Informed Consent Form

Keeping on Course: A Communication-Focused Psychoeducation Program for Dyads Coping with Mild Cognitive Impairment

IRB Approval Date: January 5, 2025

NCT05423912

Emory University
Oral Consent Script
For a Research Study

Title: Keeping on Course: A Communication-Focused Psychoeducation Program for Dyads Coping with Mild Cognitive Impairment

IRB #: STUDY00003645

Principal Investigator: Kenneth Hepburn, PhD

Sponsor: Emory Roybal Center for Caregiving Mastery, which is supported by the National Institute on Aging (NIA) within the National Institutes of Health (NIH).

Introduction and Study Overview

Thank you for your interest in our Mild Cognitive Impairment research study. We would like to tell you what you need to think about before you choose whether or not to join the study. It is your choice. If you choose to join, you can change your mind later on and leave the study.

You have been invited to participate in this study because you or your family member have been diagnosed with Mild Cognitive Impairment (MCI). Coping with Mild Cognitive Impairment can be challenging for those who have the disease and those who provide informal care, such as family members. The purpose of this study is to test a new psychoeducational program designed to help you and your family member (referred to in this document as a patient-care partner "dyad") improve their ability to cope with MCI. Similar programs have successfully helped dyads cope with more advanced types of dementia, so the researchers want to know if such a program can work in the context of MCI.

The study is funded by the Emory Roybal Center for Caregiving Mastery, which is supported by the National Institute on Aging (NIA). The entire study will take at most 12 months to complete. The psychoeducational program will last no more than 12 weeks and we will follow up with you 4 weeks and 8 weeks after you complete it. Study staff expect to enroll about 48 people into the research study.

If you join, you will be asked to take part in weekly or biweekly virtual education sessions with several other MCI patients and care partners. The sessions will last no more than 12 weeks and each session will be 1-2 hours long. The sessions will take place over Zoom video conference. Study staff will interview you by phone or over Zoom video conference three times throughout the study: Once before you begin the psychoeducational program; again 4 weeks after completing the program, and finally 8 weeks after completing the program. The interview questions will ask about your relationship with your family member/ care partner, your beliefs about caregiving, emotions related to caregiving, stress and anxiety, and coping strategies related to caregiving. Interviews will last no more than one hour. Your total participation in the study will last no more than 20 weeks. After completing the study, you may be asked to participate in a more detailed interview over Zoom to discuss your experience and to offer recommendations for changes. This is optional. If you express interest in participating, study staff will provide more information. Total time spent participating in the study, including the optional end-of-study interview, will not exceed 26 hours.

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.

Risks and Discomforts

We do not think there is much risk in taking part in the study. The lessons, homework assignments, and survey questionnaires are focused on caregiving, which may be an emotional topic. If you become uncomfortable during any of the educational sessions, you can take a break, end the session early, or stop participating at any time. Similarly, if you feel uncomfortable answering any of the survey questions, you may skip questions or stop participating at any time. Several study staff have experience and skill in managing emotional distress and can provide additional resources to you if needed. The Emory Roybal Center and the National Institute on Aging, however, have not set aside funds to pay for additional care.

There is also a risk of loss of confidentiality of your personal information that is used in this study. While we will take measures to protect your information, we cannot guarantee complete confidentiality. See the sections below on "Storing and Sharing your Information" and "Confidentiality" for more details.

Benefits

You may not benefit from joining the study. You or your family member's condition may improve while you are in this study or it may get worse. This study is designed to learn more about how people living with MCI and their care partners can improve their ability to cope with that condition. If you are a care partner, you may benefit from the study by becoming better equipped to handle your caregiving role. The lessons you will get are designed to help you understand the disease your loved one has and improve your communication skills. If you are a person living with MCI, you may experience positive changes in your relationship with your care partner during and/or after participating in this study. Even if you do not benefit personally, the information gained may help others in the future. Your participation will help us improve this program and inform future MCI caregiving education programs.

You will receive a $25 gift card for each interview with study staff that you complete. We will ask you to participate in three interviews, so you will have the opportunity to earn three gift cards, totaling $75.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,

- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. A file linking your study ID number to your name will be kept in the Principal Investigator's password-protected server in the School of Medicine.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. Only your first name will be known by other participants in your assigned education group and a study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results. No study results will appear in your medical records.

People Who will Use/Disclose Your Information:

The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study.
- Emory may use and disclose your information to get payment for study related activities and to run normal business operations.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your information to make sure the research is done correctly and safely:

  - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
  - Government agencies that regulate the research including the Office for Human Research Protections.
  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Study information will also be publicly posted, maintained, and available for review at ClinicalTrials.gov.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. Kenneth Hepburn at [redacted] or [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____

Name of Participant

_____

Name of Legally-Authorized Representative (if non-treatment study, must be parent/legal guardian of minor, or have Power of Attorney for Research)

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Relationship of Legally-Authorized Representative to Participant

Signature of Person Conducting Informed Consent Discussion | Date | Time

Name of Person Conducting Informed Consent Discussion