Reaching and Engaging Depressed Senior Citizen Clients (REDS II)

NCT04289298

January 6, 2022

WEILL CORNELL MEDICINE

Consent Form for Clinical Investigation

Project Title:	Reaching and Engaging Depressed Senior Center Clients Phase II (REDS II)
Research Project #	19-09020810
Principal Investigator:	Dr. Patricia Marino, Ph.D.
Arm/Group:	CLINICIAN SUBJECT FORM
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 Medicine

INTRODUCTION

You are invited to consider participating in a research study. The study is called "Reaching and Engaging Depressed Senior Center Clients Phase II" (REDS II). You were selected as a possible participant in this study because you are a clinician.

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

(c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other 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. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you

need to discuss the study with your physician and family. 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 is being sponsored by the National Institute of Mental Health (NIMH). NIMH is called the Sponsor and Weill Cornell Medicine (WCM) is being paid by NIMH to conduct this study. Dr. Patricia Marino, Ph.D. is the primary investigator.

This study will take place at Weill Cornell Medical College and the New York City Department for the Aging (DFTA) Senior Centers.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to investigate whether community-based social workers can achieve and maintain competence in a new type of interventions called Augemented Engage (Engage-A), and to study its effectiveness of treating depression in older adults in community settings. This research is being done because the researchers are trying to learn if these approaches could be used by therapists in community social service agencies to treat older adults with depression.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as clinician subjects.

About 10 clinician subjects will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

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 be trained in Engage-A. Training involves a half-day workshop followed by role play and practice cases. If you achieve certification by study investigators, you may be asked to provide psychotherapy to elderly depressed patient subjects over the next 24 months. If you do not achieve certification by study investigators, your participation may be terminated.

You will be asked to audio tape 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.

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. Patricia Marino, the primary investigator first. Your relations with WCMC, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

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 should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

Your participation in the project involves the risks 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 subject participates in the study and decides to initiate a specific depression treatment, the possibility exists that they may not respond to such psychotherapy.

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 late life depression that can be used by community clinicians.

WHAT OTHER OPTIONS ARE THERE?

Your decision to participate in the study is strictly voluntary. Your decision will have no influence on your job status or your performance evaluations. If you decide to participate, you are free to discontinue participation at any time.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect any personal information obtained during this study to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements. 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 records for quality assurance and data analysis include groups such as:

- Weill Cornell Medicine
- New York Presbyterian Hospital
- The WCMC Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services
- National Institutes of Health

By signing this consent form, you authorize access to this confidential information.

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 will be password protected to prevent unauthorized disclosure, tampering, or damage of the information kept in computers. Master lists identifying clinician subjects with numbers will be kept in locked file cabinets. In addition, all the staff participating in the study are trained in protecting human subjects in research and 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 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.

Additionally, information regarding your performance on the study will not be shared to any other employers.

DATA SHARING:

Data from this study may be submitted to the National Database for Clinical Trials related to Mental Illness (NDCT). NDCT is a computer system run by the National Institutes of Health that allows researchers studying mental health to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about chronic pain and depression more quickly than before.

During and after the study, the researchers will send information about your health and behavior, if applicable, to NDCT. However, before they send it to NDCT, they will remove information such as name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with the National Institutes of Health to obtain access to your study data for research purposes. Experts at the National Institutes of Health who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDCT. The information provided to NDCT might help researchers around the world treat patients with chronic pain and depression so that they have better outcomes. NDCT will report to Congress and on its website about the different studies that researchers are conducting using NDCT data; however, NDCT will not be able to contact you individually about specific studies.

You may decide now or later that you do not want to share your information using NDCT. If so, contact the researchers who conducted this study, and they will tell NDCT, which can stop sharing the research information. However, NDCT cannot take back information that was shared before you changed your mind. If you would like more information about NDCT, this is available on-line at http://ndct.nimh.nih.gov.

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 Medicine researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medicine 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 Medicine 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 Medicine 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 Medicine.

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. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study.

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 information that may be shared with the sponsor and/or government agencies could include 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.

Future Research: You may agree to allow your data to be used for future research within Weill Cornell Medicine or at outside institutions and private companies. If information goes to an outside entity then Weill Cornell Medicine cannot ensure the privacy rule is followed.

CANCELING AUTHORIZATION

Canceling Permission: If you give the Weill Cornell Medicine 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 Weill Cornell Medicine 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 Medicine 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?

There will be no cost whatsoever to you for your participation in this study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for the Sponsor are as follows: The National Institute of Mental Health will not pay for care necessitated by a research related injury.

The Policy and Procedure for Weill Cornell Medicine are as follows: In accordance with Federal regulations, we are obligated to inform you about Weill Cornell Medical College'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 Weill Cornell Medical College. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will be hired and paid as a per diem or 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 employment record will not be affected nor will your relations with Weill Cornell Medicine.

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 or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Patricia Marino, 914-997-8691, or the Institute of Geriatric Psychiatry, Weill Cornell Medical College, 914-682-9100.

If you have questions about your rights as a research participant, contact the Weill Cornell Medical College IRB Office. Direct your questions to:

Institutional Review Board at:
Address: 407 East 61st Street, First Floor
New York, NY 10065
Telephone: (646) 962-8200

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 (Primary Investigator or Co-investigator)	Print Name of Person	Date / Time

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 employment and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Patricia Marino and the research staff if I experience any problems related to participating in this study.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date / Time