INFORMED CONSENT FORM

Official Title: Healthy Aging Research Program (HARP): Engage Coaching Project for Latinos

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CONSENT FORM

Healthy Aging Research Program: Engage Coaching Project for Latinos

Principal Investigator: Caroline Silva, PhD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

1. Being in this study is voluntary – it is your choice.
2. You are being asked to take part in this study because you are Hispanic/Latino, at least 40 years of age, and reported some stress related to caring for a loved one with dementia. You also reported feeling some dissatisfaction with your relationships.
3. The purpose of this study is to identify useful strategies for improving relationships for individuals who are caring for a loved one with dementia.
4. Your participation in this study will last for up to three months.
5. Procedures will include: Sessions with an Engage Coach up to 8 times. Meetings with the Engage coach are brief (approximately 30 mins) and are done over Zoom either by phone or your computer. The coaching is designed to help you enhance your relationships and improve well-being while managing caregiving stress. You will also answer questions about your health and relationships at 3 and 6 months after you start.
6. There are risks from participating
    - The most common risk is fatigue due to the length of the follow-up interview (up to 2.5 hours).
    - One of the most serious risks is emotional stress due to the personal nature of the interview questions and coaching sessions.
7. You might not benefit from being in this research study. The potential benefit to you might be increased satisfaction with your relationships and increased quality of life.

Purpose of Study

The purpose of this study is to identify useful strategies for improving relationships for individuals who are caring for a loved one with dementia.

Description of Study Procedures

1. If you decide to participate in the study, you will participate in what we call 'Engage Coaching.' This involves sessions with an Engage Coach up to 8 times. Typically, sessions will occur weekly, but you will have up to three months to complete your sessions. These virtual meetings are brief (approximately 30 mins) and can be done by Zoom on your computer. If you cannot or do not want to use the video feature of Zoom you can choose not to use it, or you can choose to use the phone to call in to the Engage meeting. The coaching is designed to help you enhance your relationships and improve well-being while managing caregiving stress. Your coach will help you identify aspects of your social relationships that are helpful to you and aspects that are not. Using this information, your coach will help you identify goals for improving your social relationships. Each session, your coach will help you complete a process we call 'action planning,' in which you set a goal for the week, brainstorm strategies to meet the goal, and identify concrete steps to take to achieve the goal. You will work with your coach to identify any aspects of caregiving that may present barriers to improving your relationships and develop strategies to address these barriers.

2. Three months from now (after completing Engage Coaching) the first follow-up interview will be completed using Zoom on your computer or by phone and online. This interview will take approximately 2 hours. 6 months from now, you will complete some questionnaires online (or by phone if you need assistance). The 6 month online questionnaires will take approximately 30 minutes to complete. There are multiple-choice and open-ended questions about your physical health, emotional health, social relationships, experiences with caregiving, and sense of well-being.
    - Some of the questions in the interview ask about depression, anxiety, and suicidal thoughts.
    - Some of these questions you will complete on your own online.
    - We will invite you to share with us your experience with the assessments and the programs at the 3 month interview so we can make improvements in the future; this portion will be recorded.

    - The Engage sessions and parts of the interviews will be recorded. The feedback recording from the interview will be transcribed by research personnel and erased once the transcriptions are checked for accuracy. Transcripts of your interview may be reproduced in whole or in part for use in presentations or written products that result from this study. Neither your name nor any other identifying information (such as your voice or picture) will be used in presentations or in written products resulting from the study. The Engage session recordings will be used to supervise Engage coaches to

ensure that all participants receive a consistent treatment. Also we will use the recordings to help learn which strategies used by the coaches work the best. The use of the audiovisual recordings will be limited to research personnel, and will NOT be used for teaching purposes or in presentations to other professionals without your permission. With written notice, you may have any or all audiovisual recordings erased at any time. Recordings will be made through Zoom so that a member of the research team can listen to what your therapist says and ensure that all subjects receive a good "dose" of ENGAGE. If you are not comfortable having the visual recording, you can choose to disable the video feature or just use your phone so only the audio portion is recorded.

What type of recording will you allow?

☐ Audio and visual recording ☐ Audio ONLY

Initial to acknowledge audio/audiovisual recordings: _____

Number of Subjects

Approximately 30 subjects will take part in this study.

Duration of the Study

Your participation in the study will last approximately 6 months.

Risks of Participation

1. Some of the questions are personal in nature, and could evoke emotional responses. You are not obligated to answer any questions that you are not comfortable with.
2. The interview could cause fatigue. You are free to stop the interview at any time and resume later.
3. We will record the part of the 3 month interview in which you tell us about your experiences in the program so that we can transcribe your feedback and learn as much from you as possible. We will also record the coaching sessions. Given this, there is a risk of a loss of privacy. To minimize that risk, your audiovisual data and questionnaire data will be stored separately on password protected computers and will only be linked by random subject ID numbers to further protect your privacy. Access to all data will be strictly restricted to project staff.
4. Email communication will be limited to scheduling (e.g., appointment reminders) or providing resource information. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be

shared beyond you and the study team. The University of Rochester is not responsible for any interception of messages sent through email.

5. Some of the interview questions ask about depression and suicide. If we become concerned about your safety (or the safety of others) and/or your responses indicate a high level of depression, we will notify Dr. Silva (or their associate) for recommendations. One action they may take is to notify your primary care provider. In the case of suspected elder abuse, subjects will be given an immediate referral to the Elder Abuse Prevention Program (EAPP) of Rochester or a similar program in your area. In addition, the researchers are required to report information regarding potential child abuse or neglect reported by you during the research study.
6. The researchers will also report if there is a reasonable suspicion, based on information provided by you that you may present a danger of harm to others or that you may harm yourself unless protective measures are taken.

We use a HIPAA compliant Zoom environment for online study visits. This allows us to videoconference through an online system that allows both video and sound. This easy to use technology is available using a computer or mobile apps or by calling in from your phone. There are risks associated with use of this technology such as interruptions and technical difficulties.

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 website at any time.

Benefits of Participation

You might not benefit from being in this research study. However, you might find the Engage program beneficial. In addition, we hope that the results will help us better understand the health needs and experiences of community-residing Latino adults.

Alternatives to Participation

The alternative to participation is to decline participation.

Costs

There will be no cost to you to participate in this study.

Sponsor Support

The University of Rochester is receiving payment from the National Institutes of Health for conducting this research study.

Payments
You will be paid $60 for taking part in the 3 month interview for this study and $30 for the 6 month online questionnaires. Payments may be made by check, which can take 4-6 weeks.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes. The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we have trained all of our study interviewers in confidentiality procedures. Additionally, we will enter and store the information you share with us using coded identification labels; thus, any data we collect from you will be kept separate from individually identifiable information. Your named file is stored in a locked filing cabinet in a locked office, kept separate from your coded data file. All information and video data is maintained on project computers in secure locations with restricted access by enforced password protection.

Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Audiovisual recording data from your follow-up interview and Engage sessions

Who may use and give out information about you?
- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester
- The National Institutes of Health

Why will this information be used and/or given to others?
- To do the research

- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Caroline Silva at (585) 275-2392.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;

- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date