Problem Adaptation Therapy for Mild Cognitive Impairment and Depression (PATH-MCI)

Weill Cornell Medicine

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Operations Manual
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BACKGROUND

Problem Adaptation Therapy for elders with major or minor depression and mild cognitive impairment (PATH-MCI) is a non-pharmacological intervention that facilitates problem-solving and adaptive functioning. The goals of PATH-MCI are to reduce patients' depression, disability, and stress through emotion regulation.

PATH-MCI aims to reduce negative emotions and promote positive emotions associated with depression, including depressed mood, hopelessness, helplessness, guilt, anxiety, and anhedonia. The tools to achieve emotion regulation are: a) a hands-on problem-solving approach, simplified from Problem Solving Therapy (PST); b) compensatory strategies and environmental adaptations to bypass mild cognitive deficits or functional and behavioral limitations, due to depression or physical disability; c) careful integration of significant other involvement; and d) engagement in pleasurable activities. Using these tools, PATH-MCI can create an environmentally friendly "ecosystem" that decreases everyday stressors, empowers patients, instills hope, and promotes emotion regulation.

A simplified problem-solving approach from PST was chosen because: a) PST has been found effective in cognitively-intact depressed elders and in depressed elders with mild executive dysfunction; b) PST creates a forum within which patients and therapists can collaboratively set treatment goals, and it provides the structure and the process for patient problem-solving pertinent to decreasing depressive symptoms and functional limitations; and c) problem-solving strategies can be appropriately modified, and when this is done, they can help remedy behavioral limitations resulting from depression and mild cognitive impairment. Because solutions of problems may not necessarily reduce depression, the focus of PATH-MCI's problem-solving approach is to reduce negative emotions and promote positive emotions that are associated with the specific problem. To achieve emotion regulation, the PATH- MCI therapist guides the patient to find the best possible solution but also helps the patient adapt, if the solution is not satisfactory.

Consistent with the NIMH *Objective 3* for a person-centered approach using RDoC, PATH-MCI uses a neurobiological model to streamline and structure its interventions for use in primary care practices.

Elders with depression and MCI may benefit from PATH-MCI. Preliminary results have demonstrated that PATH-MCI reduces depression and disability in elders with major or minor depression and mild cognitive deficits. PATH-MCI is not designed for patients with dementia as these patients may require additional assistance.

STUDY AIMS

The goals of the study are:
MONTHS 1-3:

1. Finalize the PATH-MCI Manual and establish feasibility of therapist training. We will train 4 LMSW/LCSWs: 2 will be trained in the PATH-MCI therapy, 2 will be trained in Supportive Psychotherapy. We will determine the success rate of training and number of hours needed to achieve PATH-MCI certification.

MONTHS 4-60

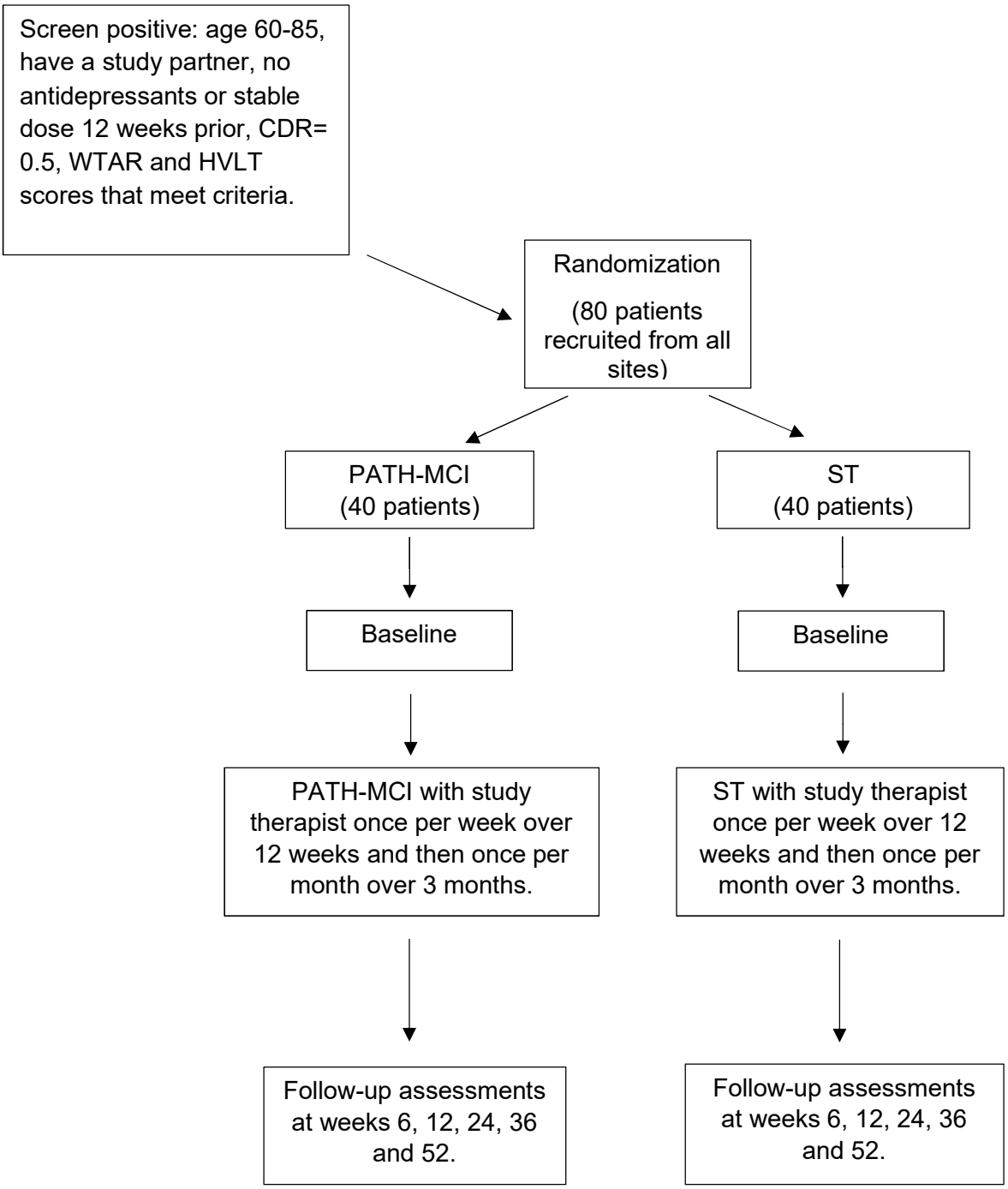
2. Assess PATH-MCI's reach, feasibility and acceptability: We will assess across conditions:
    a. Reach: Number of patients screened, and those who meet inclusion criteria;
    b. Feasibility: Number of patients who receive PATH-MCI or ST for mental health care and research procedures (timely referrals, assessments);
    c. Acceptability: Patient's treatment satisfaction at 6, 12, 24, 36 and 52 weeks.

    Benchmarks of the study progress: Feasibility: At least 75% of PATH-MCI participants will complete PATH-MCI. Acceptability: We will obtain treatment satisfaction score at the end of PATH-MCI treatment.

3. Preliminary Effectiveness: Over the course of 52 weeks, PATH-MCI patients, compared to patients receiving Supportive Psychotherapy, will have better global cognition and greater (effect size) and clinically significant reductions in disability and depression. Furthermore, better episodic memory and executive function will mediate the effects on cognitive outcomes

OVERVIEW OF DESIGN

Figure 1.



RECRUITMENT PROTOCOL

1. Patients are assessed and recruited from New York City Locations and Westchester.
    - Patients in NYC will be seen at 425 E 61st St., Penthouse Floor.
    - Patients in Westchester will be seen at 21 Bloomingdale Rd, White Plains, Institute of Geriatric Psychiatry.
    - Patients at Montefiore will be seen at 1515 Blondell Ave, Bronx, NY.
    - Note: There is no compensation for transportation expenses for patients. Any special cases must be discussed with Dr. Kiosses and Laurie Evans.
    - Patients who are not able to meet in person may be assessed by phone or video.

2. Study staff may recruit using flyers, posters and referrals.
    - Flyers

      NYC
        - Flyers for the study are placed in the waiting room of doctor's offices at 425 E. 61st Street, as permitted by the doctor's office. RAs must talk to the front desk before leaving flyers. Preferred floors are the 11th and 12th floors.
        - Flyers also can be placed in the elevators of the main hospital building on 72nd Street. Permission for this has been granted.

      WP
        - Flyers can be placed in the waiting room of the Institute of Geriatric Psychiatry.
        - Flyers also may be distributed at events, eg. Salute to Seniors, etc.
    - Posters
        - A poster version of the flyer can be placed in the lobby of the 425 E 61st Street office.
        - RAs must communicate at all times with the building manager, Kim Canazi: Kim.Canzani@colliers.com. Inform her that we will be placing a poster in the lobby. Confirm with her the schedule for this, and that the easel obtained is the correct one to use.
        - Order posters through Marcella Sanchez or Andrei Gangal.
    - Referrals
        - We obtain referrals from different doctors. I.e. Dr. Ravdin.
        - Make sure to follow up with the referral sources and to update referral sources about the patients they referred to us (meet criteria, did not meet, did not reach out to us, etc.).
        - We may also obtain referrals from sources, like the 4331 line at the Institute of Geriatric Psychiatry, and outside sources like JASA.
        -

3. Phone screens
    - When calling a potential patient, RA makes sure to first explain the study (quick overview) and answer any questions.

- Proceed with the phone screen, if a patient is interested in the study and agrees to the phone screen. Phone screens must be conducted with patients prior to scheduling a screening appointment
- Phone screen form for PATH-MCI study can be found at *I:\Cores\DMB\KIOSSES STUDIES\Phone Screens*
- RAs must conduct phone screens on days and times that therapists and psychologists at the Institute are available. In case of an emergency, ie. a patient endorses suicidal ideation, the RA must communicate this information immediately to the therapists and psychologists present. RA must follow the suicide risk protocol. (See comprehensive SRA protocol at end of this document.)
- If the patient seems eligible from the phone screen (i.e. endorses some depression and low mood and some memory problems), schedule a screening session with the patient.

STUDY PROTOCOL

1. RAs obtain potential patient information from various referral sources.
2. RA contacts a potential patient to complete a phone screen about memory/neurological problems, mood/depressive symptoms, current involvement in treatment, and medical illnesses.
3. If the individual is interested in participating in our study and does not appear to meet exclusion criteria, the RA will invite the individual to come to our offices in White Plains or NYC, or to schedule a video or phone appointment, depending on the circumstances.
4. At the onset of the screening interview, the RA will conduct the informed consent process. If the patient has capacity to consent, the RA will conduct the screening assessment.
5. The RA will discuss the results of the assessment with Dr. Kiosses.
6. If the patient is eligible, the RA will email the data manager with the individual's information.
7. The data manager will randomize the patient to either PATH-MCI or Supportive Therapy.
8. The data manager will notify Dr. Kiosses and the supervising therapist (not administering the intervention) about the randomization.
9. The supervising therapist will assign a therapist to the patient and inform the therapist to contact the patient to schedule first appointment (to take place following the baseline assessment).
10. The RA will schedule the baseline assessment with the patient and study partner. The patient will receive $30, and the study partner will receive $20 for the baseline assessment.
11. Team weekly meetings:
    - Review recruitment (specifically the numbers of positive screen patients)
    - Referrals
    - Tracking of all patients; we will discuss:
        - The status of assessments
        - The status of therapy sessions
    - The data manager will generate charts with recruitment progress.
12. The RA will conduct assessments with patients and their study partners at the following time points: 6, 12, 24, 36, and 52 weeks after the baseline assessment. Patients will receive $30 (cash, check or gift card) for each set of assessments. Caregivers will be compensated $20 (cash, check, or gift card) for each set of assessments.
    - Note: Genetic testing does not have an additional compensation.
13. If the caregiver does not come in person for assessments and they agree we can give their compensation to the patient, they must first sign the reimbursement form stating that it's okay for the patient to receive the money on their behalf. (See form **I:\Cores\DMB\KIOSSES STUDIES\PATH-MCI\Reimbursment Forms**)

14. If the caregiver reimbursement can't be given to the subject, then we can do a payment requisition through WBG (during COVID-19), send a gift card, or send a money order. If possible, for money orders, send the caregiver a reimbursement form and self-addressed stamped envelope, so they can sign and mail the form back to us. Once the form is received, send a money order for the amount of the reimbursement.
15. All technology lent to patients will be returned to study staff.

Montefiore Medical Center Site

1. Patients will be recruited from Montefiore. When a patient is identified (by Montefiore) and agrees to be contacted by Cornell, a WCM RA will call the patient to schedule a screening appointment at the Blondell Site (1515 Blondell Ave, Bronx, NY).
2. RAs will schedule Montefiore patients for Tuesdays, when there is space and Dr. Erica Weiss is there to supervise. There is room for one RA; if more than one RA needs to go, email Dr. Weiss to see if she can find more room. Montefiore therapists will see study patients on Mondays and Fridays. Patients must sign both the Montefiore and WCM consent forms.
3. If a Montefiore subject signs the Genetics consent form, we will pay for transportation to Cornell for the blood draws. Blood draws can only be done at Cornell (White Plains or NYC), not Montefiore.
4. If RAs are there for the entire day, we will not pay for transportation, except for the cost of the parking garage.
5. If the RA is going to both the Montefiore and White Plains offices in the same day, we will pay for the transportation between the two sites (mileage for those driving, Uber/Lyft for those without a car).
6. RAs should bring data/work with them to Montefiore, regardless of how many patients they have scheduled, as there may be downtime if a patient screens out early. If only one patient is scheduled (am or pm), RAs should plan on being in White Plains the other half of the day.
7. Scheduling Patients at Montefiore: To aid the front desk in managing the patients coming in, please email Dr. Weiss (and Dr. Ceide, so she can troubleshoot if Dr. Weiss is away) every Friday the schedule of patients you are seeing the following week. These can be individual emails (ie. the RA's cases do not have be on the same email as the therapist's cases). Please use the following format:

Schedule for [insert date]
9am- [patient name]
10 am- [patient name]
11am- [patient name]
1pm [patient name]
2pm [patient name]
3pm [patient name]

Email Sample:
Schedule for 12/10/2019
10am- Erica Weiss
2pm- Mirnova Ceide

In addition to helping the staff know whom to expect, this will facilitate locating the RA when a patient calls to confirm their appointment or if they come on the wrong day.
1

[1] As of June 2020, we are not recruiting patients from the Montefiore Medical Center site.

FULL SAMPLE COLLECTION AND PROCESSING PROTOCOL

1. All blood draws must be tracked in RedCap.

2. General Guidelines
    - Blood specimens will be collected at the following time points:
        - baseline, week 12, and week 52.
    - Baseline
        - ~16cc collected.
            - 10cc DNA that will be serum frozen
            - 6cc of red top tube
    - Week 12 and Week 52
        - ~ 6cc
        - DNA should only be collected from individuals who consent during screening visit to have their bio-specimens stored for future research.

3. Supplies
    - Lavender top tube will be collected at the baseline visit for DNA.
        - BD Vacutainer© K2 EDTA Plus Blood Collection Tubes (REF 366643)
        - 10 mL tubes
    - Red top tubes (SST) will be collected at the baseline, week 12 and 52.
        - BD Vacutainer© Serum Blood Collection Tubes (REF 367815)
        - 6 mL tubes
    - BD Vacutainer Blood Collection Set
        - Safety-Lok
        - 0.6 x 19mm x 305mm
    - BD Vacutainer one-use holder
    - Gloves
    - Alcohol pads
    - Large gauzes sterile
    - Medical tape sterile
    - Band-aids regular sized
    - Kimwipes
    - Waterproof thin sharpies

SAMPLE COLLECTION VISIT PROTOCOL

BASELINE VISIT:

Specimen Collection

1. Label one lavender tube with study name (PATH-MCI), patient #, date, visit #.
2. Label one red tube with study name (PATH-MCI), patient #, date, visit #.
3. Collect blood in labeled lavender tube for DNA (10mL tube).
4. Collected blood in one labeled red tube for processing (6ml tube).

Specimen Processing

1. Gently mix lavender tube collected.
2. Take the lavender tube to the deep freezer for immediate storage. Deep freezer settings -70 °C (-80 °C is also acceptable).
3. Allow red top tube to clot for 30 minutes standing up right at room temperature.
4. Centrifuge 4.4 RPM for 15 minutes until clot and serum are well separated. (This can either be chilled centrifuge or room temperature).
5. Pipette serum into 2mL aliquot tubes -approx. 1 mL in each tube.
6. Label the tubes with study name (PATH-MCI), patient #, date, visit #.
7. Store aliquot tubes in the deep freezer -70 °C (-80 °C is also acceptable).

WEEK 12 VISIT:

Specimen Collection

1. Label one red tube with study name (PATH-MCI), patient #, date, visit #.
2. Collected blood in one labeled red tube for processing (6ml tube).

Specimen Processing

1. Allow red top tube to clot for 30 minutes standing up right at room temperature.
2. Centrifuge 4.4 RPM for 15 minutes until clot and serum are well separated. (This can either be chilled centrifuge or room temperature).
3. Pipette serum into 2mL aliquot tubes -approx. 1 mL in each tube.
4. Label the tubes with study name (PATH-MCI), patient #, date, visit #.
5. Store aliquot tubes in the deep freezer -70 °C (-80 °C is also acceptable).

Week 52 Visit:

Specimen Collection

1. Label one red tube with study name (PATH-MCI), participant #, date, visit #.
2. Collected blood in one labeled red tube for processing (6ml tube).

Specimen Processing

1. Allow red top tube to clot for 30 minutes standing up right at room temperature.
2. Centrifuge 4.4 RPM for 15 minutes until clot and serum are well separated. (This can either be chilled centrifuge or room temperature).
3. Pipette serum into 2mL aliquot tubes -approx. 1 mL in each tube.
4. Label the tubes with study name (PATH-MCI), patient #, date, visit #.
5. Store aliquot tubes in the deep freezer -70 °C (-80 °C is also acceptable).

SAMPLE COLLECTION SITE PROTOCOL

NYC

1. Choose time for blood draw with the patient (Monday-Friday 9AM-5PM). Location: 525 E.68th St F building 2nd floor F260
2. Email Carol Brook (clbrook@med.cornell.edu), Marc Vieux (mav9041@med.cornell.edu) about time slot, and cc Andrika (anm2134@med.cornell.edu) and Barbra (bhormann@nyp.org).
3. In the email, send a copy of the consent form (study consent and genetics consent form), order form with subject name and assay form (iDrive link: I:\Cores\DMB\KIOSSES STUDIES\PATH-MCI\Blood Draws\Forms for CTSC NYC). The order form needs to be signed by Dr. Alexopoulos.
4. In the email **clarify to Carol and Marc to make sure they print the assay request form and include it with the sample.**
5. To fill out the assay request form, please follow the template included and previously completed assay request forms found on the iDrive.
6. The CTSC will take care of processing and storing of the samples.

   ***Note: Even though the CTSC is doing the processing, please make sure to track how many tubes, etc. they processed. Track in the WP about notebook.**

WHITE PLAINS:

1. When Blood Draw is conducted by RA who is Phlebotomy-Certified, follow the protocol called, "PATH-MCI Blood Processing Instructions" in the following iDrive location: I:\Cores\DMB\KIOSSES STUDIES\PATH-MCI\Blood Draws
2. When Blood Draw is conducted by the Health Clinic/Lab in Westchester:
   - Make sure patient has been registered. All of our PATH-MCI patients should have an MRN provided by the registration done in On-Core, so their MRN number can be found on the On-Core spreadsheet. If they do not have an MRN assigned for some reason, first check with Laurie, but you can register the patient using the registration form found on the iDrive: I:\Cores\DMB\KIOSSES STUDIES\PATH-MCI\Blood Draws\WP Registration for Venipuncture
   - Fill out a requisition form, which is located in the RA office 106. A sample of how this needs to be filled out is included below.
   - Once the patient has been registered, call Mary Ann at the Clinical lab x2259, to schedule a blood draw. Try to schedule the blood draw a day or two before the actual date. Phlebotomy lab hours are 8:30AM-2:30PM. When you call Mary Ann, give her the following information:
     - Remind her of the study. Let her know that we only require the blood draw, not the processing.
     - Give the patient's first and last name

  - Patient's date of birth
  - Billing Code for Reqs: 12R
  - WBS (account # for petty cash, etc.)
  - MD name (Dr. Alexopoulos)
  - Diagnosis code
  - Time and date of blood draw
- Once a date and time have been established, send Mary Ann the requisition form with the date. You can fax this form to her at x6912.
- Call to confirm appointment.
- The day of the appointment, walk the patient to the clinic, bring a sterile glove with you because you will be transporting the samples back with you. Obtain the sample from the phlebotomist, and immediately go to the lab to process the samples and store. Follow the specimen processing steps detailed above.

[2]

PATH-MCI Adverse Events – Safety Report Form

1. The Safety Report form is in RedCap.
2. RAs will keep this form with each research assessment they do and ask the patient at each visit whether they've experienced any new health or medical problems since their last visit (At Baseline, the time frame is since screening/consent.).
3. If the patient says yes, then complete the form (date of onset, severity, medical care received, etc.). The guidelines for assessing what constitutes an AE, the severity level, etc. can be found in the NIA guidelines (saved on the I drive: (**I:\Cores\DMB\KIOSSES STUDIES\PATH-MCI\Adverse Events**)
4. Therapists do not need to ask about new health problems. If the patient spontaneously says something in a session, the therapist should try to get as much of the above information as possible and let the RA know, so that the RA can complete this form.

[2] As of June 2020, the Westchester Division no longer has a clinical laboratory. Only a certified RA may collect samples at the White Plains site.

SUICIDAL IDEATION/ BEHAVIOR PROTOCOL

When a patient reports passive suicidal ideation on the MADRS Suicide Ideation item or the Scale for Suicide Ideation:

1. Complete a Suicide Risk Assessment
2. Reach out to the patient's study therapist. If the therapist is not available, reach out to Dr. Kiosses or another attending psychologist at the Institute.
3. The clinician will speak to the patient and assess the situation.

When a patient reports active suicidal ideation or any kind of suicidal behavior (suicide attempt, self-injurious behaviors, interrupted or aborted attempts, preparatory acts) on the MADRS Suicide Ideation item or the Scale for Suicide Ideation:

1. Complete a Suicide Risk Assessment.
2. Reach out to the patient's study therapist. RA or therapist also needs to reach out to Dr. Kiosses and inform him about the situation and ask him to assess the patient. If Dr. Kiosses is not available, contact another attending psychologist at the Institute (Dr. Kiosses needs to be informed later on about the situation.)
3. Preferably, the assessment by a clinician is done during the same phone call or when the patient is still in the office.

*Please see comprehensive SRA protocol at the end of this document.

RESEARCH ASSESSMENTS

The RA will describe the study, ask potential patients to sign consent, and administer a screening assessment to evaluate eligibility. Once this is confirmed, the RA will administer a baseline assessment. At this assessment, the RA will explain that follow-up assessments will be administered at 6, 12, 24, 36 and 52 weeks after the baseline assessment. The RA also explains that patients will be compensated $30 for each set of completed assessments. Caregivers will be compensated $20 for each set of assessments.

Inclusion Criteria:

1. Have a study partner.
2. Be 60-85 years old.
3. No antidepressants or have been on a stable dose of antidepressants for 12 weeks prior to start of study.
4. CDR = 0.5
5. WTAR and HVLT scores that screen the participant in (see: *I:\Cores\DMB\KIOSSES STUDIES\PATH-MCI\HVLT and WTAR Scoring)*
6. English speaking.
7. Capacity to consent.

Exclusion Criteria:

1. Age is less than 60 or greater than 85 years old.
2. CDR ≠ 0.5
3. MADRS score < 7 or > 30
4. WTAR and HVLT z-score difference > -1.5
5. Change in antidepressant, cholinesterase inhibitors or memantine in the last 12 weeks prior to start of study and/or with medical recommendation to adjust dosage in the next 3 months (during treatment)
6. Current involvement in psychotherapy
7. Deemed to have a significant suicide risk
8. Deemed too unstable medically, psychiatrically or neurologically to safely enroll
9. Lack of English fluency
10. No available study partner
11. Screening incomplete

INTERVENTION

PATH-MCI:
PATH-MCI follows the process model of emotion regulation. According to this model, emotions such as those associated with depression, can be regulated with five broad strategies: situation selection (selecting the situations a person is exposed to), situation modification (changing potentially emotion-eliciting situations), attentional deployment (shifting one's attention within a situation), cognitive change (changing how one thinks about a situation), and response modulation (utilizing direct efforts to alter one's emotional responses). In conjunction with these strategies, PATH-MCI incorporates a simplified problem-solving approach, compensatory strategies, environmental adaptations and significant other involvement to achieve emotion regulation. At the end of treatment, PATH-MCI therapists provide to patients a personalized summary of treatment that highlights the problems that were addressed and the successful techniques that were used to solve them.

Comparison Condition: **Supportive Therapy:**
ST is a control intervention not aimed to improve emotion regulation. The ST therapist strives to create a positive alliance with the patient by emphasizing non-specific therapeutic interactions and techniques that convey to the patient, interest, concern and understanding. For the purposes of this study, an effort will be made to avoid all emotion regulation techniques that relate to PATH-MCI.

FOLLOW-UP ASSESSMENTS

Follow-up assessments are conducted by the WCM RA at 6,12, 24, 36 and 52 weeks after the baseline and include measures of mood, cognition and suicidal ideation. Patients will receive $30 (cash, check or gift card) as compensation for assessment completion at each time point. Study partners will receive $20 (cash, check or gift card) as compensation for assessment completion at each time point.

PROCEDURES FOR TREATMENT AFTER STUDY COMPLETION

Patients whose follow-up assessments indicate a need for continued mental health services will be provided with mental health referrals.

DATA MANAGEMENT

Data will be collected by the study RA at baseline and at follow-up assessments. The RA also will be responsible for writing and presenting patient summaries to the PI. The social worker will complete updates on the progress of their therapy sessions. Brian Liles manages the PATH-MCI database and weekly reporting.

Research records will be kept confidential to the extent permitted by law. Patients will be assigned ID numbers by the PATH-MCI study team, and all identifying information will be removed from records that are submitted to Weill Cornell Medicine for data analysis. Paper research records will be kept in locked file cabinets. When necessary for purposes of auditing, the Cornell IRB, NIMH, and all Federal oversight agencies will be provided access to these files. Computers will be password-protected, and all staff participating in the study will be trained in protecting human subjects in research. Data will be published in aggregate form without unique identifiers. No analyses will be published in which it is possible to identify individuals based on data.

SUSTAINABILITY

Dr. Kiosses will train two LCSWs in PATH-MCI (or more if needed). Training will consist of a one-day workshop with didactics, role-play and review of previously audiotaped sessions. After the workshop, the therapist will administer 6 PATH-MCI sessions to 2 pilot patients during the first four months. To be certified in PATH-MCI, therapists must achieve a score of greater than or equal to 4 (very good) out of 5 on the PATH-MCI Adherence Scale.

Conducting the Study Remotely

Due to COVID-19, and other circumstances where a patient would not be able to be seen in person, the study may take place remotely. E-consenting can take place via REDCap if the patient has access to Internet. The consenting process would be the same as in-person consent, with a member of the study team speaking with the patient over the phone or videoconference to explain the consent in detail. The consent form may also be mailed to the potential participant with a self-addressed stamped envelope to return to the study team.

Research assessments and both interventions (PATH-MCI and ST-CI) can take place over the phone and/or videoconference. Therapy visits will be conducted in a private room (home or office) and sessions will be recorded only if subjects have consented to that.
Research assessments will also take place in a private room with no one else present; if patients do not have access to video, some assessments may not be able to be completed in full. Please reference most recent Assessment Grid for list of assessments that can be done remotely and via which method (phone and/or video).

If the study is being conducted remotely, the genetics blood draws cannot be done.

PROTOCOL FOR ASSESSING AND DOCUMENTING SUICIDAL IDEATION

Emotion, Cognition, and Psychotherapy Lab
Dr. Dimitris Kiosses

If suicidal ideation is expressed during the assessment research assistant should:

1. Complete Suicide Risk Assessment (SRA) or
2. Start SRA; finish completing it based on information from clinical evaluation

PASSIVE SUICIDAL IDEATION EXPRESSED TO RESEARCH ASSISTANT
CSSRS=1 (wish to be dead, wish to not wake up) or having thoughts that life is not worth living

Action Step 1: Research Assistant reaches out to clinician.
Action Step 2: Clinician speaks with patient to evaluate them either in person or by phone.

PATIENT ASSESSED AS MILD SUICIDE RISK BY CLINICIAN
Action Step: Clinician emails Dr. Kiosses with a brief summary of the situation.*

Action Step: Review & Finalize SRA
The clinician evaluates the following and the RA or clinician include the appropriate language on page 6 (last page) of the SRA:
"The patient has been evaluated and is not in imminent need of hospitalization at this time. Patient confirmed that if the intensity or frequency of thoughts increased, they would take appropriate action (ie, speak with family, call 911, go to the ER.) SRA completed in collaboration with… and reviewed by …."
Amy Stern, Jody Monkovic, or Dr. Kiosses signs the SRA.
Study therapists should include this in the clinical notes as well.

PATIENT ASSESSED AS INTERMEDIATE OR HIGH RISK BY CLINICIAN

- Action step 1: Clinician informs primary clinician (if they are not the treating clinician)
- Action step 2: Clinician reaches out to Dr. Kiosses to evaluate the patient.* If Dr. Kiosses isn't available then:
  - Clinician reaches out to attending psychologist/psychiatrist to evaluate whether the patient needs hospitalization, or
  - Clinician takes the patient to evaluation center or calls 911

PATIENT ASSESSED AS MILD OR INTERMEDIATE SUICIDE RISK BY SUPERVISING CLINICIAN

PATIENT ASSESSED AS HIGH SUICIDE RISK BY SUPERVISING CLINICIAN

Action Step: Hospitalization required

In Westchester: The clinician and/or the supervising clinician will call the Evaluation Center (914-997-5700) to inform them that there is a patient in need of immediate evaluation and to provide preliminary demographic and clinical information. The clinician and/or supervising clinician will walk patient to EC. If needed, clinician and/or supervisor will call Security to request an escort (x2424).
In Manhattan: The clinician or supervisor clinician will call 911. Notify the front desk in the building lobby (212-308-2289) so they may facilitate entrance of the police/EMS. All clinical information should be provided to EMS by the clinician and/or supervising clinician.

Action Step: Complete SRA

ACTIVE SUICIDAL IDEATION EXPRESSED TO RESEARCH ASSISTANT
C-SSRS ≥ 2 or reports any kind of suicidal behavior (suicide attempt, self-injurious behaviors, interrupted or aborted attempts, preparatory acts)

<u>Action Step 1:</u> Research Assistant reaches out to clinician.
<u>Action Step 2:</u> Clinician evaluates patient in person.
<u>Action Step 3:</u> Clinician or Research Assistant contact primary clinician (if they aren't the primary clinician) and informs them of the situation.
<u>Action Step 4:</u> Research Assistant or clinician reaches out to Dr. Kiosses.* Dr. Kiosses evaluates the patient. If Dr. Kiosses isn't available then:

- Clinician reaches out to attending psychologist/psychiatrist to evaluate the patient; or
- Clinician takes the patient to evaluation center or calls 911

PATIENT ASSESSED AS INTERMEDIATE SUICIDE RISK BY CLINICIAN AND SUPERVISING CLINICIAN

<u>Action Step: Review and Finalize SRA</u>
The clinician evaluates the following and the RA or clinician include the appropriate language on page 6 (last page) of the SRA:
"The patient has been evaluated and is not in imminent need of hospitalization at this time. Patient confirmed that if the intensity or frequency of thoughts increased, they would take appropriate action (ie, speak with family, call 911, go to the ER.) SRA completed in collaboration with… and reviewed by …."
Amy Stern, Jody Monkovic, or Dr. Kiosses signs the SRA. Study therapists should include this in the clinical notes as well.

PATIENT ASSESSED AS HIGH SUICIDE RISK BY CLINICIAN AND SUPERVISING CLINICIAN

<u>Action Step: Hospitalization required</u>

<u>In Westchester:</u> The clinician and/or the supervising clinician will call the Evaluation Center (914-997-5700) to inform them that there is a patient in need of immediate evaluation and to provide preliminary demographic and clinical information. The clinician and/or supervising clinician will walk patient to EC. If needed, clinician and/or supervisor will call Security to request an escort (x2424).
<u>In Manhattan:</u> The clinician or supervisor clinician will call 911. Notify the front desk in the building lobby (212-308-2289) so they may facilitate entrance of the police/EMS. All clinical information should be provided to EMS by the clinician and/or supervising clinician.

<u>Action Step:</u> Complete SRA

* *Therapist should have clear information re. the nature of the SI, any consideration of methods, suicide plan, or intent.*

If the participant is a patient of one of NYP psychiatric services (eg OPD, partial hospital, inpatient service), these clinical team must be informed of the patient's SI and/or hospitalization. If patient is receiving treatment at the PHP program, additionally notify Dr. Alexopoulos, pager:914-321-7042, gsalexop@med.cornell.edu

PROTOCOL FOR ASSESSING AND DOCUMENTING SUICIDAL IDEATION

Emotion, Cognition, and Psychotherapy Lab
Dr. Dimitris Kiosses

If suicidal ideation is expressed during the therapy session, the therapist should:

1. Use the SRA assessment as a guideline to evaluate the patient
2. Start completing SRA during the evaluation or complete the SRA after the evaluation based on clinical notes.

PASSIVE SUICIDAL IDEATION EXPRESSED TO STUDY THERAPIST

PATIENT ASSESSED AS MILD SUICIDE RISK BY CLINICIAN

Action Step: Clinician emails Dr. Kiosses with a brief summary of the situation.*

PATIENT ASSESSED AS INTERMEDIATE OR HIGH RISK BY CLINICIAN

Action step: Clinician reaches out to Dr. Kiosses to evaluate the patient, if he thinks necessary.* If Dr. Kiosses isn't available then:

- Clinician reaches out to attending psychologist/psychiatrist to evaluate whether the patient needs hospitalization, or
- Clinician takes the patient to evaluation center or calls 911

Action Step: Review and Finalize SRA

The clinician evaluates the following and the RA or clinician include the appropriate language on page 6 (last page) of the SRA:

"The patient has been evaluated and is not in imminent need of hospitalization at this time. Patient confirmed that if the intensity or frequency of thoughts increased, they would take appropriate action (ie, speak with family, call 911, go to the ER.) SRA completed in collaboration with… and reviewed by …."

Amy Stern, Jody Monkovic, or Dr. Kiosses signs the SRA.

Study therapists should include this in the clinical notes as well.

PATIENT ASSESSED AS MILD OR INTERMEDIATE SUICIDE RISK BY SUPERVISING CLINICIAN

PATIENT ASSESSED AS HIGH SUICIDE RISK BY SUPERVISING CLINICIAN

Action Step: Hospitalization required

In Westchester: The clinician and/or the supervising clinician will call the Evaluation Center (914-997-5700) to inform them that there is a patient in need of immediate evaluation and to provide preliminary demographic and clinical information. The clinician and/or supervising clinician will walk patient to EC. If needed, clinician and/or supervisor will call Security to request an escort (x2424).

In Manhattan: The clinician or supervising clinician will call 911. Notify the front desk in the building lobby (212-308-2289) so they may facilitate entrance of the police/EMS. All clinical information should be provided to EMS by the clinician and/or supervising clinician.

Action Step: Complete SRA

* *Therapist should have clear information re. the nature of the SI, any consideration of methods, suicide plan, or intent.*

ACTIVE SUICIDAL IDEATION EXPRESSED TO STUDY THERAPIST

Action Step: Clinician reaches out to Dr. Kiosses. Dr. Kiosses evaluates the patient, if he thinks necessary.* If Dr. Kiosses isn't available then:

- Clinician reaches out to attending psychologist/psychiatrist to evaluate the patient OR
- Therapists takes the patient to evaluation center or calls 911

PATIENT ASSESSED AS INTERMEDIATE SUICIDE RISK BY CLINICIAN AND SUPERVISING CLINICIAN

Action Step: Review and Finalize SRA

The clinician evaluates the following and the RA or clinician include the appropriate language on page 6 (last page) of the SRA:

"The patient has been evaluated and is not in imminent need of hospitalization at this time. Patient confirmed that if the intensity or frequency of thoughts increased, they would take appropriate action (ie, speak with family, call 911, go to the ER). SRA completed in collaboration with… and reviewed by …."

Amy Stern, Jody Monkovic, or Dr. Kiosses signs the SRA.

Study therapists should include this in the clinical notes as well.

PATIENT ASSESSED AS HIGH SUICIDE RISK BY CLINICIAN AND SUPERVISING CLINICIAN

Action Step: Hospitalization required

In Westchester: The clinician and/or the supervising clinician will call the Evaluation Center (914-997-5700) to inform them that there is a patient in need of immediate evaluation and to provide preliminary demographic and clinical information. The clinician and/or supervising clinician will walk patient to EC. If needed, clinician and/or supervisor will call Security to request an escort (x2424).

In Manhattan: The clinician or supervising clinician will call 911. Notify the front desk in the building lobby (212-308-2289) so they may facilitate entrance of the police/EMS. All clinical information should be provided to EMS by the clinician and/or supervising clinician.

Action Step: Complete SRA

* *Therapist should have clear information re. the nature of the SI, any consideration of methods, suicide plan, or intent.*

If the participant is a patient of one of NYP psychiatric services (eg OPD, partial hospital, inpatient service), the clinical team must be informed of the patient's SI and/or hospitalization. If patient is receiving treatment at the PHP program, additionally notify Dr. Alexopoulos: pager: 914-321-7042, gsalexop@med.cornell.edu

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