

*An AI-Embedded Intervention to Promote
Financial Wellbeing Among Latino Family
Caregivers*

NCT06134180
Informed Consent

Updated 11/3/2024



Informed Consent Document

Confidently Navigating Financial Decisions and Enhancing Financial Wellbeing in Dementia Caregiving CONFIDENCE 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 financial stress of caregiving when helping a family member living with dementia.

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 helps reduce 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 high these out-of-pocket costs and improve the financial well-being of 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 in partnership with the University of Southern California's Family Caregiver Support Center and Amicus Brain Innovations.

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

During this study, you will be asked to complete three (3) 30- to 45-minute online surveys about your demographic information, caregiving situations, financial stress, and out-of-pocket caregiving costs. The first survey will be sent within 3 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.

You will also be asked to participate in the 4-week CONFIDENCE Program. This program will include attending four 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

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resources to lower out-of-pocket care costs. You will also be asked to complete take-home activities, such as short exercises. It is estimated these will take 1 hour to complete. **The first survey, described above, must be completed before you begin attending program sessions.**

In addition, before attending group sessions, you will be registered for the NeuViCare App. This app, developed by study partner Amicus Brain Innovations, will be used to deliver parts of the CONFIDENCE program. The app includes features such as a conversational AI assistant to answer your questions about financial wellbeing and caregiving, informational text messages, and access to a community forum. Registration requires providing your name, email address, and phone number. You may also be prompted to provide zip code and insurance information to receive tailored information about resources. *You do not have to provide this information.* You may discontinue text messages from the app anytime by texting “STOP.” Registration for the app is estimated to take 10 minutes.

Please be aware that standard text message rates will apply from your service provider. You will be responsible for carrier fees when sending and receiving these text messages. Costs will depend on your mobile service provider.

Participation in this app also requires that you agree to the Terms of Service and Privacy Policy for Amicus Brain, found at the links below. Please note that if you consent to participate in this research, you also consent to these Terms of Service and agree to the privacy information from Amicus Brain.

Amicus Brain Innovations Terms of Use: <https://amicusbrain.com/termsofservice/>

Amicus Brain Innovations Privacy Notice: <https://amicusbrain.com/privacy/>

What is Artificial Intelligence (AI)?

Artificial Intelligence (AI) is a type of technology that allows computers to complete tasks that mimic a human being’s cognitive skills. With the NeuViCare app, you can message an AI digital assistant (“Keiko”) with questions you may have about caregiving. The AI will generate an answer based on trusted sources, and its response may look like one from person. *Remember, Keiko is an AI assistant, not a human being.* If you would like to contact a human being, please contact your facilitator or the research team.

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 participating 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 prevent anyone outside the research team from connecting your identifying information with other sensitive information you provide. **We will not ask you for data about your Social Security, banking, credit card, or other private financial or benefit accounts.**

You will be asked to provide your email and phone number to register for the NeuViCare app by Amicus Brain Innovations, our study partner. Amicus Brain Innovations stores user data in a HIPAA-compliant Google Compute Platform (GCP), also called Google Cloud, where data are encrypted. Study team members and those who facilitate the intervention and members of the research team will be able to view your completion of activities in the app. These individuals will not be able to see questions you send to NeuViCare's Care or Resources Advisor. For example, if you ask the Care Advisor for information about Medicaid, the researchers will not know that you searched for this information.

It is also possible that other caregivers could share information you share about yourself during the CONFIDENCE Zoom discussion sessions or in the NeuViCare community forums. 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 and the NeuViCare app to deliver the CONFIDENCE program, your privacy and confidentiality are not guaranteed by Case Western Reserve University.

Negative emotions. Some participants may experience discomfort, such as embarrassment or guilt, when answering questions financial wellbeing and spending. Members of the research team are not able to provide licensed counseling or mental health services. 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

As a reminder, NeuViCare's digital assistant, Keiko, is powered by AI. Keiko may supply responses to the information you share with it that could be therapeutic, but it is not intended to replace mental health professionals.

Accuracy of Information. Finally, while the study team tries to provide accurate information related to financial wellbeing, we cannot guarantee the guidance provided is correct for your unique situation. We do take steps to ensure that the information we provide during the program is trustworthy. For example, the conversational AI assistant used in the program, "Keiko," is informed by trusted sources selected or created by the study team.

How will I benefit from participating?

You may not receive any personal benefits from being in this study, though you may find participating in this program therapeutic and may learn new information. 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 from the NeuViCare app, you may be charged for receiving SMS by your carrier. The study team does not provide reimbursement for this cost. You may opt out of receiving text messages at any time.

Will I receive payment for my participation?

You will be compensated for your time for completing the surveys. You may receive up to \$160 for completing all study activities. Payments will be Amazon gift certificates sent by email. Payment will be provided based on each study activity you complete. For example, you will receive \$50 for the baseline and first follow-up survey, and \$60 for the second follow-up survey, sent two months after the end of the CONFIDENCE program. You may be paid up to 3 times: once after the baseline survey, once after the first follow-up survey is complete, and once after the second follow up survey is complete. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the surveys 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 of Southern California Family Caregiver Support Center, Amicus Brain Innovations, or Case Western Reserve University. 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 or 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.

If you elect to withdraw or are withdrawn from this research study, the researchers will retain your existing study data unless you request otherwise. If the data collected are de-identified (anonymous) the researchers will be unable 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 and Amicus Brain Innovations involved in delivering the CONFIDENCE intervention, and National Institutes of Health, which is funding this research. 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 the 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. Your email address will also be used to connect your NeuViCare account to your study record so that the study team can assess app utilization (e.g., completion of activities). At the end of this study, this data will be removed from the Amicus Brain Innovations Google Cloud system.

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

Data Retention

The researchers intend to keep the research data until the research is published and/or presented. This typically occurs within 2 years of all data being collected.

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. Further, you should know that a description of this clinical trial will be available on <https://www.clinicaltrials.gov/>. 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.

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

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

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