STUDY TITLE: Social Reward and Its Effect on Brain Functions in Psychotherapies for Mid- and Late-Life Depression

NCT04487730

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WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title:	Social Reward Psychotherapy and its Effect on Brain Functions in Mid- and Late-Life Depression
Research Project #:	20-04021860
Principal Investigator:	Nili Solomonov, Ph.D.
Subject Name or Number:	

INSTITUTION: Weill Cornell Medical College

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you are a middle-aged or older adult with symptoms of depression.

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 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. 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 study is being funded by the National Institute of Mental Health (NIMH). The NIMH is providing funding for Dr. Nili Solomonov, the primary investigator.

The study will take place remotely and at Weill Cornell Medical College, on either the Westchester or Manhattan campus. Some portions of the study may take place at facilities of New York Presbyterian Hospital, where the investigators are members of the medical staff. New York Presbyterian Hospital is neither a sponsor nor an investigator for this study. The MRI scan will take place at the Citigroup Biomedical Imaging Center (CBIC) of Weill Cornell Medicine.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to examine changes in brain function, thoughts, feelings, and behavior that occur during treatment for depression with two types of psychotherapy called SRP (Symptom Review and Psychoeducation) and Engage & Connect. This research is being done because the researchers are trying to learn how these approaches work, which may allow us to improve the therapies or help us determine who will be most likely to benefit from them in the future.

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, all of whom will be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the following tests and procedures:

Therapy Assignment:
You will be assigned to one of the two study therapy groups:

- One group will be treated with a form of psychotherapy called Engage & Connect, which encourages people to engage in social activities that they find pleasurable or rewarding.
- The other group will be treated with a form of psychotherapy called Symptom Review and Psychoeducation (SRP), which provides helpful education on depression and a review of the emotional difficulties one faces during depression.

Whether you receive Engage & Connect or SRP, you will meet with your study therapist for appointments once per week. These appointments will be held remotely by phone or video, or in-person at the Weill Cornell Medicine Medical Center. If you choose to have therapy sessions in person, these sessions will happen at the Department of Psychiatry at Weill Cornell Medicine within a private interview room. During these in-person sessions, a member of our research team will be present to help in setting up the Zoom call, through which you will engage in the therapy session with the clinician. Please note that therapy sessions will always be conducted remotely. However, if you prefer an in-person setting, you have the option to visit the medical center, where we will arrange the Zoom meeting for your session.

Therapy sessions will be video or audio-recorded for the purposes of supervision, and evaluation of therapist adherence to the therapy protocol (e.g., therapist interventions, therapeutic interactions, etc.). These recordings will not be labelled with information such as your name, date of birth, or other identifying information.

Research Assessments
You will be asked to participate in assessments this week and 3, 5, and 9 weeks from now. The assessments will be conducted remotely by video. Each assessment will consist of questions about your mood, thoughts, and physical health. If you choose to do the assessments in person, these sessions will happen at the Department of Psychiatry at Weill Cornell Medicine within a private interview room. During these in-person sessions, a member of our research team will be present to help in setting up the Zoom call, through which you will engage in the assessment. Assessments will always be conducted remotely. However, if you prefer an in-person setting, you have the option to visit the medical center, where we will arrange the Zoom meeting for your session.

Research assessments or the initial eligibility assessment may be video or audio-recorded for the purposes of exploratory analyses, supervision, and evaluation of study personnel. These recordings will not be labelled with information such as your name, date of birth, or other identifying information.

MRI Scan Session

You will be asked to participate in 3 magnetic resonance imaging (MRI) scans this week and 5 and 9 weeks from now. The scans will be performed at the Citigroup Biomedical Imaging Center (CBIC) of Weill Cornell Medicine in Manhattan. The MRI scan will take place within a week of the clinical and cognitive assessment session. The entire MRI scan session will last approximately 2 hours, including preparation for the scan, a brief practice session, and the scan itself. The MRI is non-contrast and is limited to a scan of your head. The scan itself will last approximately 60 to 90 minutes, during which time your head and upper body will be immobile and at rest in the MRI scanner.

During part of the MRI scan, you will be asked to complete tasks while looking at a screen using a button response pad in the MRI scanner. The tasks involve looking at a series of pictures and words. You will practice these tasks outside of the scanner and have the opportunity to ask the experimenter questions before the scan begins. You will then complete two tasks inside of the MRI scanner. The tasks will be divided into runs that will last approximately 8-12 minutes each.

Schedule of Procedures:

Below is a chart showing the timeline of therapy sessions and research assessments.

Week	**Baseline**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Therapy Session		X	X	X	X	X	X	X	X	X
Research Assessment	X			X		X				X
MRI Scan	X					X				X

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

Taking antidepressant medication does not exclude you from participating in this study. However, if you are taking antidepressants, you must have been on a stable dose of an antidepressant for 8 weeks (without intending to change the dose in the next 10 weeks). The antidepressant type and dosage must be determined by your own physician, as it is unrelated to the research study and participation.

Mobile Device and Wearable Device

If you agree to participate and do not own a computer or smart device, we may provide you with a tablet to use for the duration of the study. If you agree to participate, you may be given a wearable device to use for the duration of the study. The wearable device will track your steps, sleep and heart rate while it is being worn. We ask that you wear this wearable device as much as possible. This device monitors your steps, sleep, and heart rate. You may also be asked to download an application on your smartphone that connects to the wearable device that you will use as part of the study. Data will be stored on a secure server. Please read and review the specific terms and conditions as well as privacy policies on the

manufacturer's website for the wearable device and its associated application. Study investigators may direct you to this information. You will be provided with a de-identified study ID in order to protect your privacy. At the end of the study, you are required to return all devices.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for approximately 9 weeks.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. If you decide to discontinue receiving therapy, you will still be invited to complete the remaining research interviews.

You may be withdrawn from the study if it is found that you do not meet eligibility criteria, or if you choose to terminate participation prematurely. A member of the study team will discuss termination from the study with you. You may be referred to other research studies within the Institute, or you may be referred to clinical services at NYPH; you may also continue treatment with your own provider or be referred to a provider in the community. The investigators will be available to you and your providers when requested, even after the end of the study.

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 WCMC, NewYork-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

Withdrawal by investigator, physician, or sponsor

The investigators, therapists, 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, if you need additional or different medication, 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?

For trials involving psychotherapy and MRI, there may be risks. These risks will be discussed with you by a research team member and/or your regular provider.

Risks and side effects related to the therapy we are studying include: possible distress related to answering questions about your mood, thinking, and physical functioning; possible fatigue or boredom as a result of repeated evaluation of your mood and mental state; and other unforeseeable risks. However, you do not have to answer any questions you choose not to, and you may discontinue the session if you wish.

Risks related to the clinical assessments include possible distress related to answering questions about your mood and mental state, boredom and fatigue during some of the assessments, and other unforeseeable risks. You do not have to answer any questions you chose not to, and you may discontinue your assessment session if you wish.

Risks related to the MRI scan include anxiety and discomfort. The MRI scan involves lying motionless with your head and the upper part of your body in a narrow chamber. You will also hear loud noises during the scan.

Ear plugs and headphones will be provided to minimize the noise and padding around the head will be inserted to make you as comfortable as possible. You will be able to talk to the MRI technician throughout the MRI scan, and if you wish, the scan can be paused or terminated at any time.

The magnet in the MRI scanner can cause electronic devices like pacemakers, cell phones, and watches to malfunction, and metal objects may be pulled into the magnet. If you have metal in your body, there is a chance it can become dislodged. You will be given a questionnaire prior to the scan to screen for metal or devices in your body.

The wearable device will be used in accordance with its approved and marketed use. Additionally, they may be adjusted for size for your comfort level. However, you may discontinue use if you wish to do so at any time. Additionally, there is risk of loss confidentiality that is mitigated through strict privacy protection protocols and use of study specific ID numbers.
Additional physical risks associated with wearing the wearable device (smartwatch) may occur, primarily discomfort or skin irritation from the watchband. Please inform the study team immediately if you experience physical discomfort from the smartwatch.

There may also be side effects other than those listed above that we cannot predict. For more information about risks, ask the research assistant or contact Dr. Nili Solomonov at 844 999 8746 ext. 718 or nis2051@med.cornell.edu.

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. It is possible that the therapy you receive as part of this study will treat your depression effectively. We hope the information learned from this study will benefit other patients with depression in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have the option to receive therapy and/or medication for your depression outside this study. If it is clinically indicated at any point in the study, or if you request it, your therapist will provide you with referrals for further treatment. 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 and NewYork-Presbyterian Hospital
- The Institutional Review Board (IRB)
- New York Presbyterian Hospital
- All appropriate federal research oversight agencies, including the National Institute 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 NewYork-Presbyterian Hospital by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

Information about your participation in this study is stored in a computer, and we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage: computers will be password protected; master lists associating participants' names with their ID numbers will be kept in locked file cabinets and/or on a password-protected database on the ITS-maintained secure server; and data with identifying information will only be transferred over secure servers. Zoom invitations will be sent via email, collected at the initial phone screen phase as contact information and stored in a secured folder that only authorized study team members can access. If any of your sessions are recorded, the recordings will be stored on a secure server. Recordings will not be labeled with information such as your name, date of birth, or other identifying information and will be used only by research staff. Recordings will be destroyed after the research is completed. All staff involved 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.

Please also note that your MRI that is done as part of this study will be read and interpreted by a Weill Cornell radiologist and the report will be provided to the Principal Investigator. If there are any unsuspected, incidental findings that you should know about, the Principal Investigator will share the findings with you or a physician who you may designate. Incidental findings noted on the MRI scans might or might not have clinical significance and might or might not lead to further medical tests or treatments. It will be up to you and your designated physician to determine if any further testing or treatment is necessary on the basis of this information. However, you should know that the limited MRI that is done in conjunction with this study is not meant to be a comprehensive examination, therefore we may not detect abnormalities or diseases which may be present and might be detected in a full clinical and diagnostic MRI examination. Should we find abnormalities in our limited MRI examination of your brain, your doctor might recommend that you undergo the full diagnostic MRI, which would then no longer be considered a part of this study.
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, WCMC researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medical College (WCMC) and/or NewYork-Presbyterian Hospital (NYPH) 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 WCMC and/or NYPH researchers 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 WCMC and/or NYPH 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 WCMC and/or NYPH.

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 your medical and neurological history, magnetic resonance imaging scan results, as well as all information collected through paper and pencil tests and questionnaires, through computerized tests, and through in-person interviews with research staff.

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 National Institute of Mental Health (NIMH), 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 at WCMC and the NIMH.

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.

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.

Use of Psychotherapy Notes: This study uses psychotherapy notes.

What are Psychotherapy Notes for Research? WCMC and/or NYPH may use or share (disclose) information about you from the therapist's notes about your psychotherapy sessions for this study that is considered to be protected health information.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCMC and/or NYPH 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 Officer
1300 York Avenue, Box 303
New York, NY 10065

If you have questions about this, call: (646) 962-6930 or e-mail: privacy@med.cornell.edu

End of Permission: Unless you cancel it, permission for WCMC and/or NYPH 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 NewYork-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.

WHAT ARE THE COSTS?

Neither you nor your insurance company will have to pay for the study psychotherapy treatment or research assessments. You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study. If unsuspected, incidental findings are noted in the review of the MRI scans and further medical tests and/or treatments are considered, such tests and/or treatments are no longer considered part of the study and therefore would be billed to you or your insurer. You should expect no compensation or reimbursement for these costs, or any risks and anxieties associated with any such follow up care. You or your insurance company will also be charged for any 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 the Sponsors are as follows:

The Sponsor, NIMH, will not pay for care necessitated by a research-related injury.

The Policy and Procedure for Weill Cornell Medical College are as follows:

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 NewYork-Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will receive compensation for participating in this study. You will receive $30 for the baseline visit and for the assessments at 3, 5, and 9 weeks. You will receive $75 for each MRI scan

Compensation	Baseline	3 week	5 week	9 week
Research Interviews	$30	$30	$30	$30

MRI Scans	$75		$75	$75

If needed, transportation will be provided for the assessment session and the MRI scan session. The researchers will schedule a taxi to take you to and from each study session, and this transportation will be provided at no cost to you.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research 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 the Weill Cornell Medical College, NewYork-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 the Principal Investigator, Dr. Nili Solomonov at 844 999 8746 ext. 718 or the New York Presbyterian Hospital operator at 914-682-9100 and ask that he 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:
Address: 1300 York Avenue
Box 89
New York, New York 10065

Telephone: (646) 962-8200

Consent for Research Study

Project Title: Social Reward Psychotherapy and its Effect on Brain Functions in Mid- and Late-Life Depression
Principal Investigator: Nili Solomonov, Ph.D.

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 Nili Solomonov, 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