CENTER FOR HEALTH OUTCOMES AND INTERDISCIPLINARY RESEARCH (CHOIR)

CASI CENTER FOR AGING AND SERIOUS ILLNESS
Improving Outcomes in Aging & Serious Illness

MASSACHUSETTS GENERAL HOSPITAL
DIVISION OF PALLIATIVE CARE AND GERIATRIC MEDICINE

Study Title: *Supporting Our Caregivers In ADRD Learning (SOCIAL) Study: Reducing Stress for Caregivers of Persons with Dementia, an Open Pilot Study*

We are researchers from the **Center for Aging and Serious Illness and the Center for Health Outcomes and Interdisciplinary Research** at Massachusetts General Hospital who are interested in learning about how a virtual education program can be used to support the well-being of caregivers for persons with Alzheimer's disease and related dementias (ADRD). This research study is sponsored by the National Institutes of Health.

How did we get your contact information?

You may have received this information from a program you are involved in, you may have seen a flyer about it, or a friend may have told you about our research study. You may also have been referred to us by a program you are involved in or caregiver support group who mentioned that you would be interested in participating. We recorded your name, mailing address, phone number, and email address after you agreed to be screened for eligibility to participate in our study.

Study Overview

SOCIAL is a 6-week virtual support program that can help you manage some of the daily challenges of caring for someone living with dementia and reduce stress. It is normal to experience difficulties in day-to-day life, but overtime stress can begin to have effects on you physically and emotionally. This program can help you understand these effects, provide strategies to cope, and learn practical skills to support you and your loved one with dementia.

We are asking up to 88 volunteers who are 18 years or older, fluent in English, meet the criteria for an informal caregiver (e.g., family or friend of a care recipient who providers unpaid care), and live with and care for an individual with ADRD to participate. The informal caregivers must have lived with the patient for more than 6 months and must currently provide more than 4 hours (average) of supervision or direct assistance to the care recipient per day. Caregivers must also not be currently enrolled in another clinical trial for caregivers and cannot have used a mindfulness or meditation app for more than 60 min/week in the past 3 months.

What will your participation look like?

If you meet criteria and choose to take part in this research study:

- You will participate in 6 weekly virtual group sessions
- You will be asked to complete 3 assessments: baseline (before the program), post-program (immediately after the program ends) and 3-months after the program ends.
- You will learn strategies to navigate the daily challenges of dementia caregiving and finding ways to better care for yourself and your care recipient
- You will participate in various session exercises and will be asked to complete daily surveys to mark if you engaged in the assigned exercise at some point in the day

- You will interact with other caregivers of people living with dementia

Additionally, if you decide to participate you will be assigned randomly, or by chance, like flipping a coin, to one of two programs (SOCIAL 1 or SOCIAL 2). Both programs are developed to decrease stress among caregivers of persons with dementia with behavioral symptoms. We have no control over what group you will be assigned to. This is done so that a fair evaluation of the impact of this program can be made.

Compensation

You may receive up to $120 for participating in this study: $20 after enrollment and completion of the baseline survey, $40 at completion of the intervention and completion of the post-intervention survey, and $60 for completion of the 3-month survey. Participants will receive payment in the form of a prepaid Visa gift card.

What are the risks?

An unlikely but potential risk is that participants may find some parts of the discussion to be emotionally upsetting. The research team has experience in dealing with these situations and will address this situation if it arises.

Another potential risk could include breach of privacy or confidentiality. We ask that participants refrain from sharing any other participant's identifiable information outside of our group. However, participants are allowed to share their contact information with other participants if they choose to do so.

Additionally, the weekly group sessions will be audio-recorded. However, only trained members of the research team will have access to these recordings. These recordings will be stored within the Mass General Brigham firewall, which is secure, and password protected. No one will know what you said other than trained members of the research team.

Each participant will be assigned a participant ID # to keep the data we collect at the baseline, post-intervention, and 3-month follow-up confidential. Only members of the research team will know that the assigned participant ID belongs to you. Your de-identified information may be used or shared with other researchers without your additional informed consent. We will destroy all of your study documents and recordings when the project is completed, although, because research is an ongoing process, we cannot give you an exact date.

Lastly, the SOCIAL research study involves sending you text messages using the Twilio app. You do not have to agree with receiving text messages in order to participate. Twilio is an MGH approved app that has been used in similar research studies. These text messages will include information about session reminders, reminders to complete homework logs, and activity prompts to complete before upcoming sessions. We will send these messages daily during the 6-weeks.

Text messages by mobile/cell phones are a common form of communication. However, texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message communications.

You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts (Include language if participants are paid/given stipends to cover potential charges).

Text messages will only be read during regular business hours. Texts sent on nights or weekends will not be read until Monday.

Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says, "Stop Research Text."

Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

Now I will read out a statement to you which you can respond by saying "Yes" or "No":

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

- Yes
- No

Will your participation affect the medical care you receive?

Remember that participation in this research study is voluntary, and that you can refuse to answer any question or end the interview at any time. Participation in this study does not affect any medical care you choose to receive at a Mass General Brigham health care provider now or in the future.

HIPAA

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information that you provided us. This is an abbreviated notice and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

Questions?

If you have any questions about the research, you can contact the Principal Investigators: **Christine Ritchie, MD (617-726-1382) or Ana-Maria Vranceanu, PhD (617-724-4977) Monday through Friday, 9:00am to 5:00pm.** If you have questions about the scheduling of sessions compensation, call Aniyah Travis at (617) 726 – 9632 or Sahana Giridharan at (617) 726-1279. If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Mass General Brigham IRB at (857) 282-1900.

In your own words may you tell me what the study is about and what is being asked of you through your participation.

Do you consent to participating in this study?

- Yes; accepts participation.
- No; declines participation.