

**Engaging Black Youth in Depression and Suicide Prevention Treatment within
Urban Schools: A Preliminary Study**

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Summary of the Research

The overall goal of this study is to examine the effectiveness of the Making Connections Intervention, hereafter referred to as the MCI. Based on the Unified Theory of Behavior and Stages of Change Theory, the MCI is designed to facilitate adolescents' identification of perceptual and actual barriers that influence their mental health treatment acceptability (i.e. engagement, perceived relevance, and satisfaction), and equip them with the skills to overcome these barriers at the initiation and/or during the course of treatment. As a test of the MCI, our target population was urban, Black adolescents screened for depression and referred for Interpersonal Psychotherapy for Depressed Adolescents, or IPT-A, for treatment. Prior research by the PI indicates that depressed, Black adolescents are likely to have untreated depression due to negative family influences, negative perceptions of services and providers, or self-stigma associated with experiencing depressive symptoms. This is of public health significance because: (1) this group uses less mental health services than any other adolescent group, and non-financial factors (e.g. mental illness stigma, negative perception of providers/services) plays a significant role in their lower service use; (2) if/when they do enter treatment, low engagement and early termination typify their experiences; and (3) suicide, a byproduct of untreated depression, has increased among this group, narrowing the gap in suicide rates between White and Black adolescents. To date, limited work has been done to improve treatment acceptability among urban, Black adolescents with depression, especially those in their middle-school age years. This study proposes a small-scale trial in New York City DOE school-based mental health clinics throughout the Bronx, where Black youth would be randomized to receive the MCI+IPT-A or IPT-A alone.

Project Information II

Description of study procedures:

- a. The study will be conducted at six (6) New York City Department of Education (DOE) Middle and High School School-Based Mental Health Clinics.
- b. Participants will need to sign consent (caregivers) and assent (youth) forms. Following enrollment, youth and caregivers will be given a baseline assessment consisting of a series of questionnaires. Both youth and caregivers assigned to the MCI + IPT-A group will attend one or two MCI sessions lasting approximately 45 minutes. The youth participants will continue to receive IPT-A for 12 sessions and will be given additional assessment questionnaires at weeks 4, 8, and 12. Youth in the IPT-A only group will begin IPT-A sessions immediately following enrollment and will follow the same assessment schedule. Assessments, screenings, and MCI and IPT-A sessions will be conducted at the youth's school.
- c. The MCI coupled with the IPT-A will consist of 13-15 intervention sessions. The IPT-A alone will consist of 12-15 intervention sessions. The MCI will occur with parents or legal guardians and students for one hour (60-75 minutes) over 1-2 sessions (Note: the screening and initial assessment will occur prior to the MCI session). The remaining 12-15 sessions will focus on the delivery of the evidence-based depression treatment, IPT-A, which will occur in weekly 30-45 minute individual therapy sessions (over 12 weeks, additional if a week is skipped) with the students and allowing possible concurrent sessions with the parent or legal guardian as needed. Thus, the intervention should last for approximately 3-4 months.

- d. A member of the research staff will conduct interviews and assessments. SMH clinicians will deliver the MCI and IPT-A interventions. This study will feature a 2-group randomized design. Eligible students will be randomized to receive the MCI and IPT-A enhanced intervention, or to receive IPT-A only. Astor Services for Children & Families is a community based, non-profit organization that provides children's mental health services, child welfare services, and early childhood development programs. Astor serves children and families in the Bronx through school-based mental health clinics. These on-site mental health clinics, which are all licensed mental health clinics in New York State, offer individual, group, and family treatment, as well as crisis intervention on school campuses. Six to eight clinicians employed by Astor will deliver both the MCI and IPT-A interventions, or the IPT-A alone. Therefore, Astor Services for Children & Families will be responsible for administering individual psychotherapy at their 6 selected school-based sites in the Bronx, but will not be involved in the design, oversight and/or management of the study.
- e. Screening tools will be distributed to students in a take-home packet, completed along with a consent form, and collected by research staff or SMH clinicians. Assessment questionnaires will be given by a member of the research staff and delivered to the research coordinator when completed.

Incentives

Incentives will be provided to both youth and caregiver participants in the form of gift cards. If participants withdraw prior to study completion, they may keep any gift cards they received but will not receive additional gift cards that would have been distributed at a later point in the study. Participating caregivers receive a \$20 gift card at baseline, \$15 gift card following the post-MCI assessment, and then a \$15 gift card following the assessments at week 4, week 8 and week 12. Youth receive a \$15 gift card at baseline, \$10 gift card following the post-MCI assessment, \$10 gift card following the week 4 assessment, \$10 gift card following the week 8 assessment, and then a \$10 gift card following the week 12 assessment. The total gift card amount for caregivers completing the study is \$80 in gift cards; the total for youth participants completing the study is \$55 in gift cards.

Participant Identification, Recruitment, & Selection

We based our sample projections on the demographic data from our partnering NYC DOE schools. The schools we are partnering with have approximately similar percentages of male and female students, of whom over 20% are African American. The students who attend these schools are generally from low-income families (live below the poverty line, receive Medicaid). We will enroll a total of 60 subject and randomly assign them to the MCI + IPT-A or IPT-A only in a 1:1 ratio. Based on screening rates in our previous R21, we anticipate recruiting 60 adolescents (10 per school-based site). In our R21 study, we were able to recruit 24 adolescent/parent pairs from our partnering schools using similar screening processes.

At each school, students with elevated depression will be identified through a school-wide screening process. We will work in concert with NYC DOE school mental health (SMH) staff to screen participants as per usual care procedures. We will identify participants through the following procedures. First, a screening (PHQ-9) and consent form (caregivers provide permission for their child to be seen in SMH services) are sent home with all students at the beginning of the academic year. We have requested (per IRB approval) to also send home a

permission to be contacted form, along with a letter describing our study. If caregivers agree to be contacted, the SMH staff will share with the research staff the contact information of students who scoring above the clinical cutoff of 11 (range 0 to 27). Astor Services for Children & Families used the school-wide screening method with the Strengths and Difficulties Questionnaire in 2015 and had an approximately 50% return rate on the screenings/consent forms. Research staff will not receive names of students whose parents do not provide a permission to be contacted form. Of the received forms, the research staff will contact the family to set up a time to consent/assent for the study and screen the adolescent using our standard screening procedure, which is to administer the Center for Epidemiologic Studies Depression Scale (CES-D). Second way we also will recruit participants is that using another standard of care in SMH service delivery, which is to recruit through the school-based clinics among those students presenting to services for mental health needs. That is, SMH staff at the participating schools currently receive referrals from NYC DOE social workers, guidance counselors, administrators, teachers, other school-based providers, family members, and self-referrals. All referrals are screened using the PHQ-9. Upon receipt of referrals, the SMH staff person will share a brochure of the study and a letter to be shared with the family, along with a permission to be contacted form. Following assessment, Dr. Lindsey and Tracy Grogan will review assessment, establish eligibility, and follow random assignment procedures. Randomization lists will be prepared by Dr. Jaccard who will have no contact with participants, clinicians, or study staff members. We will randomize within schools and provide clinicians information per each case about whether the participant will receive the MCI + IPT-A or IPT-A only. Clinicians will complete fidelity assessments, and we will randomly listen to audiotapes of sessions to document the extent of contamination or the potential of it. We will also make sure to discuss instances of contamination (or the potential of it) during weekly supervision with the clinicians. Note: We will keep track of the % of families who return the permission to be contacted forms. Research staff will follow-up on all returned forms and schedule a time to consent/assent for the study and screen the adolescent using our standard screening procedure

Participant Population

Inclusion Criteria:

1. Must identify as Black and/or African American
2. Must be enrolled in grades 6-12 (except 12th graders in their last semester)
3. Must be able to speak English
4. Must have received caregiver consent and have assented to participate
5. Must meet depression and global functioning levels indicated by a CES-D score ≥ 16 , a Hamilton Rating Scale of Depression (HRSD) Score ≥ 10 , and a Global Assessment Scale for Children (C-GAS) score ≤ 65 at baseline
6. Students who are currently on a stable dose of anti-depressant medication, but still meet inclusion criteria, can be enrolled in the study.

Exclusion Criteria:

1. Actively suicidal with intent or plan

2. Intellectually disabled
3. Have a life threatening medical illness
4. Have a current primary substance abuse diagnosis in the moderate to severe range, schizophrenia, bipolar disorder, any evidence of psychosis, a primary diagnosis of anorexia
5. Currently in active treatment for depression (excluding medication) at baseline assessment

Note: Adult caregivers included in the study must be the adolescent's legal guardian. Otherwise, exclusion criteria similar to what is applied to the adolescents will be applied to the legal guardians.

Informed Consent

All student participants will require parental consent and student assent to participate in the study. At each school, students will be recruited through a school-wide screening process. Prior to screening, the research team will hold an informational meeting for parents, adolescents, and teachers regarding adolescent depression, rationale for screening for elevated depression, and treatment options including the current study. Parents will then be sent a PHQ-9 and a consent form for their child's participation in the screening (students will take home in a packet) as part of usual care procedures at the participating NYC DOE schools. Upon receipt of a willingness to be contacted form, the research team will contact families about their interest in participating in the study. Upon an expressed interest, a research team member will meet the family to explain the study and cover the informed consent procedures (and child assent). The research team member will explain the study to the family, including the randomization procedure. They will understand that they are participating in a research study and that participation is voluntary. The consents also give information regarding what the study entails, incentives, and requirements of participants. Students and parents or legal guardians will also be given a copy of all consents/assents signed for their records and are welcome to contact any member of the research staff or the school mental health clinicians regarding questions or concerns they may have. Participants may choose not to participate. Consents will be written at the 7th grade reading level for parents or legal guardians and at the 5th grade level for student assents. The research team member will be sure that the participants understand all aspects of the consent process. Note: For those families who do not wish to participate in the study, usual care treatment will be offered. With informed consent and child assent obtained, the research team member will administer the CES-D screen. If the student scores above the clinical cutoff on the CES-D (i.e., 16 or higher), and the Hamilton (i.e., 10 or higher), and meet other inclusion/exclusion criteria, the student will be enrolled. We anticipate these procedures will be completed at the participating schools.

Participation Consideration

Study participants are allowed to enroll or withdraw from the study at any time. The recruitment, active treatment phases, and data collection will take place over 3 years.

Privacy of Participants

Information will be obtained in a school-based setting during the normal school day. Loss of privacy and confidentiality are possible risks of participation in the study. For example, there is potential for being stigmatized by peers for participating in a study on depression, particularly if peers of the participant discover this information. For example, peers may notice that a participant is absent from class or may pass them in a hallway while a participant is on his/her way to a private setting. To protect privacy during the data collection phase, (1) research staff will have direct contact with the caregiver(s) of the participants during afterschool hours; (2) any referees will be informed that the names of participating students must be kept confidential; and (3) copies of study assessments are kept in locked files at schools (not containing identifying information).

Private Information Sources

Mental health assessments and audio taped sessions

Regulatory Risk/Benefit Determination Applicable to Children

Federal regulations (45 CFR 46, subpart D) define risk/benefit categories as they apply to children.

(404) Minimal Risk research, where the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research with children, adequate provisions must also be made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408.

Participants are subject to minimal levels of risk - not greater than that of a typical therapy session with a counselor.

Data Confidentiality and Risks & Benefits

During data collection, a participant number will be assigned to each participant and indicated on research forms, so that it is the only link on assessment instruments. Access to consent forms, assent forms, demographic information, audio tapes, and assessment materials will be limited to the research staff at the NYU in password-protected files; the school mental health clinicians have access to copies of student assessments. The document containing students' identification number assignment will be sent to school mental health clinicians via NYU's secure file transfer system. The document is password protected, and the password is provided in a separate email. Only research personnel listed in this application have access to the hard copies of any data.

a. Research data and digital recordings of therapy sessions are stored on a password-protected network at the School of Social Work, which is on a secure server in the school and accessed only by investigators who are from NYU Silver School of Social Work. Data stored on the School of Social Work servers are protected by Windows New Technology File System (NTFS) Access Control Lists (ACL) tied to users Active Directory domain accounts. Users have access to a private folder accessible only to them and group folders accessible by select groups of people. Logging will be established on group folders and files to monitor access to individual folders and files. Access will be established and tracked by the user's New York University NetID. The only

account(s) on the system with access to all files is the main administrator account (which is not named administrator and has a 15 random character password, and the system internal account for tape backup. The School's main file server uses a Storage Area Network (SAN), which distributes the data over multiple redundant hard drives for reliability. In addition, Shadow copies are created at multiple times throughout the day and servers are backed up nightly to tape. Servers, network access devices and tape backups are housed in locked limited access rooms.

b. Research data and digital recordings of therapy sessions are stored on the password-protected network at the School of Social Work. Only the PI, research coordinator, and research assistants will have access to the data and digital recordings. Co- Principal Investigator, Dr. Laura Mufson of Columbia University, will have access to de-identified data and de-identified digital recordings of therapy sessions to review for IPT-A fidelity. SMH clinicians have access to copies of assessments.

c. Research data will be kept for 3 years post the conclusion of the study. At the 3-year point, the data will be destroyed.

d. Research data has been kept in locked cabinets in the research coordinator's office at NYU. The office is locked by key whenever the research coordinator is not in the office. When the time arrives for the data to be destroyed, it will be done so by shredding the documents.

e. Additionally, we have also provided a data safety and monitoring plan.

Risks of the Study

Participants are subject to minimal levels of risk - not greater than that of a typical therapy session with a counselor. (Note: In instances where youth are on medications related to their mental health symptoms, those youth will not be asked to stop taking medication. If appropriate, they will be referred for medical or psychiatric treatment.)

During the assessment and/or treatment sessions, students are asked questions that may cause some discomfort. Participants may experience some anxiety and/or increased sadness related to discussing personal information with the SMH clinician; however, students are not pressured to respond to any questions that they did not want to answer. Additionally, the SMH clinician as well as the PI are available to provide debriefing opportunities and discuss any issues related to this study.

Loss of privacy and confidentiality are possible risks of participation in the study. For example, there is a potential for being stigmatized by peers for participating in a study on depression, particularly if peers of the participant discover this information. We will make sure, to the extent possible, to protect the participation of students from other students. For example: (1) only research staff will have direct contact with the caregiver(s) of the participants during afterschool hours; (2) referees will be informed that the names of participating students must be kept confidential; and (3) copies of study assessments are kept in locked files at schools and do not contain identifying information. It is possible that participants may themselves inform peers about participating in the study or receiving treatment.

Due to working with students showing symptoms of depression, there was a risk that their depression could worsen while engaging in mental health treatment. The PI and research team will make every available effort to safely and sensitively handle significant worsening of

depressive symptoms. For example, as a standard of practice in the IPT-A treatment, SMH clinicians assess current symptom levels at the beginning of each session. Further, SMH clinicians complete the Children's Global Assessment Scale (C-GAS) to assess for global impairment associated with mood disorder. Additionally, the Hamilton Rating Scale for Depression (HRSD) and Center for Epidemiological Studies-Depression Scale (CES-D) are administered at baseline, post-MCI session, and at weeks 4, 8 and 12. If at any time the symptoms, as indicated by the HRSD and CES-D, reach a clinically severe level (HRSD score of 28 or greater; CES-D score of 31 or greater), the PI and SMH clinicians immediately ask follow-up questions to determine whether the youth is expressing suicidal ideation; if suicidal ideation was indicated, the PI and SMH clinicians further assess whether the youth has a plan, whether there is access and means to follow through with a plan, the level of suicidal intent and the presence of current suicidal gestures. We also contact the caregiver and provided information about emergency psychiatric services for determination of whether hospitalization is necessary. If there was a pattern of worsening depressive symptoms or de-compensation in the absence of suicidal intent during the course of the study (as measured by the Clinical Global Impressions (CGI), which was given weekly by the SMH clinician and indicated by a 6 or 7 on the CGI for 2 consecutive weeks), the PI in consultation with the SMH clinicians will make a determination of whether the youth is: (1) appropriate for the study; or (2) in need of more emergent psychiatric care such as hospitalization. Referral may also be made back to a primary care physician or to community-based mental health services in instances where participants might worsen during the course of the study. Again, guidance on this determination is informed on a session-by-session basis (e.g. symptom query is a standard practice of the IPT-A treatment) and via the standardized assessments of depression (e.g. HRSD and CES-D). If hospitalization was necessary, information on psychiatric services (e.g. hospitalization) will be provided to the caregiver.

Benefits of the Study

Participants experience minimal risks and receive high quality mental health services from master's level SMH clinicians in an effort to help reduce presenting issues. Participants may gain knowledge of the therapy process and learn problem solving skills to reduce hesitancy to engage in treatment. Participants may experience a reduction in depression as an outcome of completing the full depression intervention.

However, participants may not receive any direct benefit from participating in the study.

Results of this study will inform the preparation of a future federal grant application proposal (e.g. NIH R01) to address the effectiveness of the intervention approach outlined here in a larger scale trial. In particular, a future randomized controlled trial will be conducted to further test or refine the MCI intervention for SMH/community-based services. An intervention that will help reduce barriers to care and improve engagement in therapy would benefit the community greatly, particularly for those groups who experience many challenges in obtaining mental health services such as Black adolescents in an urban setting.