Title of the study: Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study

NCT number: N/A

Date of the document: 3/12/2025

The New School for Social Research

Request for Permission for your child to be in a Research Study

Protocol Title:
Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study
Protocol #: 999530263
Sponsor: NYC Office of Community Mental Health

Principal Investigator: Adam Brown, PhD
Institution: The New School for Social Research
Address: 80 Fifth Avenue, NY 10011
Telephone: 646-909-4933

Key Information

The following is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in this research.

- You are being asked to allow your child, who you are a legally authorized representative (e.g. parent or legal guardian) of, to participate in a research study because your child expressed interest in participating in the EASE program.
- Your decision to allow your child to be in this study is voluntary. You may refuse for your child to participate or withdraw at any time without penalty or loss of benefits to which they are otherwise entitled. Please note that you can make decisions on behalf of your child because you are their legally authorized representative.
- Your alternative is to not allow your child to take part in the study.
- The purpose of the study is to evaluate the implementation of the World Health Organization's Early Adolescents Skills for Emotions (EASE) in New York City (NYC).
- Your child's participation in the study is expected to last 6 months.
- The main study procedures include 7 in-person group sessions at [CBO name] and 3 interviews.
- The risks of the study are minimal, but your child may feel uncomfortable discussing issues related to their thoughts and feelings.
- There is no direct benefit to your child from taking part in this study. However, your child may learn skills to better cope with stress and manage their emotions. We also hope that the information we learn from the study results may help people in the future.

This overview does not include all the information you need to know before deciding whether to take part. Additional detail is given in the rest of this consent form found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who is the Study Team and How is the Study Funded?
This study is being conducted by Adam Brown, PhD at The New School. The NYC Office of Community Mental Health has provided funding for this study.

How Many People Will Take Part in the Study?
About 100 caregivers and 100 youth are expected to participate in the study.

What is Involved in this Research Study?
Your child will be asked to participate in 7 in-person group sessions at [CBO name]. Please reach out to [CBO supervisor name] for more information about the dates and times of these sessions.

We will also be conducting three interviews with all participants to learn more about their overall well-being. These interviews will take place over five months:

- The first interview will be within two weeks from now; we refer to this interview as the baseline.
- The second interview will be after your child completes EASE sessions. That will be about two months later.
- The third and final interview will be three months after your child completes EASE. That will be about five months from now.

Each interview will take about 60 minutes, and they will be conducted in-person at [CBO name].

Will Participating in this Study Benefit My Child?
Participating in this study will not benefit your child directly, but we hope your child will learn valuable tools and strategies to better manage their problems and emotions.

What Are the Risks Associated with This Research?
Your child may feel uncomfortable discussing certain thoughts or feelings. If they ever feel that way, they may always ask us questions, speak to a staff member from their connected CBO, request a break, or even stop. There will not be any consequences in doing so. That said, we do not anticipate any direct risks to your child's health and we hope that youth who join will be able to participate for the full cycle, so we can learn as much as possible from their involvement.

Also, in completing interviews with the research team, answering some of the questions maybe upsetting to your child, but we expect that this would not be different from the kinds of things you discuss with family or friends. Your child may skip any questions they don't want to answer, and they may end the interview at any time.

What Are the Costs of Taking Part in This Study?
There are no costs to you for a child taking part in this study. All the study costs, including any supplies and procedures related directly to the study, will be paid for by the study.

Will You Be Paid for Participating?
Your child will be provided a $35 stipend for each interview completed. Your child can reach out

to their EASE helper at [CBO name] to receive their compensation following the completion of each interview. After the last interview session, we may also invite your child to take part in additional interviews or focus group discussions about your experience.

Please note that participating in EASE is a requirement for completing the interview assessments. It is especially important that your child completes at least 4 EASE sessions before their 2nd interview. In the case that your child cannot meet study requirements, our team reserves the right to discontinue their participation in the study interview assessments at any time.

Voluntary Participation and Withdrawal

Your child's participation in this study is voluntary. You may decide not to allow your child to participate or you may stop your child's participation at any time, without penalty or loss of benefits or medical care that your child would otherwise receive, since you are the child's legally authorized representative. If you want to withdraw your child from the sessions, please let any staff member at [CBO name] or a research team member know. Your alternative is to not allow your child to take part in the study.

Your child's participation in this study may be stopped without your or your child's consent at any time and for any reason by the [CBO name] staff and research team. Reasons your child may be withdrawn from the study include it is determined to be in your child's best interest, your child does not follow the study instructions, the study is stopped, or for other administrative reasons.

What About Confidentiality?

To the extent allowed by law, every effort will be made to keep your child's personal information confidential. However, information from this study may be looked at by the research team, the institution, the sponsor/funding agency supporting the study, and those responsible for overseeing the conduct of research. This may include representatives from the federal Office for Human Research Protections (OHRP) or other regulatory agencies and the Institutional Review Board (IRB). While these parties are aware of the need to keep your child's information confidential, total confidentiality cannot be guaranteed. The results of this study may be presented at meetings or in publications; however, your child will not be identified in these presentations and/ or publications.

If you allow your child to take part in this study, they will be assigned a unique subject code to help protect his/her privacy. Your child's study records and study samples will be labeled with this code that does not directly identify them. The study site staff securely stores the linking code between your child's name and study information.

We aim to keep the information your child shares with us in the three interviews as private and confidential as possible. We will protect their record with a password that only our team members know. In addition, we will identify this record not with their personal name but a code. We will store both the record and the list that links their personal name to their code in separate, password-protected folders on different servers. While the investigator(s) will keep your child's information confidential, there are some risks of data breeches when sending information over the internet that are beyond the control of the investigator(s).

However, if we find that what your child shares puts themselves or others at risk of harm (e.g. suicidality risk), we will need to contact [CBO supervisor name], who is the supervisor at [CBO

name] immediately. This is because [CBO supervisor] at [CBO name] will have a referral protocol to direct your child to appropriate, specialized care. This is their contact information, for your reference: [insert contact information of CBO supervisor]

We will also share with your child contact information for access to local resources for these problems, such as the National Suicide Hotline number 988.

It is also possible that your child's EASE Helper will ask to video/audio record the sessions. The sessions are recorded so that the research team supervisor(s) can review the recording to make sure that the EASE Helper(s) has/have conducted the session appropriately. Only this supervisor and the EASE Helper will have access to this recording. They will store and access it in the code-named record in a password-protected folder on a secure server. As soon as they listen to the recording, they will permanently destroy it. Only sessions in which all participants provide consent to be recorded will be recorded. What we just described will apply to other interviews or focus group discussions that we may invite your child to complete at the end of the study. You/your child can consent to participating in the research study without consenting to being recorded.

Additionally, it is possible that your child may be photographed for the EASE program. These photographs may be broadcast, published in print or online, or put to other uses by the New School, the Mayor's Office of Community Mental Health, and your community organization. The purpose of these photographs is to promote EASE in the community for potential programming in the future. You/your child can consent to participating in the research study without consenting to being photographed.

Moreover, because of the group nature of the sessions, we cannot guarantee that what your child shares will remain completely confidential, and it may be possible that other participants will know what your child has shared. That said, the information we collect will be kept confidential among our team and the parties involved.

Please note that data may be stored on a New School google drive for a minimum of five years for future use in connection with potential studies. You will not be asked to provide additional consent for such use of the data.

What about Confidentiality and Authorization to Use and Disclose Protected Health Information?

To the extent allowed by law, every effort will be made to keep your child's personal and medical information confidential. However, total confidentiality cannot be guaranteed. Your child's personal information may be disclosed if required by law.

The study institution will use your child's information collected or created as part of the study, such as age and gender. Some of this information may identify your child by name or in another way.

The study investigator and study staff may use and share information about your child's health with other professionals involved in the study, such as the study sponsor and its authorized agents.

The purposes for using and sharing your child's information include: to carry out the research study and evaluate its results, and to meet government reporting requirements. Results of this research may be presented at meetings or in publications. Your child's name will not be used in

any study reports or presentations. You have the right to review and copy your child's information, but you may not be allowed to do so until after the research is completed.

This authorization does not have an expiration date. You have the right to take away your permission to use and disclose your child's information at any time by giving written notice to the study investigator. If you withdraw your permission, your child will not be able to continue in this study, but he/she will not lose access to EASE sessions or other benefits to which they are entitled. When you withdraw your permission, no new information about your child will be gathered after that date. Information that has already been collected may still be used and given to others.

Whom Do You Call If You Have Questions Or Problems?

If you have any questions about this study, please contact Dr. Adam Brown at The New School [brownad@newschool.edu]. If you have any questions or complaints, you may contact a person not on the research team at the Biomedical Research Alliance of New York Institutional Review Board at (516) 318-6877 or at www.branyirb.com/concerns-about-research.

Adolescent eligibility screening for EASE

We would like to obtain your input to determine if EASE is appropriate for your child before we enroll your child in the program. Please note that information collected in the following screening will not be used for research. Please kindly answer the following questions with regards to your child:

1. Is your child experiencing any cognitive impairments?
   *Yes
   *No

2. In the past six months, have your child required an ambulance, been admitted to the emergency room, or been hospitalized for an alcohol- or drug-related reason?'
   *Yes
   *No

3. To your knowledge, in the past month, has your child had any thoughts that they would be better off dead, or of hurting themselves in some way?
   *Yes (if yes, please answer question 4)
   *No (if no, please skip question 4)

4. If yes, do you know if your child has a plan for ending their life, or is taking any steps to end their life?
   *Yes
   *No

Please note that if you answered "yes" to questions 1, 2, or 4, your child is not eligible to participate in EASE. This intervention has not yet been approved for individuals experiencing the aforementioned conditions. Please speak to [CBO supervisor name] at [CBO name] for additional services.

If your child is experiencing suicidal ideation or has a plan to end their life (e.g. if you responded yes to question 3 and either yes or no to question 4), please also note the following resources that you may find useful:

988: Suicide Crisis Lifeline
911: Emergency Assistance
Text "NAMI" or "HOME" to 741741 for the National Suicide Prevention Lifeline

If your child is eligible to participate in EASE, you may proceed to the following section to provide permission for their enrollment.

Permission for adolescent to participate in EASE sessions

Please indicate whether you authorize your child to participate in EASE sessions. You can take whatever time you need to discuss the sessions with your family or anyone else you want to before signing the following section. The decision to let your child take part is up to you and your child. Your child should also complete an assent form in addition to your completion of this consent form if he/she wishes to participate. The research team and [CBO name] will arrange an in-person appointment with your child to conduct the assent form review process in-person at [CBO name] after your child returns this permission form to [CBO name].

Statement of Consent - Signatures

1. I certify that I have read and understand this consent form and all my questions have been answered.

   Yes or No

2. I understand I can remove my child from the study at any time without giving a reason and without penalty.

   Yes or No

3. I agree to the collection, use, sharing and analysis of my personal child's information and study information collected as part of this study by the research team, the sponsor/funding entity, and other authorized persons and regulatory agencies as described in this form.

   Yes or No

4. I understand I will be given a copy of this signed and dated consent form to keep.

   Yes or No

5. My child and I do not give up any legal rights that we would otherwise have if I were not in this study.

   Yes or No

6. As a caregiver, I authorize my child to become a participant in the 7 in-person EASE sessions described above.

   Yes or No

7. As a caregiver, I authorize my child to participate in the 3 interviews before, after, and 3 months following EASE sessions.

   Yes or No

8. As a caregiver, I provide consent for audio and video recording during one of my child's 7 EASE sessions. We will confirm your child's consent just prior to recording as well, and they are free to disagree to recording at the time.

   Yes or No (optional)

9. As a caregiver, I provide consent for audio and video recording during one of my child's 3 interviews. We will confirm your child's consent just prior to recording as well, and they are free to disagree to recording at the time.

   Yes or No (optional)

10. As a caregiver, I provide consent for my child to be photographed during EASE sessions and understand that these photographs may be used in media coverage by the organizations mentioned above.

    Yes or No (optional)

You will be given a copy of this consent form for your records.

Subject (Child): Name (Print) _____

_____

Parent/Legal Guardian: Name (Print) Signature Date

Relation to Child_____

_____

Person Obtaining Consent: Name (Print) Signature Date

Title of the study: Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study

NCT number: N/A

Date of the document: 3/3/2025

The New School for Social Research

Minor Assent
Ages 13-15

Protocol Title:
Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study
Protocol #: 999530263
Sponsor: NYC Office of Community Mental Health

Principal Investigator: Adam Brown, PhD
Institution: The New School for Social Research
Address: 80 Fifth Avenue, NY 10011
Telephone: 646-909-4933

- You can say "Yes" or "No" to being in this study.
- You can ask as many questions as you like before you decide.

Why is this study being done?
The study may help scientists learn about whether a youth mental health program developed by the World Health Organization called EASE (Early Adolescent Skills in Emotion) can be brought to NYC.

About 100 other children and 100 other adults in NYC will be in this study.

What will happen if you are in this study?

- You will be in the study for about 6 months.
- You will be attending 7 in-person group EASE sessions of around 1.5 hours per session once a week at [CBO name]
  [CBO staff member name] will let you know about the days and times for meeting.

- You will complete 3 interviews: One before EASE sessions start, one right after they finish, and one 3 months after EASE sessions are over.
- For each interview that you complete, you will receive a $35 stipend. You will have to complete at least 4 out of the 7 total EASE sessions in order to take part in the second and third interviews and receive the gift cards. You can receive your compensation from your EASE Helper following completion of the interview(s).
- You may be asked to complete additional interviews 3 months after EASE sessions and you can decide whether to participate in them at that time.
- You might be recorded by audio and video during one of your EASE sessions so

that we can learn about whether your EASE Helper is conducting sessions appropriately. You can disagree to having your audio and video recorded but still participate in the program.
- You might be recorded by audio and video during one of your interviews for us to learn more about your experience with EASE. You can disagree to having your audio and video recorded but still participate in the program.
- You may be photographed for your organization and our team to promote the EASE program to NYC communities. You can disagree to having your photographs taken but still participate in the program.

Can you get hurt in this study?

You might feel uncomfortable answering questions about mental health, emotions, and stress. If you ever feel this way, you should share this with any member of our team or an adult like your caregiver or someone from your organization.

If you are feeling suicidal, you should tell your parents/caregivers and any member of our team or someone from your organization. We will also need to contact [CBO supervisor name], who is the supervisor at [CBO name] immediately. This is because [CBO supervisor] at [CBO name] will be able to help you get more specific care. This is their contact information: [insert contact information of CBO supervisor]. We will also share with you contact information for access to local resources for these problems, such as the National Suicide Hotline number 988.

Will this study help you?

Being in this study might not help you. But you might learn some skills to better manage emotions and problems.

Do you have to be in this study?

- You do not have to be in this study, even if your parent or guardian wants you to be.
- You can say "No." There will be no consequences. You can still be part of [CBO name]
- If you say “Yes” now, you can change your mind at any time. You just have to let [CBO staff member name] or the research team know. You don’t have to explain, and there will be no consequences for withdrawing from the study.

You can talk to your parents and the research team and staff at [CBO name] at any time and ask them questions at any time.

If you have any questions or complaints, you may contact a person not on the research team at the Biomedical Research Alliance of New York Institutional Review Board at (516) 318-6877 or at www.branyirb.com/concerns-about-research.

Agreement

1. Yes, I want to be in the study (Then fill in your information below)

Additional questions

- Would you be alright having your audio and video recorded during one of your EASE sessions? We will confirm with you again right before recording, and it is alright for you to say no then too.

  Yes or No (optional)

- Would you be alright having your audio and video recorded during one of your interviews? We will confirm with you again right before recording, and it is alright for you to say no then too.

  Yes or No (optional)

- Would you be alright having your photograph taken for program promotion purposes?

  Yes or No (optional)

Adolescent's Print name: _____

Adolescent's Signature: _____ Date: _____

Adolescent's Email _____

Adolescent's Phone Number _____

You will be given a copy of this consent form to keep for your records.

_____	_____	_____
Person Obtaining Assent: Print Name	Signature	Date

Title of the study: Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study

NCT number: N/A

Date of the document: 3/3/2025

The New School for Social Research

Minor Assent
Ages 10-12

Protocol Title:
Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study
Protocol #: 999530263
Sponsor: NYC Office of Community Mental Health

Principal Investigator: Adam Brown, PhD
Institution: The New School for Social Research
Address: 80 Fifth Avenue, NY 10011
Telephone: 646-909-4933

- You can say "Yes" or "No" to being in this study.
- You can ask as many questions as you like before you decide.

Why is this study being done?
The study may help scientists learn about whether a youth mental health program developed by the World Health Organization called EASE (Early Adolescent Skills in Emotion) can be brought to NYC.

About 100 other children and 100 other adults in NYC will be in this study.

What will happen if you are in this study?

- You will be in the study for about 6 months.
- You will be attending 7 in-person group EASE sessions of around 1.5 hours per session once a week at [CBO name]
  [CBO staff member name] will let you know about the days and times for meeting.

- You will complete 3 interviews: One before EASE sessions start, one right after you finish, and one 3 months after EASE sessions are over.
- For each interview that you complete, you will receive a $35 stipend. You will have to complete at least 4 out of the 7 total EASE sessions in order to take part in the second and third interviews and receive the gift cards. You can receive your compensation from your EASE Helper following completion of the interview(s).
- You may be asked to complete additional interviews 3 months after EASE sessions and you can decide whether to participate in them at that time.
- You might be recorded by audio and video during one of your EASE sessions so

that we can learn about whether your EASE Helper is doing their job well. You don't have to agree to this to join EASE.
- You might be recorded by audio and video during one of your interviews for us to learn more about your experience with EASE. You don't have to agree to this to join EASE.
- You may be photographed for us to share the EASE experience with NYC communities. You don't have to agree to this to join EASE.

Can you get hurt in this study?

You might feel uncomfortable answering questions about mental health, emotions, and stress. If you ever feel this way, you should share this with any member of our team or an adult like your caregiver or someone from your organization.

If you are feeling suicidal, you should tell your parents/caregivers and any member of our team or someone from your organization. We will also need to contact [CBO supervisor name], who is the supervisor at [CBO name] immediately. This is because [CBO supervisor] at [CBO name] will be able to help you. This is their contact information: [insert contact information of CBO supervisor]. We will also share with you contact information for more help, such as the National Suicide Hotline number 988.

Will this study help you?

Being in this study might not help you. But you might learn some skills to better manage emotions and problems.

Do you have to be in this study?

- You do not have to be in this study, even if your parent or guardian wants you to be.
- You can say "No." No one will be mad at you. You can still be part of [CBO name]
- If you say "Yes" now, you can change your mind at any time. You just have to let [CBO staff member name] or the research team know. You don't have to say why.

You can talk to your parents and the research team and staff at [CBO name] at any time and ask them questions at any time.

Agreement

1. Yes, I want to be in the study (Then fill in your information below)

Additional questions

- Would you be alright having your audio and video recorded during one of your EASE sessions? We will confirm with you again right before recording, and it is alright for you to say no then too.

Yes or No (optional)

- Would you be alright having your audio and video recorded during one of your interviews? We will confirm with you again right before recording, and it is alright for you to say no then too.

  Yes or No (optional)

- Would you be alright having your photograph taken for us to share with others?

  Yes or No (optional)

Adolescent's Print name: _____

Adolescent's Signature: _____ Date: _____

Adolescent's Email _____

Adolescent's Phone Number _____

You will be given a copy of this consent form to keep for your records.

_____	_____	_____
Person Obtaining Assent: Print Name	Signature	Date

Title of the study: Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study

NCT number: N/A

Date of the document: 3/3/2025

The New School for Social Research
Caregiver Participant Information and Informed Consent Form

Protocol Title:
Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study
Protocol #: 999530263
Sponsor: NYC Office of Community Mental Health

Principal Investigator: Adam Brown, PhD
Institution: The New School for Social Research
Address: 80 Fifth Avenue, NY 10011
Telephone: 646-909-4933

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a participant in a research study because you have expressed interest in the study.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the implementation of the World Health Organization's Early Adolescents Skills for Emotions (EASE) in New York City (NYC). You will not receive any experimental drugs or procedures as part of this study.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	You are expected to participate in 3 virtual sessions of around 1.5 hours long per week (3 weeks).
Procedures	The main procedures in the study include: · Complete 3 interviews - one before EASE sessions, one immediately after completion of EASE sessions, and one 3 months post-completion of EASE sessions · Participate in 3 virtual sessions of EASE
Risks	There are not expected to be any physical risks to you as part of this study.
Benefit	There is no guarantee that you will receive direct benefit as a result of your participation in this study. Possible benefits of participating in EASE include gaining valuable tools and strategies to better support your child in their socio-emotional development.

Alternatives to Study Participation	Your alternative is to not take part in the study.
Costs	There are no costs to this study.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent form, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

Informed Consent Form

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

Dr. Adam Brown, PhD, Director of The New School Center for Global Mental Health, Janus Wong, Research Associate, and Tina Xu, MA student at The New School.

Disclosure of Financial Interests
NYC Office of Community Mental Health, the sponsor of this study, is providing funds to [CBO name] on a per participant basis for conducting this research study.

Purpose of the study
The EASE program is an existing, evidence-based program/intervention (originally developed by the World Health Organization - WHO), and this study aims to evaluate the local implementation of this program. The WHO developed EASE as an evidence-based group psychological intervention for youth and caregivers that seeks to support the wellbeing of 10-15 year-olds and help them develop skills in emotional management, problem management, and stress reduction. The adaptation process of EASE was completed in Summer 2024 to make the original version more relevant, acceptable, and engaging for the NYC community. Through this pilot implementation of the adapted EASE program, our goal is to evaluate whether this mental health model can be implemented in NYC.

Number of Participants and Length of Study Participation
About 100 caregivers and 100 adolescents are expected to participate in this study at 6 research sites in NYC. Your participation in this study is expected to last about 6 months.

Procedures
You will be participating in EASE sessions and completing interviews before, after, and 3 months post-completion of EASE.

EASE caregiver sessions aim to improve the caregiver-child relationship and enable caregivers

to better support their child who may be experiencing emotional distress. Throughout these sessions, you'll develop essential caregiving skills including active listening techniques, methods to identify and process both your own and your child's emotions, strategies for creating quality time together, effective ways to offer praise for your child, and practical self-care techniques to maintain your own well-being. These sessions are scheduled to align with your adolescent's sessions, ensuring both programs complement each other for optimal family outcomes.

Sessions will be hosted on Zoom. Your participation will consist of one 1.5-hour session per week for 3 weeks. These sessions will be led by trained staff members as your community organization. Staff members will contact you about the session dates closer to the start of sessions (mid-end of April).

In addition to EASE, we will also need you to participate in three key interviews with the research team. The interview timeline is as follows:

- A 1st interview, also known as a baseline interview, will be conducted before EASE sessions begin.
- A 2nd interview will be conducted after EASE sessions are completed.
- A 3rd interview will be conducted three months after the 2nd interview. At this point, we may invite you to complete more individual interviews and/or focus group discussions. These will be in person or online.

Participant Responsibilities

As a participant in this study, you will have certain responsibilities, including the following:

- Participating in EASE sessions
- Completing the three interviews or focus group discussions

Risks

We do not anticipate any direct risks to your health. However, we do recognize that you may feel uncomfortable discussing certain thoughts or feelings. If you ever feel this way, you may ask us questions, speak to a staff member from a connected CBO, request a break, or stop participating. There will be no consequences if you choose to do so.

New Information

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Benefits

We cannot promise any benefit to you or others from your participation in this research. However, you may gain valuable tools and strategies to better support your child in their socio-emotional development. As a caregiver, we hope you'll be empowered with enhanced skills to navigate parenting challenges effectively. The sessions aim to strengthen your own capacity for problem management and stress reduction, enabling you to create a more supportive and nurturing environment for both yourself and your child.

Alternatives to Study Participation

Your alternative is to not take part in the study.

Costs of Participation

There are no costs to participate.

Reimbursement
In terms of compensation, for each interview that you complete, you will receive a $35 stipend. You can obtain the stipend from the CBO you are connected with by contacting your EASE helper following completion of the interview. For your reference, here is the contact information for [CBO name]: [insert contact information for CBO]. Please note that participating in EASE is a requirement for completing the interview assessments. It is especially important that you complete at least 2 EASE sessions before your 2nd interview. In the case that you cannot meet study requirements, our team reserves the right to discontinue your participation at any time.

Voluntary Participation and Withdrawal
Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care that you would otherwise receive. If you want to withdraw from the sessions, please let any staff member at [CBO name] or a research team member know.

Your participation in this study may be stopped without your consent at any time and for any reason by the [CBO name] staff and research team. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you do not follow the study instructions, the study is stopped, or for other administrative reasons.

Confidentiality
To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study may be submitted to the study sponsor or the Institutional Review Board, the committee that reviews and approves the study. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

If you take part in this study, you will be assigned a unique participant code to help protect your privacy. Your study records will be labeled with this code that does not directly identify you. The research team securely stores the linking code between your name and study information.

However, if we find that what you share puts you or others at risk of harm (e.g. suicidality risk), we will need to contact [CBO supervisor name], who is the supervisor at [CBO name] immediately. This is because [CBO supervisor] at [CBO name] will have a referral protocol to direct you to appropriate, specialized care. This is their contact information, for your reference: [insert contact information of CBO supervisor]

We will also share with you contact information for access to local resources for these problems, such as the National Suicide Hotline number 988.

It is also possible that your EASE Helper will ask to video/audio record the sessions. The sessions are recorded so that the supervisor on the research team can review the recording to make sure that your EASE Helper(s) has/have conducted the session appropriately. Only this supervisor and your EASE Helper(s) will have access to this recording. They will store and access it in your code-named record in a password-protected folder on a secure server. As soon as they listen to the recording, they will permanently destroy it. Only sessions in which all participants provide consent to be recorded will be recorded. What we just described will apply to other interviews or focus group discussions that we may invite you to complete at the end of the study. You can consent to participating in the research study without consenting to being recorded.

Additionally, it is possible that you may be photographed for the EASE program. These photographs may be broadcast, published in print or online, or put to other uses by the New School, the Mayor's Office of Community Mental Health, and your community organization. The purpose of these photographs is to promote EASE in the community for potential programming in the future. You can consent to participating in the research study without consenting to being photographed.

Moreover, because of the group nature of the sessions, we cannot guarantee that what you share will remain completely confidential, and it may be possible that other participants will know what you shared. That said, the information we collect will be kept confidential among our team and the parties involved.

Please note that data may be stored on a New School google drive for a minimum of five years for future use in connection with potential studies. You will not be asked to provide additional consent for such use of the data.

Contacts for Questions, Complaints, Concerns

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact:

- Dr. Adam Brown, Professor at The New School University [brownad@newschool.edu]
- If you have any questions or complaints, you may contact a person not on the research team at the Biomedical Research Alliance of New York Institutional Review Board at (516) 318-6877 or at www.branyirb.com/concerns-about-research.

Statement of Consent

1. I certify that I have read and understand this consent form and all my questions have been answered.

   Yes or No

2. I understand that I can leave the study at any time without giving a reason and without penalty.

   Yes or No

3. I agree to the collection, use, sharing and analysis of my information and study information and samples collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.

   Yes or No

4. I understand I will be given a copy of this signed and dated consent form to keep.

   Yes or No

5. I understand that I do not give up any legal rights that I would otherwise have if I were not in this study.

Yes or No

6. As a caregiver, I agree to become a participant in the 3 virtual EASE sessions described above.

   Yes or No

7. As a caregiver, I agree to become a participant in the 3 interviews described above.

   Yes or No

8. I agree to video/audio recording during one of my interviews. We will confirm your consent just prior to recording as well, and you are free to disagree to recording at the time.

   Yes or No (optional; participants can choose to provide consent to one or both or neither)

9. I agree to video/audio recording during one of my three EASE sessions. We will confirm your consent just prior to recording as well, and you are free to disagree to recording at the time.

   Yes or No (optional; participants can choose to provide consent to one or both or neither)

10. I agree to being photographed during EASE sessions and understand that these photographs may be used in media coverage by the organizations mentioned above.

    Yes or No (optional)

Caregiver's Print name: _____

Caregiver's Signature: _____ Date: _____

Caregiver's Email (to send Zoom details) _____

Caregiver's Phone Number _____

You will be given a copy of this consent form to keep for your records.

_____

Person Obtaining Consent: Name (Print) Signature Date

Title of the study: Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study

NCT number: N/A

Date of the document: 3/3/2025

The New School for Social Research
Helper Participant Information and Informed Consent Form

Protocol Title:
Adapted Early Adolescent Skills for Emotions (EASE) to decrease psychological distress among urban youth and caregivers in NYC: a pilot study

Protocol #: 999530263
Sponsor: NYC Office of Community Mental Health

Principal Investigator: Adam Brown, PhD
Institution: The New School for Social Research
Address: 80 Fifth Avenue, NY 10011
Telephone: 646-909-4933

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a participant in a research study because you have expressed interest in the study.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the implementation of the World Health Organization's Early Adolescents Skills for Emotions (EASE) in New York City (NYC). You will not receive any experimental drugs or procedures as part of this study.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty. Refusal to participate in or early withdrawal from this research study will not affect employment at your current workplace.
Length of Participation	You are expected to participate in at least 8 days of training and weekly group supervision of your first EASE practice as well as EASE delivery and assessments, totaling about 9 months.
Procedures	The main procedures in the study include: • Participating in at least 8 days of training and weekly group supervision of your first EASE practice • Completing pre- and post-training/supervision surveys/roleplays/interviews

	• Delivery of EASE sessions to adolescents and caregivers at your organization
Risks	There are not expected to be any physical risks to you as part of this study.
Benefit	There is no expectation that you will benefit from participating in this study; however the information learned may help people in the future.
Alternatives to Study Participation	Your alternative is to not take part in the study.
Costs	There are no costs to this study.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent form, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

Informed Consent Form

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

Dr. Adam Brown, PhD, Director of The New School Center for Global Mental Health, Janus Wong, Research Associate, and Tina Xu, MA student at The New School.

Disclosure of Financial Interests

NYC Office of Community Mental Health, the sponsor of this study, is providing funds to [CBO name] for conducting this research study.

Purpose of the study

The EASE program is an existing, evidence-based program/intervention (originally developed by the World Health Organization - WHO), and this study aims to evaluate the local

implementation of this program. The WHO developed EASE as an evidence-based group psychological intervention for youth and caregivers that seeks to support the wellbeing of 10-15 year-olds and help them develop skills in emotional management, problem management, and stress reduction. The adaptation process of EASE was completed in Summer 2024 to make the original version more relevant, acceptable, and engaging for the NYC community. Through this pilot implementation of the adapted EASE program, our goal is to evaluate whether this mental health model can be implemented in NYC.

Helpers at CBOs will be trained to deliver EASE. The primary objective for Helpers is to better understand their experience in EASE, with their clients, and specifically with conducting virtual or in-person training and supervision through interviews conducted with the research team.

The secondary objective is to understand the feasibility, acceptability and perceived benefits of a competency-based training approach to improve the quality and impact of EASE when delivered by non-mental health specialist Helpers at community-based organizations (CBO) in NYC. We are interested in using validated rating scales from the World Health Organization's Ensuring Quality in Psychological Support (EQUIP) project to assess non-mental health specialist Helpers' competencies and explore how competency-based training and supervision could be improved. In order to do this, we will be observing health workers participating in the training through role-plays and mock client sessions. Specifically, we will be using the rating scales Working with Children Assessment of Competencies Tool (WeACT) and Enhancing Assessment of Common Therapeutic Factors (ENACT) to assess these roleplays, which incorporates the skills that are being trained and that need to be used by psychosocial counselors for effective therapeutic action.

Number of Participants and Length of Study Participation

Approximately 20-30 EASE helpers and 200 participants, including 100 adolescents and 100 caregivers, will participate in the research study; specifically, your organization will be delivering 2 cycles of EASE (2 for caregivers and 2 for youth), with 8-12 youth per group and 9-14 caregivers per group. If you yourself wish to participate, participation will last for approximately six months, including training and delivery.

Procedures

This study involves:

a) AT least 8 days of training and weekly group supervision of your first EASE practice.
b) pre- and post-supervision surveys,
c) two interviews, one before and one after the EASE training, which is designed to collect information from you, a EASE Helper, as someone who has firsthand knowledge and experience of the program and what it was like to conduct sessions and work with clients; and
d) structured pre-training, post-training, and post-supervision role plays (WeACT and ENACT) to assess core EASE competencies.

Your interviews and role plays will be video recorded. These sessions may be later reviewed and coded by trained coders according to the WeACT and ENACT rating scale. This information

will be reviewed by the researchers to help identify aspects of the program that are working well and areas that need further adaptation or contextualization .

The EASE training includes the following:
● Participants learn to competently deliver EASE intervention to persons affected by adversity
● Participants will learn to effectively deliver remote mental health and psychosocial support interventions competently and safely over Zoom and in-person
● Participants will learn about signs and symptoms of common mental health problems (e.g., depression, anxiety, stress)
● Participants will learn basic helping skills
● Participants will learn how to conduct EASE assessments
● Participants will learn who should be included or excluded from EASE
● Participants will learn how to teach EASE strategies
● Participants will learn how to engage in supervision and provide feedback to others in a meaningful way
● Participants will explore ways of implementing EASE in their own context and adapting material for their communities

Participant Responsibilities

As a participating Helper in this study, you will have certain responsibilities, including the following:

- EASE Helper training. This training will be conducted in person and remotely. The training will entail two to three (tentative) in-person days and 6 virtual sessions (3.5 hours per session, 1 session per week) with trainers, as well as asynchronous, offline work, totaling approximately 40 hours. The training will take place between March to April 2024. In order to complete the EASE training, trainees must also participate in weekly group supervision for the duration of their first cycle of EASE. Helpers must attend at least 80% of the synchronous classroom training sessions to be considered for the study and receive a certificate of completion.
    - The tentative dates for training are:
        - In-person kick-off days: March 6th and March 7th, 2025 (10am-1:30pm; location: tbd)
        - 6 virtual sessions of 3.5 hours per session: Either every Tuesday from 10am-1:30pm starting from March 11th or every Friday from 10am-1:30pm starting form March 14th. Staff members can sign up for the virtual training option that best suits their schedules.
- pre-/post-supervision surveys to measure progress towards the objectives listed above.
- focus group discussion and/or key informant interviews to discuss your experience in EASE training, supervision, and conducting services in EASE. This discussion will be conducted online over Zoom and will last approximately 1 hour. Video will be recorded.
- pre-training, post-training, and post-supervision assessments of WeACT, ENACT, and EASE core competencies including structured role plays that are video recorded for research purposes. You may be asked to participate in a follow-up role play exercise to assess maintenance of skills and competencies over time.

- The approximate time of participation for each role play exercise is 45 minutes and for each focus group or key informant interview is 30 minutes to an hour.

Risks
We do not anticipate any direct risks to your health. However, we do recognize that you may feel uncomfortable discussing certain thoughts or feelings with EASE clients or during training/supervision. If you ever feel this way, you can stop immediately. There will be no consequences if you choose to do so.

New Information
You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Benefits
We cannot promise any benefit to you or others from your participation in this research. This research is designed to learn more about conducting and enhancing mental health services delivered by non-specialist providers delivering EASE in the NYC community. The information that we collect through these interviews will be an important medium for evaluating and improving the program and EASE services delivered to others like you, and, ultimately, will be used to improve mental health services being delivered to youth and caregivers in NYC.

Alternatives to Study Participation
Your alternative is to not take part in the study.

Costs of Participation
There are no costs to participate.

Reimbursement
There is no reimbursement for this study.

Voluntary Participation and Withdrawal
Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care that you would otherwise receive. If you want to withdraw from the sessions, please let any research team member know. Refusal to participate in or early withdrawal from this research study will not affect employment at your current workplace.

Your participation in this study may be stopped without your consent at any time and for any reason by the research team. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you do not follow the study instructions, the study is stopped, or for other administrative reasons.

Confidentiality

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study may be submitted to the study sponsor or the Institutional Review Board, the committee that reviews and approves the study. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

If you take part in this study, you will be assigned a unique participant code to help protect your privacy. Your study records will be labeled with this code that does not directly identify you. The research team securely stores the linking code between your name and study information.

However, if we find that what you share puts you or others at risk of harm (e.g. suicidality risk), we will need to contact [CBO supervisor name], who is the supervisor at [CBO name] immediately. This is because [CBO supervisor] at [CBO name] will have a referral protocol to direct you to appropriate, specialized care. This is their contact information, for your reference: [insert contact information of CBO supervisor]

We will also share with you contact information for access to local resources for these problems, such as the National Suicide Hotline number 988.

We may also video record EASE sessions. If you consent to recording, a supervisor on the research team will review the recording to make sure that you have conducted the session appropriately. Only this supervisor will have access to this recording. They will store and access it in a code-named record in a password-protected folder on a secure server. As soon as they listen to the recording, they will permanently destroy it.

Additionally, role plays that are recorded on video will be reviewed by the research team supervisor to ensure fidelity of EASE skills. The recorded interviews will also be reviewed by the research team for research data analysis purposes. Similarly, these recordings will be destroyed permanently following use, and they will be stored in a code-named record in a password-protected folder on a secure server before they are viewed.

Please note that data retrieved from watching these video recordings may be stored on a New School google drive for a minimum of five years for future use in connection with potential studies. You will not be asked to provide additional consent for such use of the data.

Finally, it is possible that you may be photographed for the EASE program. These photographs may be broadcast, published in print or online, or put to other uses by the New School, the Mayor’s Office of Community Mental Health, and your community organization. The purpose of these photographs is to promote EASE in the community for potential programming in the future.

Contacts for Questions, Complaints, Concerns

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact:

- Dr. Adam Brown, Professor at The New School University [brownad@newschool.edu]
- If you have any questions or complaints, you may contact a person not on the research team at the Biomedical Research Alliance of New York Institutional Review Board at (516) 318-6877 or at www.branyirb.com/concerns-about-research.

Statement of Consent

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form
- I consent to being video recorded for any interviews, role plays, and EASE sessions as part of the study.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.
- I certify that I have read and understand this consent form and all my questions have been answered.

Please also select from the following

- I agree to being photographed during EASE sessions and understand that these photographs may be used in media coverage by the organizations mentioned above. Agree or disagree (optional – you can still participate in the study without agreeing to being photographed)

I voluntarily agree to participate in this study.

Helper's Print name: _____

Helper's Signature: _____ Date: _____

Helper's Email (to send Zoom details) _____

Helper's Phone Number _____

You will be given a copy of this consent form to keep for your records.

_____

Person Obtaining Consent: Name (Print) Signature Date