The Alexithymia Intervention for Suicide

Informed Consent Document

NCT ID: 05724953

IRBNet ID: 1737717

Date of IRB Approval for this consent: 06/20/2025

Version Date: 02/22/2024	**Page 1 of 14**
Subject Name:	**Informed Consent Date:**
Protocol #: RX004089 **Principal Investigator: Marianne Goodman, MD**	**VAMC: James J Peters VA Medical Center**
Title of Study: Alexithymia Intervention for Suicide	

You are being asked to participate in a research study. The purpose of this study is to test the feasibility and impact of an intervention aiming to improve social functioning and reduce suicide risk. The intervention involves attending a weekly psychoeducation course about emotions and using a smartphone to practice labeling of emotions over an 8-week period. The study is being sponsored by the Department of Veterans Affairs Office of Research and Development.

You are being asked to participate in this study because you have: 1) received a diagnosis of PTSD, bipolar disorder, major depressive episode, or schizophrenia; and 2) have been identified as at risk of suicide or have attempted suicide in the past year.

Your participation in this study is completely voluntary and would not impact your regular clinical care and will last approximately 8 weeks. We plan to enroll 80 veterans in the study. All study-related visits will be held at the Mental Illness Research Education and Clinical Center (MIRECC) offices on the 4th floor of the James J. Peters Medical Center (JJPVAMC) in the Bronx, NY.

If you consent to participate in this research study, you will first take part in an in-person screening evaluation that will assess your eligibility for the study. The screening evaluation will include a diagnostic interview, an assessment of suicide risk, and measures assessing emotion processing and reading ability using the following measures:

SCREENING EVALUATION

a. Diagnosis (Structured Clinical Interview for DSM Disorders; SCID-5).
b. Suicide risk (Columbia Suicide Severity Rating Scale; C-SSRS).
c. Emotion awareness (Toronto Alexithymia Scale; TAS-20).
d. Reading ability (Wechsler Adult Reading Test; WTAR).

The screening evaluation will take approximately 1½ hours to complete.

Participants who meet the study's inclusion and exclusion criteria will be offered to enroll in the study and will complete three research evaluations at the beginning of the study (baseline), and after 6- and 8-weeks. The in-person baseline evaluation will include questionnaires and clinical interviews assessing mood symptoms, emotion regulation, social and global functioning, history of trauma, and quality of life and will include the following measures:

BASELINE RESEARCH EVALUATION

a. Mood symptoms (Beck Depression & Anxiety Inventories; BDI/BAI).
b. Emotion regulation (Emotion Regulation Questionnaire; ERQ).
c. Social functioning (Provision of Social Relations Scale; PSRS)
d. Global Functioning (MIRREC Global Assessment of Functioning scale; MIRREC-GAF).
e. History of trauma (Childhood Trauma Questionnaire; CTQ and the PTSD Scale for DSM-5; CAPS-5 version lifetime).
f. Quality of life (WHO Quality of Life Scale-Brief; WHOQOL-BREF).
g. Penn Emotion Recognition Text (ER-40)
h. ""EmBODY" mapping tool
i. UCLA Loneliness Scale

Overall, the in-person baseline research evaluation will take approximately 1¾ hours to complete.

Following the baseline evaluation, you will be provided with a study-dedicated smartphone (e.g., iPhone) and asked to complete a series of brief questionnaires on the smartphone's screen during the course of the day over a 7-day period. No participant information will be stored on the smartphone. The smartphone will be set up to sound a soft beep to prompt you to complete the questionaries up to 10 times a day at random times between 10am and 10pm. The questionnaires will inquire about your current mood, emotion regulation, symptoms, suicidal ideation, side effects, and social context and functioning. Additionally,

information about previous day medication intake, previous night's sleep, and overall daily experience will be collected at the first and last questionnaires each day. Each questionnaire takes approximately 2-4 minutes to complete. You will be encouraged to complete as many questionnaires per day as possible during the 7-day baseline research assessment. Please do not respond to questionnaires while driving, crossing the street, or while engaging in activities which may put you or others at risk if focused on responding to the smartphone.

INTERVENTION

The intervention involves attending a weekly telehealth psychoeducation course about emotions and using a smartphone to practice labeling of emotions over an 8-week period. The intervention will involve:

Group Telehealth Psychoeducation Course: The virtual psychoeducation meetings will be held weekly for 8 weeks. Each meeting will be attended by up to 8 study participants, along with Dr. Kimhy and a group co-leader. The telehealth psychoeducation meetings will include presentations and discussions about emotions, the impact of emotions on social functioning, and activities to improve negative emotions. Each group telehealth psychoeducation meeting will last approximately 45 minutes.

Smartphone Practice: Following each weekly psychoeducation meeting, participants will practice labeling emotion for 3 days. Using the smartphone provided by the study, you will be asked to practice reflecting on and labeling your emotions on the smartphone's screen during the course of the day over a 3-day period. The smartphone will be set up to sound a soft beep to prompt you to complete the practice up to 6 times a day at random times between 10am and 10pm. There will be no scheduled intervention activities at nighttime, so as to not interfere with your sleep. Each emotion labeling practice takes <1 minute to complete. You will be encouraged to complete as many practices per day as possible during the 3-day assessment period. Please do not respond to questionnaires while driving,

crossing the street, or engaging in other activities which may put you or others at risk if focused on responding to the smartphone.

FOLLOW-UP RESEARCH EVALUATIONS – WEEK 6

The Week-6 follow-up in-person research evaluation will include questionnaires and clinical interviews assessing mood symptoms, emotion regulation, social and global functioning, suicide risk, and quality of life and will include the following measures:

a. Mood symptoms (Beck Depression & Anxiety Inventories; BDI/BAI).
b. Emotion awareness (Toronto Alexithymia Scale; TAS-20).
c. Emotion regulation (Emotion Regulation Questionnaire; ERQ).
d. Social functioning (Provision of Social Relations Scale; PSRS)
e. Global Functioning (MIRREC Global Assessment of Functioning scale; MIRREC-GAF).
f. Suicide risk (Columbia Suicide Severity Rating Scale; C-SSRS).
g. Quality of life (WHO Quality of Life Scale-Brief; WHOQOL-BREF).

Overall, the Week-6 follow-up research evaluation will take approximately 1¼ hour to complete.

END OF STUDY RESEARCH EVALUATIONS – WEEK 8

The Week-8 follow-up research evaluation will include questionnaires and clinical interviews assessing mood symptoms, emotion regulation, social and global functioning, suicide risk, and quality of life and will include the following measures:

a. Mood symptoms (Beck Depression & Anxiety Inventories; BDI/BAI).
b. Emotion awareness (Toronto Alexithymia Scale; TAS-20).
c. Emotion regulation (Emotion Regulation Questionnaire; ERQ).

d. Social functioning (Provision of Social Relations Scale; PSRS)
e. Global Functioning (MIRREC Global Assessment of Functioning scale; MIRREC-GAF).
f. Suicide risk (Columbia Suicide Severity Rating Scale; C-SSRS).
g. Quality of life (WHO Quality of Life Scale-Brief; WHOQOL-BREF).
h. Penn Emotion Recognition Text (ER-40)
i. ""EmBODY" mapping tool
j. UCLA Loneliness Scale

Overall, the Week-8 follow-up in-person research evaluation will take approximately 1½ hour to complete.

Following the 8-week in-person evaluation, you will be provided with a study-dedicated smartphone (e.g., iPhone) and asked to complete a series of brief questionnaires on the smartphone's screen during the course of the day over a 7-day period. No participant information will be stored on the smartphone. The smartphone will be set up to sound a soft beep to prompt you to complete the questionaries up to 10 times a day at random times between 10am and 10pm. The questionnaires will inquire about your current mood, emotion regulation, symptoms, suicidal ideation, side effects, and social context and functioning. Additionally, information about previous day medication intake, previous night's sleep, and overall daily experience will be collected at the first and last questionnaires each day. Each questionnaire takes approximately 2-4 minutes to complete. You will be encouraged to complete as many questionnaires per day as possible during the 7-day baseline research assessment. Please do not respond to questionnaires while driving, crossing the street, or while engaging in activities which may put you or others at risk if focused on responding to the smartphone. These entries will NOT be reviewed by a healthcare professional in real time, so if you are experiencing high levels of suicidal ideation, distress, or depression, you should reach out to a primary care or emergency medical provider for treatment.

POTENTIAL RISKS

There are no risks for physical injury in participating in the research assessments and answering research questions about suicide risk and behavior, psychiatric history, mood and symptoms. However, there is a potential risk for anxiety, psychological discomfort, or experiencing boredom in answering these questions about yourself.

There are no risks for physical injury in participating in the group psychoeducation course. However, there is a potential risk for anxiety, psychological discomfort, or experiencing boredom in listening to presentations about emotions and social functioning.

There are no risks for physical injury in participating in the smartphone practices and answering research questions about your emotions, as long as you don't use the smartphone while engaged in an activity that requires your full attention (such as driving a vehicle or crossing the street). However, there is a potential risk for anxiety, psychological discomfort, or boredom in answering these questions about yourself.

Over the duration of the study, you will continue to receive your routine psychiatric and medical care, and no attempt will be made to influence or change your psychiatric and/or medical care. During the research assessments, group psychoeducation, and/or smartphone practices we may see something that should be checked by your primary mental health provider or primary physician. If that happens, we will let you know and contact your primary mental health provider or primary physician and inform them about our findings and/or concerns.

You may feel bored when you complete some of the assessments, and in rare cases, may cause some emotional distress or an increase in suicidal thinking or urges. Please let a study team member know of any concerns that come up during the interview or self-report portions of the assessments. Should you become suicidal during the assessment procedure, research staff will contact Drs. Kimhy or Goodman who will evaluate you, and you may be escorted to the emergency room for a more detailed examination.

It is also possible that you may still experience suicidal thinking and urges even with participation in this treatment. The research team has developed a safety management plan for the emergence of suicidal thoughts, urges or acts that occur during the treatment. The research team investigators (Drs. Kimhy and Goodman) will be available to perform a suicide assessment at any point if you are experiencing a change in your suicidality. They will ask questions regarding any suicidal ideation and suicide plan and arrange for transfer to the psychiatric emergency room and/or inpatient stabilization at the JJPVAMC should imminent suicidal behavior be expressed.

There also may be risks that are unknown. All measures are taken to minimize hazards.

Although individually identifying information will be protected by coding patient data and storing all information in locked offices and/or behind computer firewalls, participation in the study will involve obtaining sensitive medical information (i.e., psychiatric history, diagnoses). Therefore, there is a potential risk for loss of confidentiality. It is entirely up to you to participate in this study. If you choose not to participate, you will be assisted in finding clinical treatment if you wish. Your choice not to participate in this study will in no way compromise your access to any treatment.

PROCEDURES FOR MINIMIZING RISK:

Precautions will be made to minimize potential risk, including risk to privacy including:

1. Confidentiality of your responses: Steps will be taken to maintain your confidentiality. The information you provide, and all findings, will be kept strictly confidential with access limited to the research staff at the JJPVAMC, as well as state or federal regulatory personnel. Only the Primary Investigator (Dr. Marianne Goodman), co-investigator (Dr. David Kimhy), and the project coordinator will have access to the master list linking your identifiable information to code numbers, and all information obtained will be coded. No research participant will be identified in any publication or

correspondence in such a way that you can be recognized. The master list is kept under strict lock and key. All results will be published in aggregate form and will not reveal any individual identifying information. The study's primary and co-investigator (Drs. Kimhy and Goodman) have extensive experience collecting confidential data as part of clinical trials.

2. Diagnostic and Clinical Interviews: There are no physical risks involved in any of these assessments, although there is a potential risk for anxiety in answering these questions about yourself. You have the option of not responding to a particular question, or not completing a questionnaire or interview.
3. Psychoeducation Course: You may stop participation in the group psychoeducation meetings at any time for any reasons.
4. Smartphone Practices: You may snooze a smartphone practice, skip it, or stop participation in the smartphone practices at any time, for any reason. Smartphone entries will NOT be reviewed by a healthcare professional in real time, and if you are experiencing high levels of suicidal ideation, distress, or depression, you should reach out to a primary care or emergency medical provider.

If you begin to show signs of deterioration in your clinical status, including increase in symptoms and suicidal risk, your participation in the study will be terminated, your treating clinician will be informed, and appropriate follow-up care will be arranged for you. We encourage you to voice any discomfort you may experience throughout the duration of this study and remind you that you are free to decline to answer any questions and terminate your participation at any time. If you wish the end your participation in the study at any time please contact:

Dr. Marianne Goodman - [redacted] (during day or night)

EXPECTED BENEFITS OF THE STUDY:

There are possible individual benefits by taking part in this study, such as improved ability to label and manage emotions, improved social functioning, and reduction in suicide risk.

However, the extent of such potential benefits is unknown. Additionally, you will receive free diagnostic evaluations as part of your participation in this study.

There is also potential for benefits for the treatment of other veterans if the intervention proves to have efficacious. Information obtained from the study can lead to the development of novel and more effective treatment strategies for suicide risk for veterans and civilians. Thus, the potential benefits of the study seem to outweigh the limited risk associated with participation.

OTHER TREATMENTS AVAILABLE:

It is entirely up to you to participate in this study. If you choose not to participate, you will be assisted in finding other treatments that might help reduce suicide risk, which include individual psychotherapy, group psychotherapy, and medications. Your choice not to participate in this study will in no way compromise your access to other treatments.

USE OF RESEARCH RESULTS:

We will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. Only Drs. Kimhy, Goodman, and their staff will have access to research materials and data generated from the study (e.g., questionnaires, clinical interviews, data collected from the smartphones). The data will be stored at James J. Peters VAMC. Hard copies of your answers will be stored in a locked filing cabinet at Dr. Kimhy's office. Electronic data will be stored and secured on the VA network and will only be available to the study staff. Your name will be removed from all results and replaced with a code. All data will be coded and de-identified

We will let you and your primary provider know of any significant new findings made during this study which may affect your willingness to participate in this study. Otherwise, clinically relevant research results will not be disclosed to subjects.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor, VA Administration's Rehabilitation Research and Development (RR&D), of this study, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and the Office for Human Research Protections (OHRP). In compliance with U.S. law, a description of this study will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search and access this website at **any** time.

Do you give the researchers permission to contact you in the future to collect additional information about you, or to discuss possible participation in another research project? Please initial your choice:

Yes _____ No_____

If consenting over the phone, staff members initial below:

Your initials as the study team member obtaining consent on this form indicates you provided information about future contact, and you initialed Yes/No to indicate the participants' response.

Yes _____ No_____

Your initials as the witness on this form indicates the study member obtaining consent provided information about future contact and you too initialed Yes/No to indicate the participants' response.

Yes _____ No_____

Otherwise, your de-identified information may not be used for future research without additional consent.

A copy of your signed informed consent form and signed HIPAA authorization for participation in the study will be in your health record.

COMPENSATION AND/OR TREATMENT IN THE EVENT OF INJURY:

The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees.

VOLUNTARY PARTICIPATION:

You are not required to take part in this study; your participation is entirely voluntary. You can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

TERMINATION OF PARTICIPATION:

You may decide to end your participation in the study at any time and for any reason. There are no consequences if you choose to withdraw from this study and it will in no way compromise your access to any treatment. For subjects that withdraw from the study, our research team will attempt to establish contact, assess reasons for discontinuing, and attempt to address any potential concerns. The research team will ask for emergency contact numbers and an emergency contact person that may assist us if you drop from treatment or an emergency occurs. If you wish to end your participation in the study, you may contact:

Dr. Marianne Goodman - [redacted]

COSTS AND REIMBURSEMENTS:

As a veteran, you will not be charged for any treatments or procedures that are part of this study.

You will be paid up to **$280** for completing all study-related tasks during the study. Payment will be made via a check - it usually takes a minimum of 6 weeks for processing the payments. You will be offered financial compensation based on completion levels of the following:

Study Activity	Participant Compensation
Baseline Research Assessment (including a 7-day assessment with a smartphone)	$45
During Weeks 1-8, you will be paid $20 for each week you attend the psychoeducation virtual meeting and complete at least 2/3 of the emotion awareness practices on the smartphone (12 or more practices out of 18 scheduled over 3 days)	Up to $160
Week 6 Research Assessment	$30
Week 8 Research Assessment (including a 7-day assessment with a smartphone).	$45

CONTACT PERSON(S):

To obtain answers to questions about the research study, report or seek treatment for a research-related injury, or to voice concerns about the research, please contact:

Dr. Marianne Goodman - [redacted] (during day or night)

If you have questions about your rights as a research subject concerns and/or complaints or to offer input and would like to speak to someone outside of the research team, you may contact the Associate Chief of Staff for Research (ACOS/R) Office at [redacted] or the hospital extension 4228 first floor in the research building, room 1F-01 to request an appointment with the ACOS/R or designee.

RESEARCH SUBJECTS' RIGHTS:

I have read or have had read to me all of the above.

Dr. Kimhy or his delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent	Date