years of age or older, living with HIV, and may be at risk of developing chronic diseases such as dementia and Alzheimer's disease.

PROCEDURES

You will be asked to complete two assessments (now and at the end of the study), 2 blood tests and a walking program. We are also asking your permission to look at your medical records to review your viral load (amount of the HIV virus in your blood), medications, co-occurring health conditions, and your height, and weight.

During the first interview, we will ask you questions about yourself (e.g., gender, education, income, preferred language, country of origin, time in the US, etc.); your cognitive functioning (how your brain processes information); your mood; your stress levels; your ability to walk (you will do a walking test);how much you exercise; your quality of life; and your social support. These interviews will be conducted at two time points (at the start of the study and after the walking groups at 16 weeks) and will each last about an hour. All assessments will be done by trained staff in a private office at UM/JMMC AdultOutpatient HIV Clinic or another location convenient to the participant where privacy canbe protected.

We will ask to take some blood to look at the apolipoprotein E (APOE) gene, which has been linked with Alzheimer's disease, and other markers that have been linked with cognitive functioning (how your brain processes information). About 20mL (2 tablespoons) of blood will be collected by a trained phlebotomist at each visit.

You will then be asked to take part in HOLA, which is a health program that has 3 parts:

(1) Two individual sessions with a community health worker (CHW) which will last 30 minutes;
(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. You are asked to do the pleasant events listed in between each walking session.

You will be given a Fitbit tracking device, that you can keep at the end of the study. This will allow us to keep track of your activity throughout the program.

Description of the above-mentioned Intervention**:**

Prior to beginning the group walk phase, you will meet individually with a CHW for 30 minutes to learn about the goals of the intervention, about age-related memory loss vs. dementia, the difference between dementia and Alzheimer's disease, and ways you can prevent cognitive decline (loss of memory and/or functioning). You will also discuss how to develop skills and stay motivated to engage in physical activity, increase social activities, identify obstacles that may get in the way with your ability to meet the demands of the intervention, and brainstorm ways to overcome these obstacles.

You will again meet individually with the CHW for another 30 minutes session after week 8 to discuss how things are going.

The second part is a group walk, led by a CHW for 45 minutes, 3 times a week, for 16 weeks. The group walks start slowly and gradually increase in intensity. Walks will be

conducted with a group of 6 participants. Each walk will begin with 10 minutes of stretching and warm up. Then, a 30-minute walk.

The walk will conclude with 5 minutes of cool down. The groups will include bilingual and monolingual Spanish speaking participants.

The third part consists of scheduling pleasant events. During the cool down phase of each walking session, the CHW will ask you to identify a pleasant event that you intend to do with another person before the next meeting. You may choose to do this activity with another member of the group, with family, or with friends outside the group. Subsequent sessions will start with your reporting on how effectively you accomplished your pleasant event plan. The group walks will take place at a centrally located public park.

DOES THIS STUDY INVOLVE GENETIC RESEARCH?

This study also involves genetic testing. Genes control how your body grows and changes, and how your body reacts to certain things. Genes are what we get from our parents that help make our bodies what they are. For example, eye and hair color depend on the genes we received from our parents.
Genes can be collected from blood, saliva, or other tissue samples. We want to find out how genes increase the risk of Alzheimer's disease. It may be true that some people are more likely to have Alzheimer's disease because of their genes and we would like to learn more about this.

You will not receive the results from this genetic testing. Genetic testing is performed for research- only purposes and is not nor should it be considered usual medical care. If you are concerned about a possible genetic disease or problem, you may want to ask yourstudy doctor whether you can have a separate test done specifically for this. You should discuss this option with your study doctor or a genetic counselor. No one will know that the blood sample came from you.

At some point in the future, we may be required to share genetic data with federal repositories. Because this research receives funding from the National Institutes of Health (NIH),we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government. The NIH and other central

repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body.

These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely at UM. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study awide variety of diseases.

RISKS

The risks related to this study are no different than encountered in daily life. 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. You may also feel frustration in answering some of the neuropsychological questions. 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 assist you to set up an

appointment with a doctor or psychologist.

The study also involves talking in a group setting during some walk sessions. You do not have to share information you are not comfortable discussing. Although the CHW will remind all participants to keep the walk discussions private, this cannot be guaranteed.

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 Primary Care Provider (PCP) and call 911 if it is an emergency.

Blood draws: Removal of blood by a needle poses a small risk of pain, bleeding, or bruising at the site of the needle stick, but this is temporary. Some people may experience fainting or dizziness, and there is also a slight risk of infection at the site ofthe needle stick

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 doctor. If you are concerned about any medical issues, you should discuss this with your Primary doctor.

BENEFITS

The potential benefits to you is that you may learn about new health behaviors that lead to improved wellbeing. We hope that your participation in the study may contribute to the advancement of knowledge, and health benefits to others, such as the best ways to prevent chronic diseases like dementia, and Alzheimer's in midlife and older Latino adults living with HIV.

COMPENSATION

You will be paid $25 in cash on the first visit (Baseline Interview), and $35 in cash on the last study visit (for a total of $60 in cash).

COMPENSATION FOR STUDY-RELATED INJURY

Although risks are unlikely, if injury should occur, treatment will in most cases be

available. 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. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

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. 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.

If you are, or have been, a patient at a University of Miami/Jackson Health System facility, you will have a University of Miami/Jackson Health System medical record to improve access to information important to your medical care. Your electronic medical record will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in your electronic medical record. This specifically includes investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well. Including this information in the electronic medical record system is intended only to give information to caregivers providing treatment for you while you are

on this study.

This information will be available to University of Miami/Jackson Health System doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in your electronic medical record will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami/Jackson Health System doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

Federal law provides additional protections of your medical records and related health information.These protections are described in the second part of this document, University of Miami/Jackson Health System HIPAA Authorization for Research.

A Certificate of Confidentiality (CoC), issued by the NIH, covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research except as described above.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute on Aging may need information to assess thisproject.
- You can still share information about yourself. You can also freely discuss your involvement in this research, but this is your choice. The information you share will

no longer be protected by the CoC.

- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others.
- 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. If 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.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

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. 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.

WILL INFORMATION OR LEFTOVER SPECIMENS BE USED FOR OTHER RESEARCH?

Information collected about you and biospecimens collected from you will be used for this research and may also be used for other research studies here at the University of Miami/Jackson Health System. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

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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 (305-243-9373). 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.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Permission to Take Part in a Human Research Study-- SBS

COVID-19 Witness Consenting, if applicable:

_____ _____

Signature of Witness Date

_____

Printed Name of Witness

PART 2: UNIVERSITY OF MIAMI/JACKSON HEALTH SYSTEMS

RESEARCH AUTHORIZATION

What is the purpose of this part of the form?

State and federal privacy laws protect the use and disclosure of your Protected Health Information "PHI". Under these laws, your health care providers generally cannot disclose your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the University of Miami, Jackson Health Systems, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. These people and institutions are called "Providers" in this form.

What Protected Health Information will be used or shared?

You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

- Your past medical history,
- Medical information from your primary care physician,
- All other medical information relating to your participation in the study listed at the top of this document

Who may receive my Protected Health Information?

The Providers may use and share your health information with:

- The Principal Investigator and his/her research staff
- Representatives of government agencies that have oversight of the study or who the law permits to access the information such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the Florida Department of Health
- Groups that collaborate and sponsor research (Cooperative Groups)

- Institutional Review Boards (groups of people who oversee research)
- Other persons who watch over the safety, effectiveness, and conduct of research
- The Sponsor of the research, its agents, monitors, and contractors
- Other participating researchers; and
- Independent data and safety monitoring boards

Authorized staff such as doctors and nurses who are taking care of you but are not involved in this research may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, any study-related information may be placed in your permanent hospital, clinic, or physician's office records.

Why will my PHI be used and disclosed?

- Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
- The research sponsor and its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in this informed consent document and for other activities related to the research, such as assessing the safety or effectiveness of the drug, device or treatment being studied, improving designs of future studies or obtaining approval for new drugs, devices or healthcare products.
- The University of Miami's clinical trial organizations and Jackson Health System will use your information to review and support clinical trials at the University and Jackson Health System.
- Other University of Miami and Jackson Health System offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, Compliance, and JHS Clinical Trials Office may use your information to ensure the research is performed correctly.
- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who

are authorized by law may use your information to review or oversee this research or to see if a new drug, device or other health care product should be approved for marketing.

What other information should I know?

1. Once your information has been disclosed to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your right to other medical treatment will not be affected.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason.To revoke this Authorization, you must write to the study doctor or to the Human Subjects Research Office at 1400 NW 10th AVE, Suite 1200A, Miami FL 33136.
4. If you revoke this Authorization, you will not be able to continue taking part in the research. Also, even if you revoke this authorization, the institutions and people listed above will continue to use and disclose the personal information they have already collected if the information is needed to protect the reliability of the research.
5. While the research is in progress, you will not be allowed to see your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.
6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years and it is not possible to know when they will complete the analysis.
7. You will be given a copy of this authorization after you sign it.

_____ _____

Signature of participant or participant's legal representative Date

_____

Printed name of participant

_____
Printed name of legal representative (if applicable)

_____
Representative's relationship to the participant

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.