

*Confidently Navigating Financial Decisions and
Enhancing Financial Wellbeing in Dementia
Caregiving*

NCT05292248

Informed Consent

Updated 8/16/2022

Informed Consent Document

Confidently Navigating Financial Decisions and Enhancing Financial Wellbeing in Dementia Caregiving for Latino/Hispanic Family Caregivers

Thank you for your interest in the **CONFIDENCE Study, which is being conducted by researchers at Case Western Reserve University**. Your participation in this study will help researchers to better understand how learning information about finances and community resources can help family caregivers. Our goal is to help caregivers to lower the out-of-pocket costs of caregiving when helping a family member living with dementia.

By “out-of-pocket care costs,” we mean how much money family members spending on caregiving. Some of these costs include medications, home modifications, adult briefs, and transportation expenses. We also hope to learn whether participating in CONFIDENCE reduces stress related to finances.

This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate. Your participation in this research is voluntary.

Who is conducting the study?

Kylie Meyer, PhD, MSc
Assistant Professor
Case Western Reserve University

What is the purpose of the research?

The purpose of this study is to determine if using an online course is helpful to reduce out-of-pocket costs of caregiving and financial stress among Latino family caregivers. Some studies suggest that Latino and Hispanic family caregivers to persons living with dementia have, on average, the highest out-of-pocket costs of caregiving. We hope that the results of this study will help to reduce these out-of-pocket costs and improve financial wellbeing for Latino family caregivers.

Who is asked to participate?

You are being asked to participate because you indicated an interest in attending the CONFIDENCE Education and Training Program, offered by the University of Southern California’s Family Caregiver Support Center.

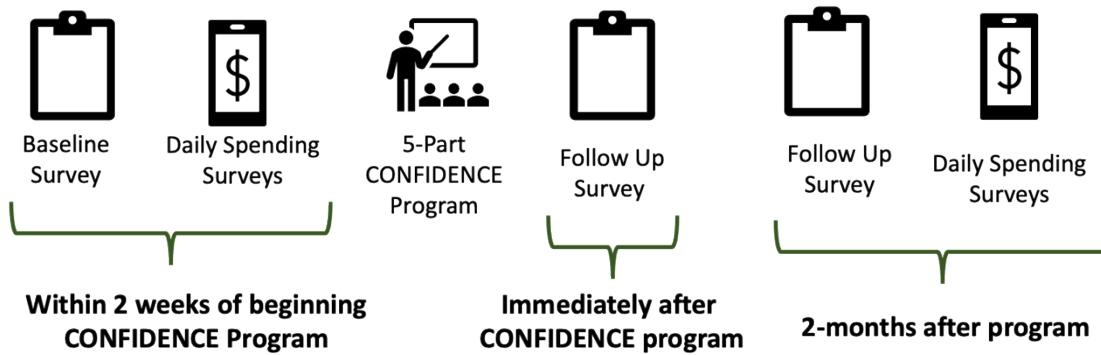
What will I be asked to do if I choose to participate?

During this study, you will be asked to complete three (3) 20- to 30-minute surveys asking about your demographic information, caregiving situations, financial stress, and out-of-pocket caregiving costs. (See the figure below, which illustrates study activities.) The first survey will be sent within 2 weeks of your beginning the program, the second will be sent within 1 week after you complete the CONFIDENCE Program, and the last one will be sent 8 weeks after completing the CONFIDENCE Program.

After completing the initial and second follow up surveys, you will be asked to complete 1 spending diary per day for 5 days (1 survey/day). For these surveys, you will be asked to complete a short (10-minute) survey each day for 5 days. We will ask about your daily spending on caregiving. You will have from 7 pm to 11 pm to complete these surveys each day, which will be sent by email. You can choose to receive text message reminders regarding the surveys each day. You do not have to agree to the text messaging in order to participate in the research. Standard text messaging rates will apply, based on your carrier and data plan, if you do choose to receive the text messages.

In addition, you will be asked to participate in the 5-week CONFIDENCE Program. This program will include attending 5 group-based sessions delivered by videoconference. Each session will last approximately 1.5 hours each. Sessions will cover topics such as how to make a budget, track spending, and how to identify community resources to lower out-of-pocket care costs. You may also be asked to complete take-home activities, such as short exercises.

CONFIDENCE Study Activities



All surveys will be completed online.

What are the risks involved with participating?

There are some risks to participating in this study, which are considered relatively minor. We describe these below to help you make informed choices about your participation in this study.

Breach of confidentiality. There is small risk that data confidentiality could be breached. This means that others outside the study team could connect your identifying information (e.g., name, phone number) with sensitive information you may provide, such as your income. We take steps to make sure no one outside the research team will likely be able to connect your identifying information with other sensitive information you provide.

It is also possible that other caregivers could share information you share about yourself during the CONFIDENCE program. We ask all participants to keep information shared during the program private. We will record some sessions of the CONFIDENCE program using Zoom. This is done to monitor how the program is delivered. These recordings will only be viewed by a member of the research team and will be deleted after the study is complete.

Remember, due to the use of Zoom to deliver the CONFIDENCE program, your privacy and confidentiality is not guaranteed.

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Negative emotions. Some participants may experience discomfort, such as embarrassment or guilt, when answering questions financial wellbeing and spending. We encourage you to contact the Alzheimer's Association 24/7 helpline should this occur:

Alzheimer's Association 24/7 Helpline:

https://www.alz.org/norcal/helping_you/24_7_helpline

How will I benefit from participating?

You may not receive any personal benefits from being in this study. We hope the information learned from this study will benefit other family caregivers in the future.

Are there any costs to participating?

For most participants, there will be no costs to you for study participation. If you choose to receive text message reminders for study surveys, you may be charged for receiving SMS by your carrier. The study team does not provide reimbursement for this cost.

Will I receive payment for my participation?

You will be compensated for your time for completing the surveys. You may receive up to \$125 for completing all study activities. Payments will be Amazon gift certificates sent by email. Your name and email address shared with a third-party solely for the purposes of compensation processing. This information will only be used to send compensation and will be kept strictly confidential.

Payment will be provided based on each study activity you complete. For example, you will receive \$25 for the baseline survey and each follow up survey, as well as \$25 for each series of daily spending surveys you complete. You may be paid up to 3 times: once after the baseline survey and first set of daily spending surveys are complete, once after the first follow up survey is complete, and once after the second follow up survey and second set of daily spending diaries are complete. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

Are there any alternatives to participating in this research?

There are no alternatives to participation besides not participating. As a reminder, we welcome and encourage caregivers to participate in the CONFIDENCE Program, regardless of whether you choose to or are eligible to participate in the study.

Is my participation voluntary?

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University or the University of Southern California Family Caregiver Support Center. There is no penalty or loss of benefits for not participating or for discontinuing your participation.

You are free to withdraw from this study at any time. If you decide to withdraw from this study, you should notify the research team as soon as possible. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety or welfare are at risk.

If you withdraw from the study, the researcher may ask you to share why you are withdrawing to help us to improve our future studies, but you may choose not to participate in these activities.

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If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what will happen to your study data. The researchers will ask for your permission to retain and analyze the study data already collected. If the data collected are de-identified (anonymous) the researchers will not have the ability to remove your study data.

How will my private information be handled?

Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Research records will be kept in a secure location and access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies, and partners at the University of Southern California involved in delivering the CONFIDENCE intervention. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant.

However, you should understand that in cases where we suspect elder or child abuse or neglect or imminent harm to self or others, we will take the necessary action in an effort to prevent such harm or injury, including reporting to authorities.

Handling of Information that Identifies You

Once the study team has an opportunity to share a summary of results, such as in academic journals, all information that identifies you will be removed and replaced with a code. While the study is ongoing, your email address and telephone number will be connected to information you share in study surveys. In this study, we use your contact information to send study surveys. A list linking the code and your identifiable information will be kept separate from the research data.

Video recordings of CONFIDENCE sessions will also be briefly stored to allow the study team to monitor how the CONFIDENCE program is being delivered. Access to these recordings is limited to the intervention facilitators and study team members. Recordings will be deleted within 2 weeks of being created.

Data Retention

The researchers intend to keep the research data until the research is published and/or presented.

Your identifiable information that are collected as part of this research will not be used or distributed for future research studies. We may retain your de-identified study information for future use.

Disclosure of Results

We will share a summary of results with you at the end of this study. We will not identify you as an individual. You may also choose to receive copies of your daily spending surveys we ask you to complete after completing the study baseline. You can download these surveys on your own or may request copies from the research team.

Contacts and Questions

The researchers conducting this study are **Kylie Meyer, PhD**. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact the researchers:

Email: knm77@case.edu
Phone: 216-368-1928

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If you would like to talk to someone *other than the researchers* about questions or complaints regarding this study, research participant rights, research-related injuries, or other concerns, please contact:
Case Western Reserve University Institutional Review Board

10900 Euclid Ave.
Cleveland, OH 44106-7230
(216) 368-4514

Statement of Consent

Please indicate whether the following statements are true by saying "Yes" or "No".

- You are at least 18 years of age.
- You understand the information provided to you about this study.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

You will be given a copy of this form for your records. I will send this form by email.