

INFORMED CONSENT FORM

Date: 07/31/2023

NCT Number: Not yet assigned

Informed Consent Form

Principal Investigator (PI): Cristina Colón-Semenza, PT, MPT, PhD

PI Phone Number: 860-486-0019

Title of Research Study: Peer partners to improve physical activity in older Latinx adults with Parkinson's disease

Sponsor: National Institutes of Health(NIH)/National Institutes on Aging(NIA) Older American Independence Center (OAIC), UConn Health

Name of Research Participant: _____

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

This research is being done to determine if having the support of another person with Parkinson's disease will help you to be more active. This study will only include people with Parkinson's disease who are Hispanic/Latinx and who are 50 years old or older. We will test if people become more active and have a better quality of life.

You will be asked to complete several questionnaires through an interview with the research assistant by telephone to determine if you are eligible. If you are eligible, you will then have an orientation meeting with a research assistant in a virtual meeting, using your mobile or internet connected device.

You will be sent a research-grade activity monitor, **Actigraph GT9X** device, in the standard mail to your residence. After receiving the device, you will engage in a telephone or virtual meeting with a research assistant to learn how to use the device. (approximately 30-40 minutes)

You will be asked to wear the activity monitor for 10 days at the beginning the study. You will be asked to continuously wear the device on your wrist for the 10 days. When completed, you will return the device in a pre-paid envelope that we provide for you. The same procedure will occur again at the end of the study, we will mail you back the monitor and ask you to wear it for another 10 days and then return it back in the provided pre-paid mailing envelope.

You will be given access to peer coach/partner training videos that are on a website. There are a total of 11 videos (approximately 5 minutes in length) that will be sent to participants to watch over a 2-week period. The total amount of time spent watching videos will be approximately 55-88 minutes. You can choose to complete watching these videos on your own schedule, in your home, local library, or wherever you feel comfortable. The videos will be available in Spanish and English. There will be two virtual meetings with a group of participants to review the

material in the videos to be sure that you understand everything. You will have access to a weekly virtual exercise class that is available to all of the participants in the study at the same time.

After you have completed the training, you will receive a commercially available activity tracker (Fitbit Inspire 2) and instructions on its use. You will be asked to wear this activity tracker for the duration of the 8-week period except for showering/bathing.

All participants will be matched up with another person with Parkinson's disease (Peers) who is their same gender and you will support each other to be more physically active. Participants will be connected on an app and will meet in a virtual meeting once per week. A research assistant will call or text you to check in on how the program is going once per week. Peers will become "FitBit Friends/*Amigos*" through the FitBit application. Peer pairs will be able to see each other's accumulated steps over the week and communicate as a pair.

The most severe risk is the risk of falling. The most common risks are minor muscle or joint pain. Because peer coaching/partnering intervention is investigational there may also be risks that are not yet known. Some of the questions in the surveys may cause you to feel upset. Risks are described in more detail later in this form.

There may also be benefits from participation. If the training you participate in as part of this study is effective you may experience an improvement in your health; but this is not guaranteed and your health may decline. This research may also result in information that leads to an approved treatment that may help others in the future.

A more detailed description of this research follows.

Purpose of This Research

The purpose of this research study is to determine if a peer-supported mobile health physical activity intervention for exercise in Latinx people with Parkinson's Disease will be beneficial to participants, increase physical activity and improve disease self-management.

Voluntary Participation

You are invited to take part in this study because you are aged 50 or older, are Latinx, and have Parkinson's Disease.

Participation in this study is voluntary. Before making a decision about whether to participate in this research, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members, your primary care physician, or a friend before making a decision.

You can choose to not participate in this study. If you choose to participate in this research study, you can choose to withdraw from it at any time. If you decide not to participate or you later choose to withdraw from participation, your decision will not affect your present or future medical care and there will be no penalty or loss of benefits to which you are otherwise entitled.

Number of Other People Who Will Participate

We estimate that 20 people will participate in this study.

Length of Participation

Your participation in this study will be between 4- and 5-months total. After consent has been obtained, you will be asked to complete several questionnaires through an interview with the research assistant by telephone or virtual meeting. These surveys will include questions about your exercise history and demographic information, depression, motivation for exercise, quality of life, and confidence with exercise. You will be asked to wear a monitor for 10 days prior to beginning the training in the study. You will be sent this monitor by standard mail. After receiving the device, you will engage in a telephone or virtual meeting with a research assistant to get oriented to the program and to learn how to use the monitor.

You will be given access to peer coach/partner training videos. There are a total of 11 videos (5-8 minutes in length) that will be sent to you to watch over a 2-week period. The total amount of time spent watching videos will be 55- 88 minutes. You can choose to complete watching these videos on your own schedule, in your home or community. The videos will be available in Spanish and English. There will be 2 virtual meetings to review the material in the videos.

All participants will be peer coaches/partners. Participants will support one another as they all strive to improve their physical activity. You will be matched with a peer of the same gender. The research team will partner you with another peer participant. We will attempt to create a successful match by matching you with others with similar characteristics (age, retired vs working, stage of the disease, etc.).

After you have completed the training, you will receive a commercially available activity tracker (Fitbit Inspire 2) and instructions on its use. You will wear this activity tracker for the duration of the 8-week period except for showering/bathing. Peers will download the FitBit application on their smart phone or tablet. If you do not have a smartphone or tablet, one will be provided to you, along with a data plan for the duration of the study. You can choose to receive basic training on its use with the support of a research assistant via a telephone call or virtual meeting.

Peers will become “FitBit Friends/*Amigos*” through the FitBit application. You and your peer will be able to see each other’s accumulated steps over the week. All participants will also join a FitBit closed group of all participants in the study. This group will be created by the research team and is not publicly available to others. There will be a leaderboard in the FitBit group. Peers can provide social support to each other in the group and one on one in the app with comments and emojis. You will be asked to log in to the FitBit app daily to sync your data with the app. Additionally, peer pairs will establish a weekly meeting schedule by telephone or virtual meeting. The weekly meetings will be guided by topics of discussion to help with exercise and checking in on each other’s goals. Participants will be encouraged to participate in a weekly virtual exercise class that is offered to other participants at the same time. A research assistant will call or text each week to check in on how you and your partner are doing with the program.

Will I receive compensation?

You will get to keep the FitBit after the study is complete. This can be used for your personal use and will no longer be used for research purposes. You will also have access to a free exercise class that will be carried out in Spanish and English and is targeted to the needs of people with PD. These exercise classes will be online classes that you can access to do in your home.

Physical / Psychological Risks of Procedures

Participation in this study will involve the following procedures:

- **Survey Administration:** The study coordinator will give you a survey about your exercise habits, depression, motivation, social support, and medical history.

Risks: You may feel uncomfortable answering some of the questions. There are no physical risks associated with the survey.

Safeguards: You may always choose not to answer a question that makes you feel uncomfortable.

- **Exercise:** You will have access to a weekly virtual bilingual exercise class that is geared towards the needs of people with PD with others participating at the same time. The class will have 3 areas of focus: heart-pumping exercise, strengthening exercise, and balance, breathing, and stretching exercise. The first 3 weeks will focus on heart-pumping exercise, the second 3 weeks on strengthening and the last 2 weeks will focus on balance, breathing and stretching exercise. The instructor will provide modifications of the exercises so that they are at the appropriate level for you.

Outside of this exercise class, you will be encouraged to increase your walking and general physical activity. For example, you may develop a plan with your peer partner to march in place during commercials when watching your favorite television show.

Risks Likely/Common: Exercise may cause minor and temporary muscle soreness or joint stiffness. The soreness typically begins 1-3 days after exercise begins, does not last more than 2-3 days and does not damage the muscle. You may also experience minor fatigue following an exercise session.

Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue.

Safeguards: In order to reduce this risk, you will be instructed in proper technique and progression. Modifications of exercises will be available to meet the needs of different ability levels. Additionally, the exercise class content was created by a licensed physical

therapist with a board certification in neurological physical therapy (Dr. Cristina Colón-Semenza). The exercise instructor has completed a training for fitness professionals that focuses on Parkinson's disease.

- **Peer partner:** You will be matched with another person with PD and communicate with this person once per week during a virtual meeting. You will be FitBit friends and see each others' steps per week.

Risks Likely/Common: There may be conflicts between you and your peer partner. Your peer partner may drop out of the study.

Safeguards: We will attempt to create a successful match by matching you with others with similar characteristics (age, retired vs working, stage of the disease, etc.). If there is a conflict between you and your peer partner a research assistant will be available to meet with you both to help resolve the conflict. If your peer partner drops out, we will attempt to reassign you to another partner.

- **FitBit and Activity Monitor:** .

You will be matched with another person with PD and they will be able to see your accumulated steps during the week. You will also communicate in a group of people with PD therefore there is a risk of loss of confidentiality. Everyone will be educated on the importance of confidentiality and will be instructed to only use first names. You will be given the option to only use audio and not use your camera for group engagement.

Data that is housed in the activity monitor (Actigraph) might be subject to a loss of confidentiality. Only people that have the software to download the data from the device will be able to access the data on the device. The data on the activity monitor will be downloaded onto a UConn encrypted and password protected device and will only be accessible to trained research personnel.

The FitBit data will be housed on the FitBit device and might be subject to a loss of confidentiality. Only those that have the email and password for the FitBit account will have access to this data. This data will be downloaded to an encrypted and password protected UConn computer during the course of the study. Once the study is over the password will be changed so that only you have access to your FitBit data. You can choose to remove yourself from the FitBit group at the conclusion of the study.

Risks: There is a risk of the loss of confidentiality due to the group and social connection nature of this project. There is a risk of loss of confidentiality of your data that is on the activity monitor (Actigraph) and the FitBit.

Safeguards: All participants will be educated on the importance of maintaining confidentiality of content during meetings. All participants will be informed to use first names only. Participants can choose to only communicate with voice/audio. The storage of the data on the devices is not accessible without the necessary software or passwords.

Other Consideration of Physical or Psychological Risks: Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

Other Types of Risk to Consider

Risk to Confidentiality: While we will protect the confidentiality of the information you provide, confidentiality cannot be guaranteed. All participants will be reminded not to share information about other participants that they engage with during the study. There is a chance that participants may not maintain confidentiality.

Study data will be coded with a number, and a master list linking your personal identifiable information with your study data will be kept separately from your study data, on an encrypted study computer.

The information collected for this research study will be accessible to authorized persons. Authorized persons include study team members, representatives of UConn Health; and as may be applicable representatives of the Sponsor and/or representatives of Federal agencies when required by law, such as representatives from the National Institute of Health, the study sponsor, and/or Department of Health and Human Services when the research is federally funded or supported. Representatives from these areas have access to the information so they may ensure that the study is being done correctly.

A Certificate of Confidentiality has been obtained to further help protect your privacy and the confidentiality of your data. With a Certificate of Confidentiality in place, the investigators cannot be forced to disclose research-related information about you to anyone not connected to the study, except in very limited circumstances. A Certificate of Confidentiality does not stop you from voluntarily disclosing information. It also does not stop the investigators from voluntarily reporting information about child or elder abuse, or reportable communicable diseases. The investigators on this study will report this information to State officials if it becomes known to them.

You should also know that:

- At the conclusion of this study the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.
- 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.
- If you discuss this with your personal physician it may be noted in your medical record that is with your personal physician unless you instruct otherwise.

- If you discuss this with your employer or co-workers your study participation may become known to others.

Privacy

To try to ensure privacy, you will be asked to participate in the study virtual meetings in a private environment, so that others in the area are not able to hear or see conversations/interactions.

Possible Benefits from Participating

You will not benefit directly from the information we gather in the study. You may benefit from the trainings and peer coaching/partnering and the exercise and physical activity. Other people who have the same condition may benefit in the future. We might find a better way to manage Parkinson's disease. There is also the possibility that no benefit will come from this study.

Cost of Participating

The study sponsor, will pay for the Fitbit activity tracker that you will get to keep as part of your participation. A device/tablet will be provided to you, if do not have one, so that you can participate in the study. We will ask you to return the device/tablet at the conclusion of the study. We will provide you with a stamped and self-addressed envelope for you to return the device. You do not need to pay for the return postage.

The study will also pay for the activity monitor, Actigraph GT9X, that will be sent to the you. The activity monitor you will return in a pre-paid self-addressed envelope after wearing for 10 days. This is different from the FitBit activity tracker that you will get to keep.

There will be no costs to you for any study procedures.

Alternatives

You have the option not to participate in this study.

Withdrawing from Participation

You are free to stop taking part in this study at any time without penalty of loss or benefit to which you are otherwise entitled to. While we are doing this research, if we learn new information that may influence your decision about participation we will share that with you. For example, if we learn about new risks we will share that information with you. If you choose to withdraw, it will not adversely affect your relationship with your doctors or University of Connecticut Health. To withdraw you should send written notice to Cristina Colón-Semenza, University of Connecticut, Kinesiology Building, 3107 Horsebarn Hill Rd, Storrs, CT, 06237.

If you choose to withdraw from this study, the data that has already been collected will continue to be used and remain in the study database however we will remove your name or other personal identifiers from the data that we keep. Investigators on this study may continue to review the study data collected prior to your withdrawal. If you choose to withdraw we will ask you to return the FitBit device so that it can be used by another participant. The study team will provide you instructions by phone on how to reset the Fitbit so that we will no longer have access to the data on the device. After 7 days of the phone and Fitbit not syncing, the phone and

the device are no longer paired. The researcher may require that you be withdrawn from participation. This may happen if you do not adhere to the study instructions, or participating in the study activities. If the researcher withdraws you from further participation in the study, your data that have already been collected will continue to be used and remain in the study database.

Sharing Information

We receive money from the National Institutes of Health (NIH) to do this study. NIH requires that we have a plan in place to share information we gain in this study. We anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study.

Your information will only be shared in an anonymous way. Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. If you provide permission now to share your anonymized information with the database noted below, you may withdraw your permission later without any penalty or loss of benefit. The information will be withdrawn from the database. However, if the information has already been shared with other researchers that information will not be able to be deleted.

Results of This Research

You will not be told any of the results of the research. Results will not be made available to you because additional research will be needed to determine the application of these results.

Adverse Events

If you experience an adverse event you should tell the principal investigator (PI) as soon as possible. You may contact Cristina Colón-Semenza by calling 860-486-0019 or 860-486-9555.

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health Institutional Review Board at 860-679-4849 or 860-679-8729.

UConn Health does not offer free care. However, treatment for a research related injury can be obtained at UConn Health for the usual fee.

Questions

The Principal Investigator is willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call the Principal Investigator at 860-486-0019 or 860-486-9555.

If you have questions about your rights as a research subject you may contact a coordinator at the Institution Review Board at 860-679-8729, or 860-679-4849.

You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form, you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form. You acknowledge that you have the opportunity to voluntarily provide feedback about your experience as a research participant. You may ask for a copy of the Research Participant Feedback Form, you may obtain the form online at <https://ovpr.uchc.edu/services/rics/hssp/volunteers/>, or you may submit the form online at <https://redcap.link/UConnHealth-Feedback-Research>.

By signing this form, the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form if requested, will be provided to the participant.

Role	Printed Name	Signature	Date	Time
Subject				
PI, Research Staff				

May we contact you in the future about other research studies that we have occurring in our lab? YES NO