WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title: Problem Adaptation Therapy for Mild Cognitive Impairment with Depression

Research Project #: 1603017114

Principal Investigators: Dimitris N. Kiosses, Ph.D.

Arm/Group: PARTICIPANT FORM

Participant 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 an adult who has mild difficulties in memory or in organizing or initiating activities and depressed mood.

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 supported with funds provided by the National Institutes of Health/National Institute on Aging (NIH/NIA). Dr. Dimitris N. Kiosses is the Weill Cornell primary investigator and Dr. Paul Rosenberg is the Johns Hopkins primary investigator.

The study will take place at Weill Cornell Medical College/NewYork-Presbyterian Hospital and Johns Hopkins Medical Center. The study may also take place remotely, from a location of your choosing, via phone and/or videoconference. Weill Cornell Medical College and NewYork-Presbyterian Hospital and Johns Hopkins Medical Center are neither sponsors nor investigators for this study.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to learn if a specialized program involving talk therapy is effective in improving cognitive, affective and functional outcomes in older adults with mild cognitive deficits.

Psychotherapy, also known as talk therapy, is the use of psychological methods to help a person change and overcome problems. Problem Adaptation Therapy for Mild Cognitive Impairment (PATH-MCI) differs from standard psychotherapy by offering a combination of emotion regulation techniques with the provision of environmental adaptation tools (notes, checklists, calendars, a tablet app, etc.), and the participation of a willing and available study partner. The tablet app is called WellPATH, and you will be given a device with the WellPATH app until the end of your research intervention. You will connect to this tablet with a specific ID and password. There will be no connection between your personal information and the data on the WellPATH app. Rather, data will be connected to your ID. The data that is saved to the device will be downloaded every week to a secure computer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 80 participants and 80 study partners will take part in this study worldwide; 63 participants s and 63 study partnerswill be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate, after you have reviewed and signed this consent form, a research assistant will conduct an assessment to find if you meet the criteria to participate. The research assistant will assess your mood and cognitive functioning. If you agree and meet the study criteria, the research assistant will then conduct the rest of the interview with you for approximately 1 hour to further assess your mood, memory and other cognitive difficulties, and physical functioning.

After this interview you will be "randomized" into one of two study groups: Problem Adaptation Therapy for Mild Cognitive Impairment (PATH-MCI) or Supportive Therapy for Cognitively Impaired (ST-CI) Older Adults. Randomization means that you are put into a group by chance, like flipping a coin. Neither you nor the researchers will choose what group you will be in, and you have an equal chance of being placed in either group.

Problem Adaptation Therapy-MCI (PATH-MCI) focuses on the participant, the study partner, and the participant's home environment to encourage problem solving and adaptive functioning and to reduce negative emotions. The goal of PATH-MCI is to decrease negative emotions (sadness, anxiety,

irritability, anger), memory-like difficulties and impairment in functioning. To accomplish this goal, the therapist will:

1. Teach problem solving skills to reduce negative emotions, by using emotion regulation and problem solving strategies to overcome these difficulties.
2. Use environmental adaptation tools (notes, checklists, calendars, etc.) to avoid limitations resulting from memory problems, help improve emotion regulation, and create an easier environment to live in. (Examples of messages that may be written on these tools include: take a walk, do a crossword puzzle, think about your problem from a more positive perspective.)
3. Invite study partner participation and use environmental adaptation tools to encourage participation in pleasant events that memory problems have made difficult to do alone.

Supportive Therapy for Cognitively Impaired Older Adults (ST-CI) assistsparticipants in expressing their feelings and focusing on their strengths and abilities in working through current difficulties. ST-CI sessions focus on:

1. Facilitating expression of affect;
2. Conveying to the patient that he or she is understood;
3. Offering empathy;
4. Highlighting success experiences; and
5. Imparting therapeutic optimism.

Participants in both groups will receive 15 sessions: 12 weekly sessions in the first 3 months and 3 monthly booster sessions at the 4th, 5th and 6th month. The sessions will be conducted at the therapist's office, at either Weill Cornell Medical College or Johns Hopkins Medical Center. In circumstances where an in-person session cannot be done, a phone or videoconference session may be conducted. Each study session will last approximately 50 mins.

Sessions may be audiotaped for the purposes of supervision and evaluation of therapist adherence to the therapy protocol.

Participants in both groups will be asked to participate in follow-up research assessments at 6, 12, 24, 36 and 52 weeks (please see table below outlining activities/events in the study). The assessments will include questions about your mood, functioning and cognition.

	WEEKS																	
	Study enrollment	1	2	3	4	5	6	7	8	9	10	11	12	16	20	24	36	52
Assessments	X						X						X			X	X	X
Therapy		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		

In order to take part in this study you must also have a study partner who spends more than ten hours per week with you, and can participate in research visits. Your study partner will be asked to sign a separate consent form. Based on clinical indications, the therapist may recommend that your

study partner participate in the research intervention. In this case, the therapist will discuss the potential clinical benefit to you and the therapist will get verbal consent from you and the study partner before the collateral session.

If your study partner drops out or is unable to fulfill his/her role, you will be encouraged to select another study partner. If there is no other study partner, you can still remain in the study.

There is an optional blood draw on three different occasions during the study; you will be given a separate consent form for this part of the study.

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.

With your permission, sessions will be audiotaped for the purposes of supervision and evaluation of therapist adherence to the therapy protocol. The tapes will be destroyed after the end of analyses of data. Please indicate if you do/do not wish to be audiotaped below:

☐ I do wish to be audiotaped.

☐ I do not wish to be audiotaped.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for approximately 12 months from the start of your participation.

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 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.

If you wish to continue to meet with the therapist or to have access to the same resources after the completion of the study, please discuss this with your therapist and Dr. Kiosses, the Principal Investigator at Weill Cornell. Any services after the study will need to be paid for by you or your insurance.

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; for example, 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?

Risks related to this study include: possible distress related to answering questions about your mood, thinking, and physical functioning, loss of confidentiality, possible worsening of depression, and possible fatigue or

boredom as a result of repeated evaluations of your mood and mental state. You may experience pain and/or bruising from the blood draw.

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. Your symptoms can get better, worse, or stay the same. Possible benefits include that the proposed interventions will improve your mood, decrease your memory difficulties and memory-related disability. You will also be monitored closely for depressive symptoms and thoughts of self-harm, and we will refer you for additional treatment and/or notify your physician (with your permission) if these symptoms worsen. Your participation in the study may be concluded if your symptoms worsen. We hope the information learned from this study will benefit others with negative emotions and memory problems in the future.

WHAT OTHER OPTIONS ARE THERE?

Any medications you are taking will not be changed as a result of your participation in this study. Instead of being in this study, you have the option to receive talk therapy outside this study. Your physician can discuss additional treatment options such as drugs for negative emotions or cognitive functioning, or psychotherapy treatment that you may pursue outside of the study.

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 medial 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
- Johns Hopkins University
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)

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.

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: computers will require a unique ID and password prevent unauthorized disclosure, tampering, or damage of the information kept in computers. Master lists identifying patients with numbers will be kept in locked file cabinets. 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.

OPPORTUNITIES TO PARTICIPATE IN FUTURE RESEARCH

Weill Cornell Medical College and New-York Presbyterian Hospital are involved with various studies and continually receive funding for new and innovative research.

☐ I do wish to be contacted regarding future studies for which I may be eligible.

☐ I do not wish to be contacted regarding future studies for which I may be eligible.

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 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 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 people identified in this authorization any protected health information related to this research from your medical records and from any test results which includes demographic, psychological, physical functioning, blood test results and memory questionnaires.

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 National Institute of Health/National Institute on Aging, 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 the research staff at Johns Hopkins University.

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: WCMC and/or NYPH 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.

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, provided that the disclosure of this information will not put your well-being in jeopardy.

WHAT ARE THE COSTS?

You will not have to pay to participate in this study. The costs of the intervention you receive during this study will be paid for by the research project and will not be charged to you or your insurance company. You or your insurance company will be charged 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 the Sponsor are as follows: The National Institute of Health/National Institute on Aging 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 be paid $30 for each research assessment (Study Enrollment, 6, 12, 24, 36 and 52 weeks). You will be paid in the form of cash, check, or gift card at the completion of each study assessment. You will not get paid for the screening that will determine whether you meet the study criteria. 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.

Materials or data obtained from you in this research may be used for educational or commercial purposes. It is the policy of WCMC and NewYork-Presbyterian not to provide financial compensation to you should this occur.

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.

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 particpiant 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.

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 Dr. Dimitris Kiosses at 914-882-9997 (cell phone), the Weill Cornell Institute of Geriatric Psychiatry at 914-997-4331, or the New York Presbyterian Hospital at 914-682-9100. 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

Project Title: Problem Adaptation Therapy for Mild Cognitive Impairment with Depression (PATH-MCI)

Principal Investigator: Dimitris N. Kiosses, Ph.D.

RESEARCHER'S STATEMENT

I have fully explained this study to the participant. 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

PARTICIPANT'S'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 Dr. Dimitris Kiosses and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Participant	Print Name of Participant	Date

_____	_____
Signature of Legally Authorized Representative and Relationship to Participant (When Appropriate)	Date