Project Tile: EM/PROTECT-Hybrid: Improving Depression in Elder Mistreatment Victims

Brief Title: Trial to Test Effectiveness of Depression Intervention for Mistreated Older Adults

NCT Protocol Number: NCT04258579
Unique Protocol ID: 19-09020854
Document Date: Feb 07, 2022

Principal Investigator: Jo Anne Sirey, Ph.D.

WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Research

Project Title:	EM/PROTECT-Hybrid: Improving Depression in Elder Mistreatment Victims
Research Project/Protocol #:	19-09020854
Principal Investigator:	Jo Anne Sirey, Ph.D.
Subject Name or number:	

Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.

INSTITUTION: Weill Cornell Medical College

INTRODUCTION

You are invited to participate in a research study. You were selected as a possible participant in this study because you are a social worker.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) If you choose not to participate in the study or if your decision changes, your regular care will not be affected. In addition, you will not lose any of the benefits to which you are entitled.

(c) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other important information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members

of the research team. Please take whatever time you need to discuss the study with your physician and family/loved ones/friends. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.
The research study is being sponsored by *the National Institute of Mental Health* (NIMH). NIMH is called the Sponsor and Weill Cornell Medical College ("WCMC") is being paid by NIMH to conduct this study. Jo Anne Sirey, Ph.D. is the primary investigator.

The study will take place at Weill Cornell Medical College and the NYC Department for the Aging (DFTA) Elderly Crime Victims Resource Center (ECVRC). Depending on your preference, some portions of the research assessments can take place at the ECVRC, DFTA, or your home, in addition to Weill Cornell Medical College offices.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to test the feasibility, acceptability, and preliminary effectiveness of a mental health intervention for victims of elder abuse experiencing depression. This intervention will be delivered in three different ways (in-person, in person/self-administered, video delivery). This research is being done to learn the most effective way to serve older, depressed individuals who have experienced elder abuse.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.
About 60 subjects will take part in this study worldwide; 60 subjects will be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

In this study, you will conduct therapy sessions with participants who have been randomly assigned to the EM/PROTECT group. If the participant is randomized into the traditional PROTECT therapy group, you will administer 9 in-person therapy sessions. If the participant is randomized into the hybrid PROTECT therapy group, you will administer 5 in-person sessions. If the participant is randomized into the video PROTECT group, you will administer 9 video therapy sessions. Randomization means that each participant is put into a group by chance. It is like flipping a coin.

Your participation in the study has two parts. In the first part of the study, you will be asked to complete a brief questionnaire about your socio-demographic background (age, education, etc.). The questionnaire is expected to take about 5 minutes to complete. In the second part of the study, you will attend a one-day workshop for training in EM/PROTECT therapy. The training will consist of role-play, didactics, and review of previously audiotaped sessions. After the workshop, the therapist will administer six PROTECT sessions to two pilot paticipants during the first four months. To be certified in EM/PROTECT, therapists must achieve a score of 4 or greater (very good) out of 5 on the EM/PROTECT Adherence Scale. If you achieve certification by study

investigators, you will be asked to provide therapy to depressed victims of elder abuse over the next 24 months. If you do not achieve certification by study investigators, your participation may be terminated.
You will be asked to audiotape your sessions with patient subjects for the purposes of supervision and evaluation of therapist adherence to the therapy protocol. Patient subjects will be asked during the consenting process to indicate whether or not they wish to be audio taped. You will be trained to use the audio recorder and upload files into our secure password protected drive.

Your performance will be reviewed by study investigators and you will be provided with feedback and supervision. We will hold a brief weekly meeting with EM staff pertinent to the study to review recruitment ad address procedural issues as they emerge in order to assure that the project becomes organic to each agency.

Every six months, we will ask you to complete the Client Satisfaction Questionnaire (CSQ; 4 items; 4 point scale; e.g., "How satisfied are you with the services you are offering?" supplemented by open ended comments on EM/PROTECT and EM/MH and recommendations for future project.

PROTECT Session Weeks: 1 2, 3, 4, 5, 6, 7, 8, 9

Research Assessment Weeks*:* Baseline 6* 9* 12
**During the week following the 6th and the 9th session*

	Traditional PROTECT	**Hybrid PROTECT**	**Video PROTECT**
Session 1	In-person session	In-person session	Video session
Session 2	In-person session	In-person session	Video session
Session 3	In-person session	In-person session	Video session
Session 4	In-person session	In-person session	Video session
Session 5	In-person session	In-person session	Video session
Session 6	In-person session	Self-Administered Session	Video session
Session 7	In-person session	Self-Administered Session	Video session
Session 8	In-person session	Self-Administered Session	Video session
Session 9	In-person session	Self-Administered Session	Video session

HOW LONG WILL I BE IN THE STUDY?

The study will be recruiting patient subjects over a 24-month period. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to Dr. Jo Anne Sirey, the primary investigator, first.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time if they feel it is in your best interest, if you experience a study-related injury, or if you do not follow the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent. Your participation can be terminated at any time by the investigators, and the termination of your participation in the study will also lead to the immediate termination of your per diem employment position.

WHAT ARE THE RISKS OF THE STUDY?

There is minimal risk to you for participating in this study. Your participation involves the risk of possible personal distress over your ability to provide psychotherapy for geriatric depression, and possible loss of confidentiality relating to your ability to perform this task. Every effort will be made to minimize this possibility. No individual-level data related to therapies will be made available in any communications, oral reports, or publications. If a patient participated in the study and decided to initiate a specific depression treatment, the possibility exists that they may not respond to such psychotherapy.

If at any point you feel that this study is putting you at risk, please contact research staff or the principal investigator. Your participation is strictly voluntary and you may choose to discontinue with the study at any time point with no penalty. For more information about risks and side effects, please contact the principal investigator, Jo Anne Sirey, Ph.D. at (914) 997-4333.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from this study. The study may identify effective psychotherapies for depression in elder abuse victims that can be used by community clinicians.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:
The alternative to participating in this study is to not participate in the study and continue receiving your existing services.
You may choose not to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medical College
- The WCMC Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services
- National Institutes of Health
- National Institutes of Mental Health

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Weill Cornell Medical College and New York-Presbyterian Hospital by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database: Computers are kept in a locked room; access is password protected and only study staff are authorized to view such data have the password. Master lists identifying patient subjects with numbers will be kept in locked file cabinets. All the staff participating in the study are trained in protecting human subjects in research. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

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.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, Weill Cornell Medical College researchers need your permission to use your protected health information. If

you give permission, Weill Cornell Medical College researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give Weill Cornell Medical College researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for Weill Cornell Medical College researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Weill Cornell Medical College.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes demographic information, current medications, mood symptoms, access to services, quality of life, and cognitive/memory tests.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with research staff and support personnel as well as collaborating investigators.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

Use of Psychotherapy Notes

What are Psychotherapy Notes for Research? Weill Cornell Medical College may use or share (disclose) information about you from the doctor's notes about your psychotherapy sessions for this study that is considered to be protected health information.

RESEARCH REPOSITORY

What is a Research Repository? A research repository (database) is a collection of information from the health and medical records of many individuals and can sometimes include identifiable specimens (like your tissue). The repository (database) may share the information with researchers who study medical conditions and diseases.
The repository (database) includes codes that identify each person whose information is collected. However, the repository does not share information with researchers unless the researchers promise to keep the information confidential.

RESEARCH PARTICIPANT: Please check the box below that describe your wishes:

☐ The NIMH Repository may keep my protected health information and/or specimens and share it with qualified researchers studying the research described above. If information goes to an outside entity then the Privacy Rule may not apply.

☐ The NIMH Repository may keep my protected health information and/or specimens and share it with qualified researchers studying the research described above **AND** for unspecified research to be done in the future. I understand that the samples will be stored for _____ as long as it is deemed useful and will be destroyed after the research is completed. If information goes to an outside entity then the Privacy Rule may not apply.

☐ The NIMH Repository may not keep my protected health information for a research repository.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCMC and/or NYPH and DFTA researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

End of Permission: Unless you cancel it, permission for WCMC and/or NYPH and DFTA researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, **you will have access** to see or copy your protected health information as described in this authorization form in accordance with Weill Cornell Medical College (WCMC) and/or New York-Presbyterian Hospital (NYPH) policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

CERTIFICATE OF CONFIDENTIALITY

A Certificate of Confidentiality has been granted by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators (research/study staff) from being forced to release any research data in which the subject is identified even under a court order or subpoena. This protection is not absolute. For instance, it does not override any state requirement to report child abuse to the appropriate authorities.

WHAT ARE THE COSTS?

You will not have to pay for the therapy, or any technology provided You or your insurance company will have to pay for continuing medical care and/or hospitalization that are not a part of the study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for Weill Cornell Medical College are as follows: In accordance with Federal regulations, we are obligated to inform you about WCMC's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCMC or New York Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962.8200.

COMPENSATION FOR PARTICIPATION

You will be hired and paid per diem as a salaried employee. This payment is contingent upon your participation in the study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Weill Cornell Medical College, New York Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Jo Anne Sirey, Ph.D. at (914) 997-4333 or the hospital operator at 914- 682-9100 and ask that she be paged. Be sure to inform the physician of your participation in this study.
If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
(646) 962-8200
1300 York Avenue
Box 89
New York, New York 10065

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Jo Anne Sirey, Ph.D. and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date