A Novel Cognitive Reappraisal Intervention for Suicide Prevention

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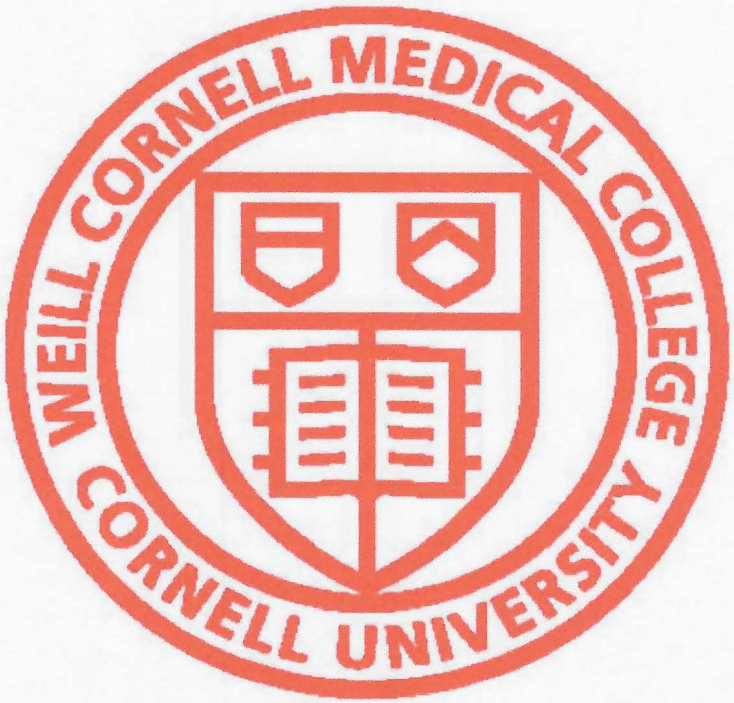

WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title: A Novel Cognitive Reappraisal Intervention for Suicide Prevention

Research Project #: 1603017115

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

Arm/Group TREATMENT SUBJECT FORM

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 an adult who has been hospitalized for thoughts that life is not worth living, thoughts of harming yourself, or an act of harming yourself, and had 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). NIMH is providing a research grant/funds for this study. Dr. Dimitris N. Kiosses is the primary investigator.

The study will take place at Weill Cornell Medical College (Payne Whitney in Westchester and in Manhattan). Some portions of the study will 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.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to find out if a form of talking therapy is effective in reducing negative emotions, thoughts that life is not worth living, thoughts of self-harm, or thoughts of suicide in middle-aged and older adults who have been hospitalized because of a suicide attempt or thoughts that life is not worth living, or wishes they were dead.

Psychotherapy, also known as talking therapy, is the use of psychological methods to help a person change and overcome problems in desired ways. Cognitive Reappraisal for Suicide Prevention (CRISP) differs from standard of care psychotherapy by offering a combination of emotion regulation techniques (including changing the perspective or the way you think to improve your emotional reaction). In addition to emotion regulation techniques used in the office, you will be trained to use additional strategies during times of emotional difficulties outside of the office. These strategies include the provision of environmental adaptation tools (notes, checklists, calendars, etc.), phone calls, and a tablet application, called WellPATH. The tablet will be provided by the study.

This research study is being done because effective psychotherapies are needed for older adults who are at high risk of harming themselves, e.g., they have been hospitalized for a suicide attempt or for increased thoughts of harming themselves. The CRISP treatment is experimental and we do not know if it is effective. CRISP treatment is not the current standard of care and will be administered in addition to any pharmacological or psychological intervention you are recommended to follow at your discharge from the hospital. For middle-aged and older adults with depression and thoughts of self-harm, a combination of different medications and psychotherapy are considered the standards of care.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as treatment subjects.

About 40 treatment subjects will take part in this study worldwide; all treatment subjects will be recruited at this site. Up to 80 subjects may be screened for study eligibility.

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 depression, hopelessness, and thoughts of potential self-harm. 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 problems and physical functioning. You will also be asked to recall situations

that have triggered negative emotions in the past and link them to specific words. Part of the assessment includes an electroencephalogram (EEG) recording during the presentation of emotional and neutral words and pictures in a computer. If you feel uncomfortable, you may stop the tasks at any time. The EEG recording is safe and non-invasive. There are no known risks to health or safety associated with the study's EEG physiological recording procedure. There is the possibility that some participants will experience mild, temporary itching or tingling sensation in response to the electrode cap or electrode gel. However, we have well-trained personnel who will guide you and help teach you how to wash the gel from your skin after the EEG collection. Additionally, you will either have your regularly scheduled CRISP session with your therapist after the EEG session, or we will schedule a debriefing session with the PI, therapist, or other clinician after the EEG.

You will be assigned to a therapist who will come and visit during your inpatient stay. The therapist will administer CRISP weekly for 3 months after your discharge.

The goal of CRISP is to help you reduce thoughts that life is not worth living or thoughts of possible self-harm. To accomplish this goal, the therapist will:

1) Help you identify negative emotions (such as sadness, anxiety, anger, irritability, guilt) that are associated with depression and thoughts that life is not worth living or suicidal thoughts. After you identify these emotions and the situations that trigger these emotions, the therapist will teach you specific strategies that can help you reduce these negative emotions.

2) Incorporate environmental adaptations/aids to help you improve your perspective and regulate your emotions during emotionally charged situations outside of the office. These environmental adaptations/aids will be based on your preference and your therapist's recommendations. They include the utilization of the WellPATH tablet application, written step-by-step plans and phone calls. WellPATH is a tablet application that focuses on strategies to reduce negative emotions when you face them outside of the therapist's office. You and the therapist have identified situations, problems, or concerns that trigger intense negative emotions and suicidal ideation. Then, you and your therapist will develop a plan to reduce these negative emotions. The plan is entered into the WellPATH app and you will take the tablet with you. The tablets are provided by the study at the beginning of treatment and will be returned at the end of treatment. When you are faced with negative emotions or during scheduled reminders, you will use the app to access and utilize pre-planned strategies. The tablets may also collect data (mood ratings, duration of use, number of times you use the techniques). These data will not be linked to your name but rather to your study ID. No PHI (personal health information) will be collected by the tablets.

3) In specific clinical situations, the therapist may recommend home-delivered or phone sessions: These situations include: 1) Concern about acute suicide risk: If the therapist and the supervising clinician are concerned about suicide risk, and you agree, home-delivered sessions may be indicated to reduce risk. 2) Significant functional limitations: Functional limitations (e.g. inability to make the appointments) may prevent some patients from following weekly outpatient treatment. By home or phone delivery, the therapist will be able to help you. 3) Ambivalence about treatment and repeated missed appointments: Negative emotions such as hopelessness, discouragement about treatment outcome, and worthlessness may interfere with your ability to participate in treatment and to follow-through with outpatient treatment. We will offer the option of home-delivery, and believe that this may increase your access to therapy.

Treatment subjects will receive 12 weekly sessions, after their hospital discharge, with the study therapist in the therapist's office. Each study session will last approximately 45 minutes to 1 hour.

Selected sessions may be audiotaped for the purposes of supervision and evaluation of therapist adherence to the therapy protocol. There will also be follow up research assessments at 6 and 12 weeks (please see table below outlining activities/events in the study) after discharge. The assessments will include questions about your mood, functioning and cognition, and an EEG recording.

			WEEKS (AFTER DISCHARGE)											
	AT HOSPITAL		1	2	3	4	5	6	7	8	9	10	11	12
Assessments	Admission	Discharge						X						X
Therapy			X	X	X	X	X	X	X	X	X	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.

With your permission, selected 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 3 months after your discharge from the hospital.

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. Any services will be covered 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 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 evaluations of your mood and mental state, and a mild, temporary itching or tingling sensation in response to the electrode cap or electrode gel. Some of the words and pictures presented during the EEG tasks may be upsetting and may trigger negative emotions. We may ask your permission to contact a family member if we think the risk to harming yourself is increased. If your condition does not improve with the treatments that we offer in this study, you may experience increased thoughts of self-harm and may have increased risk of self-harm and you will be referred for more intense treatment. However, you do not have to answer any questions you choose not to and you may discontinue the interview if you wish. For more information, please ask Dr. Dimitris N. Kiosses at (914) 997-4381.

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 unknown if CRISP is effective and helpful at improving psychological symptoms. Possible benefits include the possibility that the proposed interventions will improve your mood, your thoughts that life is not worth living or the ability to reduce negative emotions. 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 will be concluded if your symptoms worsen. We hope the information learned from this study will benefit others with depression, thoughts of self-harm and memory problems in the future.

WHAT OTHER OPTIONS ARE THERE?

The drug treatment and/or the psychotherapy that you are currently receiving outside of the study will continue and will not be controlled by the study but by your physician and your outside therapist. Instead of being in this study, you have the option to receive your treatment outside this study. If you are not currently receiving treatment outside of the study, the study investigators will discuss additional treatment options such as drug 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 New York-Presbyterian Hospital
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- National Institute of Mental Health (NIMH)

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: computers will require a unique ID and password to 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.

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 self-harm and suicide more quickly than before.

During and after the study, the researchers will send information about your health and behavior 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 suicidal ideation 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, 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, 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 (NIMH), 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 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 either within or outside WCMC and/or NYPH. If information goes to an outside entity then the privacy rule may not apply.

Use of Psychotherapy Notes

What are Psychotherapy Notes for Research? 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: (212) 746-1179 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?

Treatment subjects will not have to pay to participate in this study. You will not be responsible for any costs associated with 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. No cost will be associated if you get a tablet; the tablet will be given to you for free only during the treatment. The tablet will be returned to the PI at the end of treatment. 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 Mental Health (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 New York-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 $50 for the research assessments (including EEG) at Discharge, 6, and 12 weeks. In addition, you may also win up to $10 per EEG session during one of the computer tasks. You will be paid in the form of cash. 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, NewYork-Presbyterian Hospital and the National Institute of Mental Health (NIMH) 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, 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 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

Consent for Research Study

Project Title: A Novel Cognitive Reappraisal Intervention for Suicide Prevention

Principal Investigator: Dimitris N. Kiosses, 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 Dr. Dimitris Kiosses 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