Empowerment Self-Defense Training for the Prevention of Victimization of Transgender Women

03/30/2021

University Integrated Institutional Review Board
205 East 42nd Street
New York, NY 10017
http://www.cuny.edu/research/compliance.html

Initial Application
2021-0291
Danielle Berke

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2021-0291 **Initial Application** **Danielle Berke**

1. Summary

Protocol Title

Empowerment Self-Defense Training for the Prevention of Victimization of Transgender Women- Phase II

Primary College	Hunter College
PI relationship to CUNY	Full-time Faculty

Application Initiated By	Maiya Hotchkiss
Are you seeking an approval for a project that is lacking definite plans for involvement of human subjects (45 CFR 46.118)?	No
Research Type	Social Behavioral
Research Type	Social Behavioral
Are you seeking an exemption from IRB review?	No

Lay Summary

Transgender women (TW) are at the highest risk for exposure to interpersonal violence even compared to other sexual and gender minority individuals. Empowerment Self-Defense (ESD) training, a specific violence prevention approach that teaches participants strategies for actively resisting assault, holds tremendous promise for reducing risk of violent victimization. Indeed, research consistently shows that assertive and physical forms of resistance are effective in deterring rape. Moreover, in randomized controlled trials, ESD violence prevention training has been shown to reduce rates of victimization among college students by nearly half at 1-year follow-up. Unfortunately, diverse TW are rarely included in ESD violence prevention research and programming. This exclusion is problematic not only because TW comprise the highest need population for targeted violence prevention, but also because theoretical models of gender identity stigma hold that social and psychological stressors specific to gender-minority identity increase risk for interpersonal violence along multiple unique pathways. Standard ESD violence prevention programs do not incorporate content, materials, or strategies tailored to the specific pathways by which TW are impacted by interpersonal violence. This study fills this substantial gap in prevention science by developing an ESD violence prevention training specifically tailored to TW. The proposed project aims to develop and refine a tailored ESD violence prevention training for diverse TW through a series of sequential Aims: a) develop an initial draft of an ESD violence prevention curriculum tailored to TW (Aim 1); b) evaluate the feasibility and acceptability of recruitment, assessment procedures, retention and follow-up procedures, and implementation of the new intervention (Aim 2); and c) assess the preliminary efficacy of the tailored intervention program to increase use of self-protective resistance strategies, mitigate minority stressors and attitudinal barriers to self-defense, and reduce rates of exposure to violence (Exploratory Aim).We will accomplish these aims using a two-phase research design that begins with formative qualitative work engaging research partners on a community board and a small sample of research participants. Information for Phase 1 can be located in Protocol number 2020-0017. Further refinement and assessment of the feasibility and acceptability of the curriculum using Phase 1 findings will occur in Phase 2 through the delivery of the tailored ESD curriculum to 3 groups of 16 TW. To assess the preliminary efficacy of the tailored intervention, program participants will complete a battery of validated questionnaires assessing use of resistance strategies, gender-minority and general psychological factors hypothesized to mediate the behavioral effects of the intervention, and exposure to victimization experiences prior to, immediately following, and 6 months

post-completion of the training. Together, the proposed research will lay the foundation for a large-scale randomized controlled trial (RCT) of the tailored ESD violence prevention curriculum.

Do you have a scientific protocol or a sponsors protocol? No

2. Research Personnel

Name/Department	Role/Status	Contact	Access	Signature Authority	Phone	Email
Danielle Berke / Hunter College	PI /		Yes			
Maiya Hotchkiss / Hunter College	Study Coordinator /		Yes			
Ashley Smith / The Graduate School and University Center	Study Coordinator /		Yes			
Craig Gilbert / Hunter College	Research Assistant /					
Lisbeth Rubi / Hunter College	Research Assistant /					
Jessica Palatnik / Hunter College	Research Assistant /					

3. Other Personnel

None

4. Research Sites

Name	CUNY
Sub-Location	Hunter College
Site PI	99999999
Role of the site in research	9999999
Has IRB?	No
Permission Granted?	No

5. Research Design - Overview

Research Purpose and Hypothesis

This study leverages the strong evidence-base for Empowerment Self-Defense (ESD) violence prevention to address disparities in violence exposure among TW. The overarching goal of this R21 is to develop and refine a tailored ESD violence prevention training for diverse TW through a series of sequential Aims: a) develop an initial draft of an ESD violence prevention curriculum tailored to TW (Aim 1) (See protocol number 2020-0017); b) evaluate the feasibility and acceptability of recruitment, assessment procedures, retention and follow-up procedures, and implementation of the new intervention (Aim 2); and c) assess the preliminary efficacy of the tailored intervention program to increase use of self-protective resistance strategies, mitigate minority stressors and attitudinal barriers to self-defense, and reduce rates of exposure to violence (Exploratory Aim). Together, the proposed research will lay the foundation for a large-scale randomized controlled trial (RCT) of the tailored ESD violence prevention curriculum. We will accomplish these aims using a two-phase research design that begins with formative qualitative work engaging research partners on a community board and a small sample of research participants (See protocol number 2020-0017). This data will be used to inform the development and refinement of the ESD violence prevention curriculum for TW. Further refinement and assessment of the feasibility and acceptability of the curriculum will occur in Phase 2 through the delivery of the tailored ESD curriculum to 3 groups of 16 TW. To assess the preliminary efficacy of the tailored intervention, program participants will complete a brief survey assessing the program directly after completion, as well as a battery of validated questionnaires assessing use of resistance strategies, gender-minority and general psychological factors hypothesized to mediate the behavioral effects of the intervention, and exposure to victimization experiences prior to, immediately following, and 6 months post-completion of the training.

Research Design and Methodology

The overall goal of this study is to use findings from Phase 1 (See protocol number 2020-0017) to deliver and refine a tailored ESD violence prevention training for diverse trans women. Participants for Phase 2 (n = 48) will be recruited from online forums including social media sites (e.g., Facebook, Twitter), banner ads on social networking/dating sites (e.g., Scruff, BGC Live, OK Cupid, Lex) that are trans-inclusive and through dissemination of paper and/or electronic recruitment flyers with leaders of community organizations that connect transgender individuals (e.g., AVP; Callen Lorde, Trans-lantinx network). Participants from prior studies who consented to future contact will be sent the study flyer by email.The proposed curriculum will be systematically refined based on delivery of the intervention to 3 groups of 16 TW each in a 20-hour training program, in 5 4-hour sessions. We have contracted with Prepare, Inc., the New York City chapter of IMPACT International to deliver the tailored ESD violence prevention intervention. IMPACT is an international ESD violence prevention organization with chapters across the United States. Prepare, Inc. will provide facilitators who have completed IMPACT's nationally standardized ESD violence prevention program requirements that include receipt of over 100 hours of training. IMPACT training is open to trans and cisgender women. The extensive training of IMPACT facilitators promotes intervention efficacy, while the risk of potential bias conferred by their experience with a pre-existing curriculum is mitigated by our community-engaged approach (i.e.,TW community members, service providers, and scientists [PI and Co-I] collectively shape the content of the final tailored ESD intervention, and TW co-facilitators will be present in every training session). Prior to the start of group, facilitators will review the tailored curriculum in detail and attend 2-3 supervision/training meetings with the PI. These meetings will consist of reviewing the curriculum, role-plays of critical intervention components, and discussion of questions or concerns. The primary outcome of Aim 2 is to evaluate our ability to recruit our target (n = 48) and retain >75% over the course of the intervention. Successful completion of the pilot trial, including meeting or exceeding these benchmarks for success, will determine the feasibility and acceptability of recruiting participants into a future RCT. Preliminary efficacy of the tailored ESD violence prevention intervention will be evaluated as an exploratory aim. Participants enrolled in the pilot trial will be administered a battery of validated baseline questionnaires at baseline, immediately following the course, and 6 months after course completion (see Assessment Packet in attached below) including: - Demographics - Social Class Ladder- Community Ladder- Service Utilization Form - Sexual experiences Survey - Everyday Discrimination

Scale- Conflict Tactics Scale - Gender Minority Stress Risk and Resilience Scale - Post Traumatic Stress Disorder Symptom Checklist for DSM-5 (PCL-5)- Sexual Assertiveness Questionnaire- Resistance Tactics Survey- Dating Self-Protection - Illinois Rape Myth Acceptance - Resistance Self-Efficacy - Personal Progress- Transgender Congruence Scale - Depression Anxiety and Stress Scale - Quick Drinking Screen - DAST-10Brief acceptability checklists will be administered after each course session, which will contain a brief list of topics covered during that training session and participants will indicate which of the topics they felt were adequately covered (See page 38 of Assessment Packet, "Satisfaction and Fidelity Forms" for example items and formatting of this checklist). Lastly, an exit interview will be scheduled on the final day of the course, and will take place over the weeks immediately following the completion of the course. Interviews will be video recorded using the Zoom videoconferencing platform. The video-recorded qualitative interviews will be recorded and transcribed verbatim using the Zoom transcription function (omitting identifying information) and verified for accuracy. We will use three strategies to improve retention, based on an intensive evidence-based follow-up protocol with which the PI has considerable experience. First, participants will be compensated for completion of the assessment appointments at increasing increments over time (i.e., $40 for baseline, $30 for follow-up immediately after the course and $30 for the exit interview after the course, $80 for 6-month follow-up). Second, at baseline, participants will be asked to provide extensive locating information and to provide names of two local persons to be contacted in the event that the participant cannot be reached. This information will be updated at the time of follow-up survey administration. Third, participants will receive $10 cash for each of the five session acceptability checklists they complete (one per session attended- up to $50 total) which will be distributed at session 3/5 (up to $30) and 5/5 (up to $20). Analyses will be of two primary types: (a) examinations of whether feasibility targets were met across a variety of measures; and (b) examinations of the efficacy of the tailored ESD violence prevention intervention. We will use repeated measures one-way ANOVA to test if the tailored ESD curriculum has statistically significant effect on measures of behavioral and psychological/attitudinal change. If a significant effect is detected, we will use Tukey's pairwise-comparison procedure to compare all treatment means, with a 95% family confidence coefficient. To assess changes in exposure to victimization, we will collapse into three levels: (a) no history of victimization; (b) moderate victimization; (c) severe victimization. For this categorical data, a chi-square test of independence will be performed to compare posttreatment vs. pre-treatment, and 6-month FU vs. pre-treatment respectively to assess the preliminary efficacy of the program, with a family-wise type I error controlled at 0.05 using Bonferroni procedure. Our efficacy outcomes are exploratory and powered to detect large effect sizes. In the largest scale RCT of an ESD violence prevention program to date, rates of completed assault among women receiving resistance training were reduced by half at 1-year follow-up. However, as there are no existing studies that report on ESD efficacy among TW, we will use results of our exploratory efficacy analysis to shape power analyses for a subsequent, fully powered, RCT

Retrospective Data Review ONLY	No

Funding Requested/Obtained	Yes
Compensation for participation	Yes
Will participants incur any research related costs?	No
Is compensation available for research related injury?	No

Surveys or Questionnaires	Yes
Will the survey or questionnaire be self administered by the participants?	Yes
Do you intend to give feedback to participants based on survey/ questionnaire results?	No
Attach survey(s) / questionnaire(s)	
Title	ESD TW Phase 2 Assessment Packet (Survey Battery administration schedule on page 2, survey battery page 4-37)
Upload	Assessment packet_ESD for TW_10.12.20 (3).pdf

Interviews	Yes
Who will conduct the interview	Danielle Berke, Maiya Hotchkiss, Ashley Smith, Craig Gilbert
Will any individual(s) other than the research personnel be present during the interview?	No

Attach interview questions

Title	ESD TW Phase 2 Assessment Packet (Interview on page 44)
Upload	Assessment packet_ESD for TW_10.12.20 (3).pdf
Observation	No
Audio or Video Recording or Photograph	Yes

Please be sure to insert template language regarding recordings and/or photographs in the consent document

Check all that apply

Audio Recording Yes

List the procedures that will be recorded

We are requesting permission to audio record the one-on-one semi-structured participant exit interview using the secure Zoom teleconferencing platform.

State the purpose of recording

The recordings will only be used for verbatim transcription using the transcribe function in the Zoom teleconferencing platform (omitting identifying information) to facilitate rapid content analysis of key themes. These themes, in turn, will be used to inform the development of a tailored violence prevention curriculum for transwomen. Participants will also be offered the option to securely access and download a personal copy of the recording, if they request to do so.

Will participants be permitted to review, edit and/or erase the recording?	Yes
Will participants be identified in the recording?	Yes

How will you maintain participant confidentiality?

During the consenting process, we will communicate with all participants that they have the right to download an audio and video recording of the interview. If the participant does not make this request, electronic copies of study data will be securely downloaded as two separate files (an audio-only and video recording file) to a local server from Zoom. Local video-files will be immediately deleted. The audio-only file will be immediately uploaded for storage on an online password-protected, backed up lab server that is accessible only by lab personnel. Local audio file copies will be deleted immediately once uploaded to the secure drive. The audio recording files will be labeled with a unique participant ID number, and will contain participants' voice but will not contain names. The labels on these files will constitute a link between identifiable information and the participant ID number, which will be used to link other study data together. Only members of the study team will be able to access the audio recordings taken during the interview session. Participant data will remain confidential.If the participant makes the request to have a personal copy of the interview, we will store the audio and video recording file in Zoom for one week, during which the participant will have one week to download and store the file using a secure Zoom link to the recording, sent via email. Risk of sharing this data with the participant includes risk of loss of confidentiality. However, as the identifiable data includes the responses of the participant only (and the interviewer prompts) and would be in the hands of those at risk of being identified, risk of confidentiality loss is minimal. At the end of the one week, electronic copies of study data will be securely downloaded as two separate files (an audio-only and video recording file) to a local server from Zoom. Local video-files will be immediately deleted. The audio-only file will be immediately uploaded for storage on an online password-protected, backed up lab server that is accessible only by lab personnel. Local audio file copies and Zoom cloud copies will be deleted immediately once uploaded to the secure drive. The audio recording files will be labeled with a unique participant ID number, and will contain participants' voice but will not contain names.

The labels on these files will constitute a link between identifiable information and the participant ID number, which will be used to link other study data together. Only members of the study team will be able to access the audio recordings taken during the interview session. Participant data will remain confidential.

Who will have access to the recordings?	Danielle Berke, Maiya Hotchkiss, Ashley Smith, Craig Gilbert, Lisbeth Rubi, Jessica Palatnik
Video Recording	Yes

List the procedures that will be recorded

We are requesting permission to video record the one-on-one semi-structured participant exit interview.

State the purpose of recording

Zoom offers a video and audio recording option only (no audio-only option), thus virtual participation will include video recording. Interviews with participants who opt to take part in study procedures in-person when this option becomes available will also be video recorded, to promote similarity of treatment of virtual versus in-person participants. To ameliorate additional challenges regarding confidentiality with video-recording files, the recording will be downloaded such that audio file and video file are downloaded as separate files; the video file will be deleted immediately and will never be saved or stored. The audio-only file will be saved for transcription. The audio recordings will only be used for verbatim transcription (omitting identifying information) to facilitate rapid content analysis of key themes. These themes, in turn, will be used to inform the development of a tailored violence prevention curriculum for transwomen. Participants will also be offered the option to securely access and download a personal copy of the recording, if they request to do so.

Will participants be permitted to review, edit and/or erase the recording?	Yes
Will participants be identified in the recording?	Yes

How will you maintain participant confidentiality?

During the consenting process, we will communicate with all participants that they have the right to download an audio and video recording of the interview. If the participant does not make this request, electronic copies of study data will be securely downloaded as two separate files (an audio-only and video recording file) to a local server from Zoom. Local video-files will be immediately deleted. The audio-only file will be immediately uploaded for storage on an online password-protected, backed up lab server that is accessible only by lab personnel. Local audio file copies will be deleted immediately once uploaded to the secure drive. The audio recording files will be labeled with a unique participant ID number, and will contain participants' voice but will not contain names. The labels on these files will constitute a link between identifiable information and the participant ID number, which will be used to link other study data together. Only members of the study team will be able to access the audio recordings taken during the interview session. Participant data will remain confidential.If the participant makes the request to have a personal copy of the interview, we will store the audio and video recording file in Zoom for one week, during which the participant will have one week to download and store the file using a secure Zoom link to the recording, sent via email. Risk of sharing this data with the participant includes risk of loss of confidentiality. However, as the identifiable data includes the responses of the participant only (and the interviewer prompts) and would be in the hands of those at risk of being identified, risk of confidentiality loss is minimal. At the end of the one week, electronic copies of study data will be securely downloaded as two separate files (an audio-only and video recording file) to a local server from Zoom. Local video-files will be immediately deleted. The audio-only file will be immediately uploaded for storage on an online password-protected, backed up lab server that is accessible only by lab personnel. Local audio file copies and Zoom cloud copies will be deleted immediately once uploaded to the secure drive. The audio recording files will be labeled with a unique participant ID number, and will contain participants' voice but will not contain names. The labels on these files will constitute a link between identifiable information and the participant ID number, which will be used to link other study data together. Only members of the study team will be able to access the audio recordings taken during the interview session. Participant data will remain confidential.

Who will have access to the recordings?	Danielle Berke, Maiya Hotchkiss, Ashley Smith, Craig Gilbert, Lisbeth Rubi, Jessica Palatnik
Photograph	No
Deception	No

Access to or use of pre-existing non-medical records, including student records	No
Access or use of medical records	No
Will participants be screened?	Yes

Prospective Biological Sample Collection and Existing Biospecimens	No
Drugs or Vaccines	No
Devices	No

6. Research Design - Procedures and Risks

Participant Group

List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.	List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.
Procedure	Self-Report Questionnaires
Where it will take place?	Self-report questionnaires will be administered virtually. Participants will have the option to complete baseline and course follow-up surveys remotely at home, or using iPads or their phones at God's Love We Deliver before and after the course.
When it will take place?	Self-report questionnaires will be administered to each participant 3 times; baseline (before the ESD intervention), follow-up directly after the intervention, and 6-month follow-up.
Frequency	Self-report questionnaires will be administered to each participant 3 times; baseline, follow-up immediately following course completion, and 6-month follow-up.
Is procedure optional for participants?	Yes
Associated risk or discomfort	Questionnaires include some questions concerning personal or emotional matters that could cause mild, temporary psychological discomfort.
Anticipated severity of risk or discomfort	No more than minimal risk
Expected frequency of risk or discomfort	Self-report questionnaires will be administered to each participant 3 times; baseline, follow-up immediately following course completion, and 6-month follow-up.
Risk reduction or mitigation method	While every possible step will be taken to minimize such risk, if participants have any concerns about any aspect of the study, consent documentation will make it clear that they may refuse to continue with the study at any time, without penalty. In addition, we will remind participants during the course of all assessments that they do not have to respond to any questions they do not wish to and may discontinue participation at any time. Participants who report or demonstrate any distress during study assessments will be referred to counseling services at local agency with whom the PI has established linkages (The Center). All counseling resources are available to participants regardless of ability to pay.

Participant Group

List all research related procedures/data collection methods involving interaction or intervention with	List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.

participants; use the Add New Procedure and Risk button to add each method.	
Procedure	Tailored IMPACT Basics Intervention
Where it will take place?	IMPACT Basics Course will take place at a well ventilated space centrally located and furnished by God's Love We Deliver (166 Avenue of The Americas NYC 10013).
When it will take place?	There will be three pilot series that will take place as part of this study. Series 1: 7/11/21, 7/18/21, 7/25/21, 8/1/21, 8/8/21Series 2: 9/19/21, 9/26/21, 10/3/21, 10/10/21, 10/17/21Series 3: 11/14/21, 11/21/21, 12/4/21, 12/11/21, 12/19/21As participants are recruited, they will be assigned to one of the three series based on their availability.
Frequency	As this study involves iterative tailoring of the intervention curriculum, the pilot intervention will be rolled out in 3 groups. Each pilot intervention will be followed by tailoring before rolling out the intervention to the following group. Thus, ESD violence prevention programming will take place 3 times, but each participant will only participate in one of the series.
Is procedure optional for participants?	Yes
Associated risk or discomfort	It is possible that participants may experience some discomfort while participating in the ESD violence prevention program.Due to the COVID-19 pandemic, in-person participation poses additional risk to participants.
Anticipated severity of risk or discomfort	No more than minimal risk
Expected frequency of risk or discomfort	The schedule for each of the 3 ESD series is outlined above. Participants will be assigned to one of the three series based on best availability match, so frequency of risk or discomfort is five times for five course sessions.
Risk reduction or mitigation method	By contracting with Prepare, Inc., an organization with over 30-years of experience providing ESD training to diverse clientele, we are ensuring that every possible step is taken to manage the natural discomfort that may arise when learning new verbal and physical skills in a personal safety program. During all group sessions the lead instructor will stand near the participant providing ongoing support, encouragement, and verbal prompting to participants, as needed, during role-play scenarios. The behavior of all instructors in conducting and coaching participants through role plays will be carefully thought out and implemented. At no time will participants role-play with one another. Consent documentation will make it clear that participants may refuse to continue with the study at any time, without penalty. In addition, we will remind participants during the course of the group that they do not have to participate in any exercise or role-play that they do not wish to and may discontinue participation at any time. Participants who report or demonstrate any distress during class will be referred to counseling services at local agency with whom the PI has established linkages (The Center). Additionally, a licensed clinical psychologist (PI: Danielle Berke, Ph.D.) will be present in all ESD classes to support participants in the unlikely event that they may need additional assistance in grounding and following a role-play scenario. All counseling resources are available to participants regardless of ability to pay.Regarding the risk of COVID-19 transmission during participation in in-person procedures, there will be safety protocols in place for all participants and research staff present during the ESD program sessions. Personal protective equipment will be made available for all attendees including hand sanitizer, gloves, face shields, and N95 respirator masks. All program sessions will take place in a well-ventilated area furnished by God's Love We Deliver (outside). Participants will remain 6 feet apart during sessions, with the exception of time limited physical defense drills.

Participant Group

List all research related procedures/data collection methods	List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.

involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.	
Procedure	Brief Course Assessment Survey (See pages 38-43 of the Assessment packet attached to this protocol).
Where it will take place?	Course Assessment surveys will be administered at God's Love We Deliver.
When it will take place?	The brief self-report course assessment survey will be administered directly following completion of each of the 5 course sessions.
Frequency	The brief self-report course assessment survey will be administered to each participant up to five times- once after each course session attended.
Is procedure optional for participants?	Yes
Associated risk or discomfort	No risk is expected from the course assessment questions.
Anticipated severity of risk or discomfort	No more than minimal risk
Expected frequency of risk or discomfort	No risk is expected from the course assessment questions.
Risk reduction or mitigation method	While every possible step will be taken to minimize such risk, if participants have any concerns about any aspect of the study, consent documentation will make it clear that they may refuse to continue with the study at any time, without penalty. In addition, we will remind participants during the course of all assessments that they do not have to respond to any questions they do not wish to and may discontinue participation at any time. Participants who report or demonstrate any distress during study assessments will be referred to counseling services at local agency with whom the PI has established linkages. All counseling resources are available to participants regardless of ability to pay.

Participant Group	
List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.	List all research related procedures/data collection methods involving interaction or intervention with participants; use the Add New Procedure and Risk button to add each method.
Procedure	Exit Interview
Where it will take place?	Exit interviews will take place remotely, over Zoom
When it will take place?	Exit Interviews will be scheduled on the fifth and final session of the course, and will take place in the weeks immediately following the course.
Frequency	Each participant will be interviewed once.
Is procedure optional for participants?	Yes
Associated risk or discomfort	No risk is expected from the exit interview questions.
Anticipated severity of risk or discomfort	No more than minimal risk

Expected frequency of risk or discomfort	No risk is expected from the course assessment questions.
Risk reduction or mitigation method	While every possible step will be taken to minimize such risk, if participants have any concerns about any aspect of the study, consent documentation will make it clear that they may refuse to continue with the study at any time, without penalty. In addition, we will remind participants during the course of all assessments that they do not have to respond to any questions they do not wish to and may discontinue participation at any time. Participants who report or demonstrate any distress during study assessments will be referred to counseling services at local agency with whom the PI has established linkages. All counseling resources are available to participants regardless of ability to pay.

7. Research Design - Risks and Benefits

Does your research claim to present a therapeutic benefit to the participants? No

Expected Direct Benefit(s)

In participating in this study, participants may gain insight on the role of individual (e.g., history of victimization), interpersonal (e.g., romantic and peer relationships), and societal level factors (e.g., laws, policies, gender norms and ideology) contributing to violence, develop a comprehensive set of skills for resisting violence, and develop greater understanding of their bodies and minds as sources of strength.

Benefit to Society

Developing feasible, acceptable, and effective interventions to prevent violent victimization presents clear public health implications, especially among transgender individuals. In participating in this study, participants may gain insight on the role of individual (e.g., history of victimization), interpersonal (e.g., romantic and peer relationships), and societal level factors (e.g., laws, policies, gender norms and ideology) contributing to violence. Benefits to society in general are anticipated through the dissemination of study findings and the development of an ESD curriculum tailored for TW. Results will better inform local and national public health initiatives about violence prevention among TW and provide a tailored curriculum for targeting transgender-specific violence.

Will data safety monitoring be done? Yes

Data Monitoring method DSMB

DSMB members should not have any involvement in the research other than that of serving on the DSMB. Other involvement in the research would be perceived as a conflict of interest.

Identify members of DSM Board (DSMB):

Name Katie Edwards

Affiliation University of Nebraska

Qualifications

Katie Edwards, Ph.D., is an Associated Professor of Psychology at the University of Nebraska-Lincoln. She specializes in development and implementation of violence prevention programming, particularly focused on marginalized populations including sexual and gender minorities.

How frequently will the DSMB meet? Quarterly

Provide description of stopping rules and justification for the stopping rules

Adverse Event (AE): Defined as any untoward medical occurrence in a patient or research subject administered a pharmaceutical product or other research intervention and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product or research procedure, whether or not related to the medicinal (investigational) product or procedure.Negative events that occur during study involvement do not constitute adverse events unless they lead to physical harm (in which case the injury is the AE) or deterioration of mental health functioning (in which case the symptoms are the AE). Negative events that may potentially affect response to the intervention or study involvement should be reported as AEs. See IRB Reporting Requirements below for instructions on how to report these events. Examples might include legal

problems or traumatic events.The program facilitator should query about adverse events (AEs) at every session by asking about any notable events since the last visit. These should be reviewed in a timely manner with the supervisor.Serious Adverse Event (SAE): An AE occurring in a patient or subject enrolled in a research study is serious if it results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.Unanticipated Problems Involving Risk (UPR): Defined as being (1) unexpected given the research procedures and characteristics of the population, (2) related (or possibly related) to participation in the research and (3) indicative that the research may place the subject or others at a greater risk of harm than was previously known.Examples of possible UPRs for psychotherapeutic interventions:1. Psychosis or mania2. New onset or clinically significant exacerbation of a psychiatric disorder3. Suicide and suicide attemptsAn incident, experience, or outcome that meets UPR criteria generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others. Examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem include: modification of inclusion or exclusion criteria to mitigate the newly identified risks;implementation of additional procedures for monitoring subjects;suspension of enrollment of new subjects;suspension of research procedures in currently enrolled subjects;modification of informed consent documents to include a description of newly recognized risks; andprovision of additional information about newly recognized risks to previously enrolled subjects.Reporting Requirement: All UPRs/AEs/SAEs, regardless of relatedness to the intervention, are to be reported to the local IRB as soon as possible, no later than 10 business days from the date the investigator or research staff becomes aware of the event/problem. Fill out an AE form, SAE form, and/or UPR form, obtain the study PI's signature, and submit to the Hunter IRB. Then forward each AE/SAE/UPR form to Data Safety Monitoring Board as soon as possible. The study PI will maintain a record of all AEs/SAEs/UPRs to report to the Hunter IRB in summary or table form at the end of the study. The PI will notify NIMHD of any UPR, AE, or SAE promptly via email. Protocol Deviation/ViolationA protocol deviation or violation is any change, divergence, or departure from the study design or procedures of a research protocol. Investigators are required to conduct their research according to the plans reviewed and approved by the IRB. Instances where this does not occur, either inadvertently due to circumstances beyond the investigator's control, or due to errors of omission or commission by research project staff, must be reported.Reporting Requirement: Fill out a Protocol Deviation/Violation form, and submit to local IRB within 3 days of the occurrence (one day if there was harm to the participant). Also email the form (with encryption) to the PI and Study Coordinator, who will maintain a record of all Protocol Deviations/Violations to report to the Hunter IRB.

DSMB?s prospectively identified criteria for discontinuing the study

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Name	Jillian Shipherd
Affiliation	VA Boston

Qualifications

Jillian Shipherd, Ph.D, is the co-director of LGBT health in national office of the VA, and oversees development and implementation of LGBT health policy across medical care system. She has particular expertise in trans health with particular expertise in trauma among trans people.

How frequently will the DSMB meet?	Quarterly

Provide description of stopping rules and justification for the stopping rules

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Name	Dennis Reidy
Affiliation	Georgia State University

Qualifications

Dennis Reidy, Ph.D., is a violence prevention researcher. He previously worked at the CDC for 8 years in the Center for Violence Prevention. He has extensive expertise in monitoring and evaluating the rigor of IPV clinical trials research.

How frequently will the DSMB meet?	Quarterly

Provide description of stopping rules and justification for the stopping rules

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8. Funding - Sources

Grant or Contract Title	Empowerment Self-Defense Training for the Prevention of Victimization of Transgender Women
Grant or Contract Number	R21MD014807-01A1
Funding Status:	Funded
Grant/Contract PI:	Danielle Berke
Department	Hunter College
Division	
Phone	
Email	db2800@hunter.cuny.edu
Funding Source:	National Institutes of Health (NIH)
Contact	
Funding Category:	Federal
Do the protocol and funding proposal match?	No
Identify the substantive differences	The funding protocol includes a proposal for a two study project: Study 1 entails the qualitative interview study described in protocol number 2020-0017. Study 2 entails a pilot efficacy trial of the tailored ESD curriculum described herein. In this protocol, we are exclusively seeking IRB approval for Study 2. Other changes from the R21 include: Compensation for survey completion will now be in the form of an Amazon gift card for ease of remote distribution. Study documents will now be stored electronically on a password-protected secure lab server accessible only by lab personnel. Recruitment procedures have also been expanded to include recruitment outside of The Center.

9. Participants - Populations

Age Range(s)	18 to 65 years
Targeted Population(s)	Healthy Adults

10. Participants - Projected Enrollment

Please provide the upper limit of anticipated enrollment

Projected Enrollment 80

11. Participants - Eligibility

Inclusion Criteria and Rationale

Transgender women (i.e., male assigned at birth, currently identified on the transfeminine spectrum) between the ages of 18 and 65. This inclusion criteria is necessary to iteratively tailor and finalize the adapted ESD violence prevention program for transgender women.

Exclusion Criteria and Rationale

Cisgender men and women, and transgender men will be excluded, as our research question pertains to trans women specifically.

12. Participants - Recruitment

Method(s) Flyers, posters, brochures or print ads, Website posting, Other

Outline the recruitment process in a step-by-step fashion

The LGBT Community Center of New York (The Center) will serve as the primary recruitment site for participants. The LGBT Center has over 200 TW who utilize their services each year, and has extensive experience recruiting participants for similar projects using both active and passive recruitment methods. Potential participants will be identified through the PI's professional network with The Center staff. Additional recruitment will be done using snowball sampling techniques, with fliers posted around The Center and Hunter College, and recruitment through social media (e.g., Facebook, Twitter) and banner ads on social networking/dating sites (e.g., Scruff, BGC Live, OK Cupid) that are trans-inclusive and through dissemination of paper and/or electronic recruitment flyers with leaders of community organizations that connect transgender individuals (e.g., AVP; Callen Lorde, Trans-lantinx network). Participants from prior studies who consented to future contact will be sent the study flyer by email.Various recruitment flyers, banner ads, and email advertisements will be generated by combining content and images contained in the below attachment (see "Recruitment Text and Images.") tailored to local formatting demands.Participants recruited through social media/networking sites and community recruitment will self-refer to the study by following the link provided in recruitment materials to the online Qualtrics screener consent form and screener questions (see "ESD for TW P2 Screening Consent and Survey"). Participants who meet eligibility criteria based on the screener questions will be able to self-administer online consent through Qualtrics. They will also be invited to contact study staff via email or telephone to complete Oral consent or to ask any questions they may have. Following completion of consent, participants will be linked to the a survey where they will be asked to provide contact information for themselves and one friend/family member should we become unable to reach them (see ESD Phase 2 Contact Sheet in Attachments Tab). This contact sheet will be updated when participants complete their second survey (following course completion) (see ESD Phase 2 F/U Contact Sheet in Attachments Tab).

Reviewer should be able to clearly follow your process from subject identification to recruitment Are recruitment methods well defined? Are the location and timing of the recruitment process appropriate?

Indicate how and where these materials will be displayed, distributed or published

The LGBT Community Center of New York (The Center) will serve as the primary recruitment site for qualitative interview participants. The LGBT Center has over 200 TW who utilize their services each year, and has extensive experience recruiting participants for similar projects using both active and passive recruitment methods. Potential participants will be identified through the PI's professional network with The Center staff. Additional recruitment will be done using snowball sampling techniques, with fliers posted around The Center and Hunter College, and recruitment through social media (e.g., Facebook, Twitter) and banner ads on social networking/dating sites (e.g., Scruff, BGC Live, OK Cupid) that are trans-inclusive and through dissemination of paper and/or electronic recruitment flyers with leaders of community organizations that connect transgender individuals (e.g., AVP; Callen Lorde, Trans-lantinx network). Participants from prior studies who consented to future contact will be sent the study flyer by email. Various recruitment flyers, banner ads, and email advertisements will be generated by combining content and images contained in the below attachment (see "Recruitment Text and Images.") tailored to local formatting demands.Regardless of recruitment method, potential participants will complete the screener by following the link provided in recruitment materials to the online Qualtrics screener consent form and screener questions (see "ESD for TW P2 Screening Consent and Survey").

Attach copy of each

Type Flyers

Title Recruitment Text and Images

var toDel = model.getValue("document/@docLink", contextNode); if(toDel) model.Frm.deleteDocumentRef(toDel, ins);

Identify the web site(s) by name and URL

For social media/networking site recruitment we will post on websites such as Reddit, Instagram, Instagram, Facebook, Twitter, SCRUFF, BGC Live, OK Cupid, and Lex, and through dissemination of paper and/or electronic recruitment flyers with leaders of community organizations that connect transgender individuals (e.g., AVP; Callen Lorde, Trans-lantinx network).

Indicate who controls the web site

These social media/networking sites are independently operated.

Attach text of web site content you will use

Type Web site postings

Title Recruitment Text and Images

13. Participants - Screening

Authorizes IRBs to approve a research proposal to obtain information directly from a prospective subject, or to obtain already collected identifiable private information or identifiable biospecimens by accessing records or stored biospecimens for the purposes of screening, recruiting or eligibility assessment, without informed consent of the prospective subject or the subjects legally authorized representative.

Method(s) Internet based screening

Internet based screening

Identify the web site that will be used for screening by name and URL

Qualtrics (Qualtrics.com)

Indicate who controls the web site

Qualtrics XM owns this site and associated products and services. Control is shared with a local "brand administrators" at Hunter College who oversees operation of the local Qualtrics license.

Attach the script for Internet screening

Title ESD for TW P2 Screening Consent and Survey

Description of Screening Activities

Outline the screening procedures in a step-by-step fashion, including a timeline

Upon identification of an eligible participant, whether the participant contacts the PI after seeing a flyer, or participant hears of the study through snowball sampling techniques, the potential participant will be given a link which will direct them to a set of screening questions. Screening questions will establish that the participant identifies as a transfeminine/trans woman individual, is age 18-65, and that they understand the procedures and commitment involved in the study.

14. Participants - Consent

Documented informed consent and/ or parent or guardian permission	No
Are you requesting Broad Consent	No
Oral or internet based informed consent and/or parent or guardian permission	Yes
Waiver of informed consent and/or parent or guardian permission	No
Waiver of Informed Consent Involving Public Benefit and Service Programs	No
Alteration of Informed Consent Involving Public Benefit and Service Programs	No

Oral or internet based informed consent and/or parent or guardian permission

Select the criteria for a waiver of documented informed consent that applies to your research	The research involves minimal risk and includes no procedures for which written consent is normally required outside of the research context.
Is this a longitudinal study?	Yes

Please indicate how frequently you will re-consent participants

Consent will occur once at study enrollment. Participants will not be reconsented before the two follow-up surveys as participants will have a copy of the consent form. Participants will have lab contact information if they wish to obtain a new copy of the consent form.

15. Participants - Compensation

Type	Monetary
Amount	$180.00
Justification	Time
Description (Address the compensation schedule for participants that withdraw from the research protocol.)	Compensation will be in the form of an Amazon gift card. To promote retention, financial compensation for study participation will be distributed in three payments paired with the completion of each of the three surveys. Compensation increases overtime (i.e., $40 for baseline, $30 for followup directly after course completion and $30 for completion of the exit interview after course completion, and $80 for 6-month follow-up). Participants who consent to take part in the ESD training and self-report questionnaire sessions will be informed that they are free to withdraw from the ESD program and/or the research study at any time, without penalty. As such, participants will be compensated for any questionnaires completed, regardless of premature withdrawal from the ESD program.
When will participants be compensated?	End of each visit
Explain when	
Describe mechanism in place to ensure confidentiality when distributing compensation	Participants will be sent an email with a link to an Amazon gift card code upon completion of each questionnaire. Emails will be collected in a separate Qualtrics survey at the time of enrollment that will collect email contact information. This information will be kept separate from participation study data and any identifying information, ensuring confidentiality.

Type	Monetary
Amount	$50.00
Justification	Time
Description (Address the compensation schedule for participants that withdraw from the research protocol.)	In addition to compensation provided for surveys completed at baseline, directly following the course, and 6 months after the course (outlined above) participants will receive $10 compensation for each of the five course session evaluations they complete (one per class), to earn up to $50 total. This cash incentive will be distributed after the third class (up to $30) and after the fifth class (up to $20).
When will participants be compensated?	End of each visit
Explain when	
Describe mechanism in place to ensure confidentiality when distributing compensation	Participants will receive this cash incentive as they leave the third and fifth course sessions. As participants will be receiving cash, their name or other identifying information will not be attached to the compensation in any way. Additionally, as the course will be held in a private location at God"s Love We Deliver, confidentiality of participants as they receive this compensation will be maintained, as only course participants and course facilitators will be present during compensation distribution.

16. Participants - Privacy and Confidentiality

Describe the mechanisms in place to protect the privacy of participants during recruitment, consent process and research procedures

Strict confidentiality will be maintained and all data will be assigned a subject number. Participants will complete screening individually at a time most convenient for them. Screening procedures do not involve the collection of identifying information. If participant completes internet-based consent, participants identities will not be known to study staff until they have provided consent. If participant completes oral consent, no identifying information will be collected until oral consent is received. Strict confidentiality will be maintained and all data will be labeled using the participant's self-assigned ID. Participants will complete screening individually at a time most convenient for them. Screening procedures do not involve the collection of identifying information. Consent (if completed online) and self-report questionnaires will be self-administered by the participant at a time most convenient and comfortable for them. If participants opt to complete consent orally, a single member of the lab is responsible for guiding participants through the consenting process, and the member of the lab will complete this in a private space. The participant will complete baseline and follow-up self-report questionnaire batteries online at a time and place most comfortable to them, or on their personal device or lab iPad at God's Love We Deliver (before or after the first and last course sessions). The 6 month follow-up survey must be completed remotely. The institutional Zoom account of the PI will be used for video interviewing. Participants will receive a secure and private Zoom link to access the video interview, which will restrict access to any users other than the participant and the single member of the research staff responsible for administering the interview. Research staff will conduct the video interview in a private room, and the participant will have the ability to participate in the interview at a time and location most comfortable for them, thus protecting the privacy of the participant. During the consenting process, we will communicate with all participants that they have the right to download an audio and video recording of the interview. If the participant does not make this request, electronic copies of study data will be securely downloaded as two separate files (an audio-only and video recording file) to a local server from Zoom. Local video-files will be immediately deleted. The audio-only file will be immediately uploaded for storage on an online password-protected, backed up lab server that is accessible only by lab personnel. Local audio file copies will be deleted immediately once uploaded to the secure drive. The audio recording files will be labeled with a unique participant ID number, and will contain participants' voice but will not contain names. The labels on these files will constitute a link between identifiable information and the participant ID number, which will be used to link other study data together. Only members of the study team will be able to access the audio recordings taken during the interview session. Participant data will remain confidential.If the participant makes the request to have a personal copy of the interview, we will store the audio and video recording file in Zoom for one week, during which the participant will have one week to download and store the file using a secure Zoom link to the recording, sent via email. At the end of the one week the video recording will be downloaded such that audio file and video file are downloaded as separate files; the video file will be deleted immediately and will never be saved or stored. The audio-only file will be saved for transcription and immediately uploaded to the secure password-protected online lab server.Strict confidentiality will be maintained and all data will be coded by a subject number. Personal identifier records will be kept in a secure password-protected online server accessible only by research personnel. Any forms with identifying information will be stored separately from other study data. Records will be kept confidential to the level allowed by law and only the staff assigned to the study will have access to non-anonymous records. Information provided by study participants will not be released to outside sources unless written consent is provided by the study participant. Participants in the course will be made aware prior to consenting that participation involves a group Empowerment-Self Defense program where other participants will be present during physical training and group discussions. All program participants will be asked not to share any information about other program participants that may have come up during the program with anyone outside of the group. However, complete confidentiality cannot be guaranteed. For the interview administration, only the interviewer will be present in the private virtual call. Participants will receive a secure and private link to access the video-conferencing exit interview after course completion, which will restrict access to any users other than the participant and the single member of the research staff responsible for administering the interview. Research

staff will conduct the video interview in a private room, and the participant will have the ability to participate in the interview at a time and location most comfortable for them, thus protecting the privacy of the participant. We have considered the privacy concerns associated with including LGBTQ status in recruitment materials placed in public locations, and have determined that the benefits of this procedure outweigh its minimal risk. Individuals who see the flyer will have complete control over whether or not they decide to respond to the advertisement or to take a tab from the advertisement when they see it. By including transgender population recruitment information in the flyer, we are minimizing the number of ineligible people who will complete the screening process. We also anticipate that most participants will be recruited via online platforms using online flyers, thus allowing for privacy when interacting with study flyers.

Describe the mechanisms in place to maintain confidentiality of participant data

Screening and survey responses as well as the internet-based consent form will be submitted to Qualtrics free of identifiable information. Electronic copies of those data will be stored on a secure password-protected online backed up lab server that is accessible only by lab personnel. If the participant completes consent orally, the oral consent form will also be stored on a secure password-protected online lab server free of identifiable information (containing participant ID only). Participant contact sheets will be stored separately from the study data, so that the study data will be collected using only a unique participant ID number, and are not identifiable by participant name. The self-assigned participant ID number will be used to link consents, questionnaire responses and interviews to one another. The Qualtrics anonymize responses feature will be used to ensure that IP addresses or other identifying information are not collected. Electronic copies of those data will be stored on a secure password-protected online backed up lab server in an encrypted and password protected data file (consistent with section 12 of CUNY Policy on Acceptable Use of Computer Resources) that is accessible only by lab personnel. Qualtrics' database does not hold sensitive or confidential response information after it is downloaded, however they do hold all survey responses in their data centers. The data centers utilize many security measures. Qualtrics' database access is restricted and requires authorization. All computer equipment (servers, SANs, switches, routers, etc.) is redundant and is located in secure, environmentally controlled data centers with 24/7 monitoring. Web traffic does not directly access the database and database requests are reversed proxy via an application server to the database. All information is secured via industry standard firewalls and stringent IT security policies and procedures. Qualtrics utilizes industry standard web application firewalls and DDOS protection. At no time will the downloaded or Qualtrics data be physically portable; the server system negates any need for USB drives or CDs for electronic data. A final copy of the downloaded data will be stored for a minimum of three years after the study is complete and closed out with IRB. If the participant makes the request to have a personal copy of the interview, we will store the audio and video recording file in Zoom for one week, during which the participant will have one week to download and store the file using a secure Zoom link to the recording, sent via email. At the end of the one week the video recording will be downloaded such that audio file and video file are downloaded as separate files; the video file will be deleted immediately and will never be saved or stored. The audio-only file will be saved for transcription and immediately uploaded to the secure password-protected online lab server. Audio files from the secure Zoom video interview will be uploaded to the secure password-protected online lab server. Only members of the research staff will be able to access the audio recordings taken during the lab session, and the participant if they request a personal copy. Participants will be informed that their responses will remain confidential, and that they have the right to erase the recording taken as part of this research. The audio recording will be stored electronically on a secure password-protected online lab server, labeled with the participant-generated ID number. The audio recordings will be used for verbatim (de-identified) audio transcription. Upon transcription, audio files will be stored for one additional week. This will allow an additional lab member to perform a quality-check on the transcription. Following quality assurance, the audio files will be destroyed. Personal identifier records will be kept in a secure online password-protected file on the secure password-protected online server, and any forms with identifying information will be stored separately from other study data.Personal identifier records will be kept in a secure online password-protected file on the secure password-protected online server, and any forms with identifying information will be stored separately from other study data. Records will be kept confidential to the level allowed by law and only the staff assigned to the study will have access to non-deidentified records. Information provided by study participants will not be released to outside sources.Data will not be stored or distributed for future studies. Regarding participants who agree to be contacted for future studies - we will store this contact information in a separate password protected file, on our secure online password-protected server. We will assign a new ID number to the current participant's study ID number. Participant's contact information will be stored with this new ID. The file that links participants' contact information and new ID will be stored in a separate password protected file, on the secure online password-protected lab server. The document that links both ID numbers will be password protected and stored in a separate password-protected file on the secure online password-protected lab server. If an individual requests their contact information be removed, we will remove their contact information from our database. Participant contact information will only be accessible to approved personnel.DSM Board Information Outlined in the NIH Grant: A DSMB is being created for this study by the study PI and NIH program officer. The PI has proposed

a board comprising of; Katie Edwards, Jillian Shipherd, and Dennis Reidy (Outlined in the Research Design tab). The DSMB is tasked with independently ensuring the safety of study participants and scientific goals. The DSMB will review the initial protocol and any proposed amendments, meet and complete reports quarterly, perform expedited monitoring of all serious adverse events, perform ongoing monitoring of drop-outs and non-serious adverse events, determine whether study procedures should be changed or the study should be halted for reasons related to the safety of study subjects, and perform periodic review of the completeness and validity of data to be used for analysis of safety and efficacy. The DSMB will also ensure subject privacy and research data confidentiality. A statistical penalty will not be assessed for the ongoing unblended review of safety by the DSMB. Unblinded data will not be released to investigators unless necessary for safety reasons. Suspected information security and privacy incidents will be reported within one hour to the DSM Board.Adverse Event (AE): Defined as any untoward medical occurrence in a patient or research subject administered a pharmaceutical product or other research intervention and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product or research procedure, whether or not related to the medicinal (investigational) product or procedure.Negative events that occur during study involvement do not constitute adverse events unless they lead to physical harm (in which case the injury is the AE) or deterioration of mental health functioning (in which case the symptoms are the AE). Negative events that may potentially affect response to the intervention or study involvement should be reported as AEs. See IRB Reporting Requirements below for instructions on how to report these events. Examples might include legal problems or traumatic events.The program facilitator should query about adverse events (AEs) at every session by asking about any notable events since the last visit. These should be reviewed in a timely manner with the supervisor.Serious Adverse Event (SAE): An AE occurring in a patient or subject enrolled in a research study is serious if it results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.Unanticipated Problems Involving Risk (UPR): Defined as being (1) unexpected given the research procedures and characteristics of the population, (2) related (or possibly related) to participation in the research and (3) indicative that the research may place the subject or others at a greater risk of harm than was previously known.Examples of possible UPRs for psychotherapeutic interventions:1. Psychosis or mania2. New onset or clinically significant exacerbation of a psychiatric disorder3. Suicide and suicide attemptsAn incident, experience, or outcome that meets UPR criteria generally will warrant consideration of substantive changes in the research protocol or informed consent process/ document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others. Examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem include: modification of inclusion or exclusion criteria to mitigate the newly identified risks;implementation of additional procedures for monitoring subjects;suspension of enrollment of new subjects;suspension of research procedures in currently enrolled subjects;modification of informed consent documents to include a description of newly recognized risks; andprovision of additional information about newly recognized risks to previously enrolled subjects.Reporting Requirement: All UPRs/AEs/SAEs, regardless of relatedness to the intervention, are to be reported to the local IRB as soon as possible, no later than 10 business days from the date the investigator or research staff becomes aware of the event/problem. Fill out an AE form, SAE form, and/or UPR form, obtain the study PI's signature, and submit to the Hunter IRB. Then forward each AE/SAE/UPR form to Data Safety Monitoring Board as soon as possible. The study PI will maintain a record of all AEs/SAEs/UPRs to report to the Hunter IRB in summary or table form at the end of the study. The PI will notify NIMHD of any UPR, AE, or SAE promptly via email. Protocol Deviation/ViolationA protocol deviation or violation is any change, divergence, or departure from the study design or procedures of a research protocol. Investigators are required to conduct their research according to the plans reviewed and approved by the IRB. Instances where this does not occur, either inadvertently due to circumstances beyond the investigator's control, or due to errors of omission or commission by research project staff, must be reported.Reporting Requirement: Fill out a Protocol Deviation/Violation form, and submit to local IRB within 3 days of the occurrence (one day if there was harm to the participant). Also email the form (with encryption) to the PI and Study Coordinator, who will maintain a record of all Protocol Deviations/Violations to report to the Hunter IRB.

How will you store participant data With participant's direct identifier(s)

List the identifier(s) that will be stored

Audio recordings containing participants' voices, and any other identifying information that remains on the recording after participants have been made aware of/exercised their right to erase the recording, will be stored electronically, labeled with the participant-generated ID number. Regarding participants who agree to be contacted for future studies - we will store this contact information in a separate password protected file, on our secure online password-protected server. We will assign a new ID number to the current participant's study ID number. Participant's contact information will be stored with this new ID. The file that links participants' contact information and new ID will be

stored in a separate password protected file, on the secure online password-protected lab server. The document that links both ID numbers will be password protected and stored in a separate password-protected file on the secure online password-protected lab server. If an individual requests their contact information be removed, we will remove their contact information from our database. Participant contact information will only be accessible to approved personnel.

Will identifiers be deleted (and data anonymized) at a later date?	No
What will you do with the data once the research has been completed?	Retain data for three years, or longer when required by the study sponsor, then destroy it.

University Integrated Institutional Review Board
205 East 42nd Street
New York, NY 10017
http://www.cuny.edu/research/compliance.html

17. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Curriculum Vitae	CITI HSR Certificate-Maiya Hotchkiss	1	approved	HSR_Hotchkiss.pdf	10/12/2020
Curriculum Vitae	CITI HSR Certificate-Ashley Smith	1	approved	Ashley Smith_CITI HSR_CompletionCert_08.07.20.pdf	10/12/2020
Curriculum Vitae	CITI HSR Certificate-Danielle Berke	1	approved	DB_CITI_HSR.pdf	10/12/2020
Curriculum Vitae	CITI COI Certificate-Danielle Berke	1	approved	DB_CITI_COI.pdf	03/18/2021
Curriculum Vitae	CITI HSR Certificate-Craig Gilbert	1	approved	CRAIG HSR.pdf	03/18/2021
Curriculum Vitae	CITI HSR Certificate-Lisbeth Rubi	1	approved	Rubi_HSR Certificate.pdf	03/18/2021
Curriculum Vitae	CITI HSR Certificate-Jessica Palatnik	1	approved	Certificate.pdf	03/18/2021
Funding proposal/ Grant application/ Contract	NIH R21 Grant	1	approved	4374967_Egrant (1).pdf	03/25/2021
Advertisement	RecruitmentMaterials_ESDTWPhase2_03_25_21_DB_MH (1).docx	1	approved	RecruitmentMaterials_ESDTWPhase2_03_25_21_DB_MH (1).docx	03/30/2021
Website Text	RecruitmentMaterials_ESDTWPhase2_03_25_21_DB_MH (1).docx	1	approved	RecruitmentMaterials_ESDTWPhase2_03_25_21_DB_MH (1).docx	03/30/2021
Internet Screening Script	Screening Consent and Survey 03:25:21.pdf	1	approved	Screening Consent and Survey 03:25:21.pdf	03/30/2021
Informed Consent/ Permission Document	Verbal Consent Script	1	approved	Oral Informed Consent Script - ESD TW Phase 2 03:30:21.docx	03/30/2021
Informed Consent/ Permission Document	Online Consent	1	approved	Online Consent ESD P2.pdf	03/30/2021
Email Text	Scheduling Text/Call/ Email Templates	1	approved	Scheduling Email Template_03:25:21.docx	03/30/2021
Survey/Questionaire	ESD Phase 2 Contact Sheet	1	approved	ESD Phase 2 Contact:Informant:Scheduling Sheet.pdf	03/30/2021
Survey/Questionaire	ESD Phase 2 F/U Contact Sheet	1	approved	ESD P2 F:U Contact Sheet.pdf	03/30/2021
Survey(s)	Assessment packet_ESD for TW_10.12.20 (3).pdf	1	approved	Assessment packet_ESD for TW_10.12.20 (3).pdf	03/30/2021