

Resilient Together for Dementia: A Live Video Resiliency Dyadic Intervention for Persons With Dementia and Their Care-partners Early After Diagnosis

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CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

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Study ID: STUDY-23-01360
Form Version Date: 30.January.2024

STUDY INFORMATION:

Study Title: Open Pilot of Resilient Together for Dementia: A resiliency skills-based program for couples shortly after diagnosis

Principal Investigator (Lead Researcher): Sarah Bannon, PhD

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Phone: 212-241-5152

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to evaluate a new psychological therapy focused on coping skills to prevent distress and improve resilience in couples following one partner's diagnosis of Alzheimer's disease or a related dementia (ADRDs).

If you choose to take part, you will be asked to participate in:

- 1) An online survey on your mood, health, and relationships before and after the therapy program
- 2) 6 weekly therapy sessions (30-60 minutes each) led by a clinical psychologist
- 3) An optional 60-minute virtual interview after the therapy program

You will also agree to have private information and study data stored for the duration of the study. Your participation in this research study is expected to last approximately 8-10 weeks.

You will each be compensated with a \$80 check (\$40 per each survey assessment). There is no cost to you for taking part in this study.

If you choose to take part, the main risks to you are risk of discomfort and a risk of loss of privacy of information.

You may not benefit directly from taking part in this research.

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If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because either you or your partner has recently been diagnosed with Alzheimer's disease or related forms of dementia.

Your participation in this research study is expected to last 8-10 weeks (Initial 30 minute survey, 6 weekly therapy sessions over Zoom, followed by a 60-minute virtual interview with your partner together or separately, and then a follow-up 30-minute survey).

There are up to 10 couples (20 people) expected to take part in this research study within MSHS (Mount Sinai Health System).

Funds for conducting this research study are provided by the National Institute on Aging.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- **Medical Information:** The research team will obtain medical information from your electronic medical records related to your diagnosis, including the date you were diagnosed, your diagnosis, and current symptoms. The research team will store this information on a secure server. Only our study staff will have access to this information.
- **Pre-program Survey:** You will also be asked to complete an online survey individually containing several questionnaires about your mood, health, and relationship. You can choose to complete this survey over a secure, live-videoconferencing program (via a secure Zoom platform) with a member of our study staff. The survey may take you 30-60 minutes to complete. If you prefer, you can also be sent a link to your email address to complete the survey on your own. You can choose to skip any questions that you chose not to answer and end your participation in the survey at any time.

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- **Resilient Together Intervention:** You and your partner will attend 6 weekly sessions of a therapy program led by a licensed clinical psychologist. The program includes education and coping skills training focused on common challenges and stressors experienced by couples early after dementia diagnoses. Sessions will last 30-60 minutes each and will be held over a secure video portal (Zoom healthcare). You will be required to have access to a personal computer or smartphone equipped with a webcam or other video/audio capture device. The study will not provide you with a computer. In addition, you will be required to download and install Zoom conferencing software to participate in this research study. This software is available for download, and Zoom may run through an Internet browser. Study staff will give you specific instruction on how to locate and install this software. You can end your participation in the program at any time.
- **Exit Interview:** The research team will complete a 60-minute interview with you and your partner in which you will be asked about your experience with the therapy program and suggestions for modification (if any). The research team will conduct this interview using a secure video portal (Zoom healthcare). You may refuse to answer any questions that make you feel uncomfortable, and you can end your participation in the discussion at any time. This interview will be audio recorded, transcribed to text, and deidentified.
- **Post-program Survey:** After the therapy program, you will be asked to complete an online survey containing several questionnaires about your mood, health, and relationship similar to the baseline survey. You can choose to complete this survey over a secure, live-videoconferencing program (via a secure Zoom platform) with a member of our study staff. The survey may take you 30-60 minutes to complete. If you prefer, you can also be sent a link to your email address to complete the survey on your own. You can choose to skip any questions that you chose not to answer and end your participation in the survey at any time.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes _____ No _____

If "Yes", please indicate your preferred method of contact: (initial all that apply)

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☐ Email ☐ Phone ☐ Letter ☐ Text

USE OF YOUR DATA AND/OR SAMPLES:

The research team will never use or share your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) that are collected as part of this study for future research, even if your identity is removed. Your data and/or samples will only be used to complete this study and then they will be destroyed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things: attending a virtual study interview with your partner and completing an online survey.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this study, you will be paid with a \$80 check each for your time and effort following the completion of both pre-program and post-program surveys. Payment will be provided at the end of your participation in the post-program survey. If you only complete the pre-program survey, you will instead receive a \$40 check each.

It can take up to 6 weeks to prepare and give you a check for study participation. If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal \$600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

You may experience benefits from receiving educational resources and coping skills training to address common challenges faced by couples after diagnosis. There are also possible future benefits to others that include revised skills and content to include in a post-diagnosis support program.

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POSSIBLE RISKS AND DISCOMFORTS:

- Psychological risks (for example, embarrassment, fear, or guilt)
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. For example, all data collected will be labelled with a code instead of your name and stored securely. Only study staff will have access to your name.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

Instead of being in this research study, your choices may include:

- *Supportive care – the study team can provide a resource list to local support groups and websites containing resources related to Alzheimer's dementia and caregiving.*
- *Psychotherapy- the study team can provide referrals to individual or couple/family counselors and psychotherapists within the Mount Sinai health system.*

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

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If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number (212-241-5152).

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?

PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

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Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your: names, address, telephone number, e-mail addresses, and self-reported information on your health and relationship health. For those with a recent MCI/ADRD diagnosis, the research team will obtain your medical record number, dates directly related to you as an individual (assessment, diagnosis), measures of cognitive status.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The sponsoring government agency and/or their representatives who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institute on Aging.

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In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. *Additionally, OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?

Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?

NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

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Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information

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about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

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ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant

Printed Name of Participant

Date

Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate

Printed Name of Consent Delegate

Date

Time

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