A Physical Activity Program to Disrupt Sedentary Time in Older Latinos (PAIS)

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University of Illinois at Chicago (UIC)
Research Information and Consent for Participation in Biomedical Research
A Physical Activity Program to Disrupt Sedentary Time in Older Latinos

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The number provided will allow you to reach Dr. Bronas between 9:00 am and 5:00 pm during the day.
In the event of an immediate emergency outside of normal business hours please call 911.
Sponsor: Midwest Roybal Center for Health Promotion and Translation

About this research study
You are being asked to participate in a research study to design and test a culturally appropriate 6-week intervention to decrease sitting time in older Latinos in Chicago. This is a pilot study for practicality. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you are a Latino adult aged 55 years or older and have an ownership of a working smartphone and ability to use video calls. The study will be completed remotely using your smartphone and/or video calls. This study aims to

design a 6-week intervention that is culturally tailored to older Latinos to move more frequently to maintain cognitive and physical health. We will test if the intervention is effective to enhance your brain health compared to standard physical activity guideline. Approximately 80 subjects will be enrolled in this research study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to find out what makes Latinos adults disrupt their sitting time and be more physically active. With the factors that we identify, we will design and test a 6-week intervention that will give you with real-time feedbacks for your movement and physical activity options for your daily routine. We hope this intervention to improve your cognitive health. All participants will be Latino adults aged > 55-89 years old from the city of Chicago.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	You will be asked to answer questions about your medical history. You will also be asked to complete several cognitive function tests. These assessment and tests will be conducted via telephone calls and/or video calls and will not be recorded. Then, we will ask you some questions about things that can help interrupt sitting time. The interview will be audio-recorded and will be analyzed to develop the intervention. No identifiers will be contained in the audio records. You will be identified only by your study ID number. After the interview, you will receive a matchbox-sized physical activity monitor that record your activity level. You will be asked to wear this monitor on your waist for 8 days. You will be asked to mail the monitor back to us after 8 days. We will give you instructions on how to wear the monitor and how send back the monitor to us. If you are willing and able, you have to option to have your brain imaged by an MRI. We will also ask you to come to the College of Nursing to complete a few additional cognitive and motor function tests. Next, you will be assigned by chance to get either the intervention, or standard physical activity guidelines. You will be informed of your assignment by telephone. If you are assigned to the intervention group, we will provide you with an activity tracker (Fitbit) and smart phone app for 6 weeks. When you stay sitting for prolonged time during the day, the smartphone app will send you a real-time reminder with some physical activity options for you to choose designed based on your preferences and individual phone

	interviews (e.g., standing up 5 times, taking 20 steps, or performing a short dance routine). If you are assigned to a usual care group, you will receive standard physical activity guidelines. After 6 weeks of intervention, you will be asked to complete the same cognitive function tests and wear the physical activity monitor for 8 days, and the optional image of your brain by the MRI For more information, please see the "What Procedures Are Involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	No study site visits will be required. You can complete your study participation at home. There will be 3 study interactions: baseline assessment, intervention education, and follow-up assessment. All these interactions will be completed via telephone and/or video calls. Each interaction may take approximately 1-2 hours. If you decide that you would like to have the MRI take a picture of your brain there are two additional visit. The entire course of the study participation will be 6-weeks.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	This is a pilot study for feasibility. Being in this study will not help you directly. We hope that your participation in the study may benefit other people in the future by helping us learn more about how to improve cognitive and physical health of Latino older adults.
WHAT ARE THE MAIN RISKS OF THE STUDY?	The possible side effects will be explained in more detail later in this form. There may be other side effects we don't know about yet. For this study, the most important side effects to know about are: 1. Discomfort and tiredness associated with questions or tasks we ask you to complete (e.g. medical history, telephone interview, and cognitive function testing) 2. Physical impact of increasing physical activity level 3. Loss of privacy and confidentiality We anticipate that these will be extremely rare occurrences. Data collected will be coded and/or encrypted. Participants will have the option to discontinue participation in the study when they want. For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study.

QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Dr. Ulf G. Bronas at 312-355-5886 or email at bronas@uic.edu. If you have a research related injury, you should immediately contact Dr. Bronas at 312-355-5886. The number provided will allow you to reach Dr. Bronas between 9:00 am and 5:00 pm during the day. In the event of an immediate emergency outside of normal business hours please call 911. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

What procedures are involved?

This research will be performed remotely at your home using your smartphone and video calls. You will have two telephone or video interviews; one is at the beginning of your participation, and the other is at the end of the study course. Each interview will take approximately 1 hour to complete.

If you are eligible for the study and provide informed consent, you will be asked to do the following procedures:

Study interaction 1 (Baseline assessment, approximately 2 hours)

- You will be asked several questions for us to make sure you are eligible for our study.
- If you are identified to be eligible, you will be asked several questions about your previous medical history and your health status. This interview will not be recorded. Please make sure that you can skip a question during the interview if you are not comfortable to answer.
- Next, you will be asked to complete several cognitive function tests for us to examine your thinking ability and reasoning skills. The tests will be completed using an iPad through video calls. You will be instructed by our research staff on how to complete the tests remotely. The video calls for the tests will not be recorded.
- At the end of the phone/video call interview, you will be asked to answer several questions about individual and social factors influence your physical activity over the

phone. We will ask you these questions in relation to your individual background. Dr. Bronas or his research team member will guide this interview using a structured interview guide. With your permission, this interview will be audio-recorded. The recorded interview will be analyzed and used to develop the intervention in the study.

- Following the telephone and video calls, you will receive a matchbox-sized activity monitor called Actigraph. The Actigraph is about the size of a matchbox and will record the number of steps you take each day and how active you are. We will ask you to wear the Actigraph every day from when you get up in the morning to when you go to bed at night for 8 days. You will be instructed by our research staff on how to wear and use the sensor. You will be asked to return Actigraph after 8 days by mail using a stamped and addressed envelope provided to you by the research staff. This activity monitor will help us examine your overall physical activity level and sedentary time during daily routine. You will receive instruction on how to use the actigraph and how to mail it back.

Optional visit (approximately 1 hour) If you are willing and able to undergo an MRI scan.

- The MRI visit will take place about one-week after Visit 1. You will come to the Magnetic Resonance Imaging Center, 3T research center 2242 W. Harrison St. Chicago IL 60612 and return the actigraph to us. We will ask you to do the following:
- Have an MRI to take pictures of your brain at a scanning facility located approximately 10 minutes from the College of Nursing UIC. Scanning will last approximately 1 hour during which time you will lie on a padded table and be placed inside of a large machine shaped like a tunnel.
- Before entering the MRI room, you will be asked to remove from your person all metal objects, including jewelry, watches, hair holders, or eyeglasses; and you will be asked to empty your pockets of all materials, including keys, wallets, and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you may be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.
- Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with earplugs to reduce the noise level. When you and the researcher or technician are ready to begin the MRI scan, you will be asked to lie as still as you can.
- All of the procedures described above will be performed by qualified, licensed personnel and arranged at your convenience. You will be informed of any abnormalities found in the tests; however, the information obtained from the MRI and cognitive testing is experimental in nature and does not allow for clinical interpretation. We will, however, contact you if the MRI or cognitive test results warrant a formal clinical follow-up and discuss this with you and your medical provider (e.g., your General Practitioner). Ultimately, however, it is up to you to follow-up with a doctor for a clinical evaluation.

Following the optional MRI, you will be asked to complete a few additional in person cognitive function tests for us to examine your thinking ability and reasoning skills (total time is 16 minutes). We will also ask you complete a short series of motor function tests that includes:

a. Pegboard dexterity test, where you will be asked to place pegs in a nine-hole pegboard as fast as you can and remove them as fast as you can. You will be asked to do this once with your left hand and once with your right hand (4 minutes).
b. Balance test with for assessment of how much you sway (7 minutes).
c. A test to see how fast you walk 4 meters (3 minutes).
d. A test to see how far you walk in 2 minutes (4 minutes).
e. Grip strength using a standard hand dynamometer (3 minutes).

Study Interaction 2 (Intervention, approximately 1 hour)

- You will be randomized to get either the experimental intervention, real-time feedback of your physical activity to replace sitting time, or a standard physical activity guideline. You will be informed of your assignment by telephone.
- Being randomized means you will be assigned to one of these two groups by chance. You will have a 1:1 chance of being assigned to either group. You cannot choose which group you are in. You are assigned to a group by what is called a randomized numbers table in computer program that acts like flipping a coin to decide what group you will be placed in.

a. Intervention group

If you are assigned to an intervention group, we will provide you with an activity tracker (Fitbit) and smart phone app (Illumivu) for 6 weeks. We will teach you how to use these devices via telephone or video calls when you are informed of which group you are in. You will be asked to wear the Fitbit on your wrist, and it will record your everyday physical activity for the entire day. When you stay sitting too long during a day, the Fitbit will "buzz" as a reminder and the smartphone app (Illumivu) will send you a text message in real-time for you to interrupt sitting time and move your body. The text message will provide you with several physical activity options for you to choose designed based on your preferences (e.g., standing up 5 times, taking 20 steps, or performing a short dance routine). The physical activity options will be tailored to you individually. Resulting actions and delivery of the intervention will be automatically captured and downloaded into the devices in real time.

b. Usual care group

If you are in the usual care group, you will receive the standard guidelines for physical activity. You do not receive the activity tracker and smart phone app in this group.

Study interaction 3 (Follow-up assessment, approximately 1 hour)

- At the completion of the 6-week intervention period, you will be sent an activity monitor again and asked to wear it on the waist for 8 days. You will be asked to mail the monitor back to us after 8 days. You will be instructed by our research staff on how to wear and use the sensor. You will be asked to return Actigraph after 8 days by mail using a stamped and addressed envelope provided to you by the research staff. This activity monitor will help us examine your overall physical activity level and sedentary time during daily routine. You will receive instruction on how to use the actigraph and how to mail it back.

- Once we receive the monitor, we will download the data and schedule a telephone interview with you for follow-up assessments. This interview will be recorded and include several question for us to understand where they had difficulty and what did or did not work for them.
- You will also be asked to repeat the same memory tests via video calls. None of these activities will be audio- or video-recorded in the phase. You would also repeat the MRI picture of your brain if you decided to have the optional MRI and the in-person cognitive and motor function tests. The total amount of MRI scans you will be asked to complete is two. One at baseline and one the 6-week follow up.

During this study, Dr. Ulf Bronas and his research team will collect information about you for the purposes of this research. The information that will be collected from you includes your previous medical history, your cognitive function test performances, and audio-recorded interview with you about physical activity. All information collected from you will be deidentified. Your physical activity and movement data that are electronically collected using the activity monitors (Actigraph and Fitbit) and smartphone app will also be deidentified and used in the study.

Will I receive the results (including any psychological and/or health results) from the study?
We will not share results of the study with you.

What are the potential risks and discomforts of the study?
Side effects, risks, and/or discomforts from participation in this study include:

Medical History:
Answering questions about your medical condition may make you feel uncomfortable. Do not answer any questions that make you feel uncomfortable.

Telephone Interview:
Answering questions about factors influencing your behaviors may make you feel uncomfortable. You may also find answering the questions boring and/or tiring. We will monitor your progress and take breaks as needed. If you become upset or uncomfortable, you may skip a given question.

Cognitive Function Testing:
You may become tired and feel stressed during performing the cognitive function testing. We would like to make sure that you are not tired during the tests, so please make sure to inform us if you need break at any time.

Optional MRI scans:
The MRI scans are performed with a powerful magnet without using x-ray radiation or radioactive material. The magnetism of the machine attracts certain metals, which could put you at risk. Therefore, people with pacemakers, infusion pumps, metal prostheses, metallic-backed transdermal patches or metallic shrapnel will be excluded from the study. A checklist will be

completed that addresses issues of MRI safety. Some people may feel somewhat closed-in (claustrophobic) during the MRI procedure. The MRI scans can get quite noisy and this may cause you some discomfort. We will provide padding, a blanket as well as ear plugs to ensure your comfort. You will stay in contact with study staff during the entire MRI procedure and you can request to stop at any time

Motor Function tests:
There is a slight risk of falling during the balance testing.

Two-minute walk:
Exercise may cause abnormally high blood pressure, muscle soreness/injury, shortness of breath, muscle injury, and heartbeat disorders. Rare but serious risks include heart attack, stroke or death. If you experience pain in your chest, arm or jaw during the 2-minute walk, please inform the study staff immediately.

Increasing Physical Activity Level:
Increasing your level of physical activity by interrupting your sitting time may cause muscle soreness/injury. If you experience pain in your chest, arm or jaw while moving, call 911 immediately.

Confidentiality:
It is possible that a break in confidentiality could occur and that someone other than the researchers involved could get your access to the information that you give the investigator. We will take measures to minimize these risks. All data assessment and collection will occur in a private, secure setting. The audio-records for the telephone interview will not contain any identifiable information. You will be assigned a study number and your personal information will be kept under password protection, separate from study data.

There may be risks from the study that are not known at this time.

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

<u>What about privacy and confidentiality?</u>
Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.

- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The sponsor of the research study, Midwest Roybal Center for Health Promotion and Translation

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your personal information, research data, and research records will be coded and stored on a password protected computer, separate from study data. The data electronically collected using the wearable sensor and smartphone app will be password protected and encrypted to prevent access by unauthorized personnel.

Your individual data will be destroyed within 6 years of the completion of the study. When the results of the study are published or discussed in conferences, no one will know that you were in the study. During the study, audiotape recordings will be collected. Your identity will be protected by assigning unique study id for you and coding each data collected. The recoded data will be destroyed within 6 years of the completion of the study.

A description of this study 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 if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let Dr. Ulf Bronas know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Bronas at 312-355-8556 during the day. After the business hours, please call 911 for further medical assistance.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research team.

You or your health insurance plan will be billed for medical treatment that may be needed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or

injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?

There are no costs to you for participating in this research study.

Will I be reimbursed for any of my expenses or paid for my participation in this research study?

You will receive $25 following completion of all baseline tests and after completion of all tests at 6-weeks follow-up. If you do not finish the study, you will be compensated for the study interactions you have completed. If you complete the study, you will receive a total of $50. You will receive your payment upon completion of the baseline and follow-up study interactions in the form of gift card. There is no additional compensation for the MRI and cognitive testing. You will receive a parking voucher for free parking at the study site. Parking at the MRI center is reserved and free.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. There are no plans to compensate you for any of these developments.

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.

The researchers [and/or funder] also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

If you choose to no longer be in the study and you do not want any of your future information to be used, you must inform the researchers in writing at the address on the first page. The researchers may use your information that was collected prior to your written notice.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Ulf Bronas and his/her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes:

- Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (race, gender, ethnicity, age)
- Results of cognitive function tests
- Physical activity monitoring records
- Medical history
- Certain health information indicating or relating to a particular condition

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With the sponsor/funding agency of the research, the Midwest Roybal Center for Health Promotion and Translation, as required to conduct the research and/or confirm the results of the research.
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP).

If all information that identifies you is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your participation in this research, you will not have access to the research records or information that is not usually kept in your medical record. However, this information is available to your doctor in the case of an emergency. The researcher may provide you with access to the research records or information related to this research once the study is done.

How will your health information be protected?

The researchers and the Midwest Roybal Center for Health Promotion and Translation agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study does not have an expiration date, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Dr. Bronas at The University of Illinois at Chicago College of Nursing, Department of Biobehavioral Health Science (M/C 802)
845 S. Damen Avenue, Chicago, IL 60612-7350.

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

Yes, I agree to participate in the optional MRI_____ (Circle and provide initials)

No, I do not agree to participate in the optional MRI_____(Circle and provide initials)

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of this form.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent