Official Title: IVY: Intervention for Victimized Youth
NCT Number: NCT06631274
Document Date: October 18, 2024
Study Protocol – IRB approved

Note: This document contains portions of the protocol submitted to the IRB at FSU. Sections that were not relevant to the current study were removed to reduce document length.

1.0 Procedures Involved

1.1 Describe and explain the study design.

The study uses a quasi-experimental design with a waitlist control. Youth will be recruited and randomly assigned to either the experimental group or the waitlist control group. At the completion of the experimental group, the waitlist control group will start.

1.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Students will take pre-tests before participating in an 8-week small group therapy. Afterwards, post-tests will be administered and students will be given a chance to provide feedback. A list of the measures is below.

Recruitment will occur by advertising via social media outlets (e.g., Facebook groups targeting local moms) and through local schools. The graphic in the file titled "participants needed" will be posted on social media.

An online survey will be shared with interested caregivers to gauge eligibility. Caregivers will first provide parental consent for their child's participation, then an eligibility questionnaire will be administered electronically. To be eligible for the study, their child must 1) be a middle or high school student (via caregiver report), 2) have access to a computer with webcam and a private space for each meeting (via caregiver report), and 3) have experienced at least one instance of peer victimization in the past month. The goal is to enroll 6-7 students in the group. Once the group has been enrolled, student assent will be gathered and pre-test surveys will be administered. Participants completing the intervention will be asked to complete the post-test surveys and will be invited to be part of the focus group to gather their feedback.

1.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*

Participants in IVY may experience distress related to their participation in the program. Clinicians with training and clinical experiences working with adolescents and small groups will co-lead all sessions. If a student becomes too distressed to continue, one group leader can work individually with that participant while the other group leader continues with the lesson. In addition, strategies for dealing with distress are built into the curriculum. These strategies are introduced in the first few sessions so that participants are equipped with coping, relaxation, and self-care techniques before they are asked to reflect on their own victimization experiences. Live coding of treatment fidelity will be used so that group meetings do not have to be video or audio recorded then stored. One dataset that connects names, id numbers, and responses will be stored on a password protected computer. All other data will be identified using a study-specific ID number. For the virtual participants, best practices for telehealth will be followed (cite). A

HIPAA-compliant videoconferencing software will be used. The physical address of the participant and the name and phone number of a safety contact will be verified before each session. An alternate phone number will be gathered in case of technology problems. All participants will have access to resources for crisis counseling should the need arise between sessions. Caregivers will have the ability to contact the PI for non-crisis concerns.

SURVEYS. To screen for potential participants, the BESS and victim subscale of the BPBQ will be used. For the eligibility screener, participants will answer 40 items.

- **Victimization.** To assess victimization the victim subscale from the *Bullying Participant Behavior Questionnaire* (BPBQ; Demaray et al., 2014) will be used. This subscale contains 10 items. Participants respond to each item using a Likert scale ranging from 1 *(Never)* to 5 *(7 or more times)* in the past 30 days. The factor structure was supported via exploratory and confirmatory factor analysis. Alpha coefficients for each subscale ranged from .88 to .94 (Demaray et al., 2014). Only scores from the Victim subscale will be used.
- **Social-emotional distress.** The BASC-3 Behavioral and Emotional Screening System (BESS; Kamphaus & Reynolds, 2015) is designed for students in grades 3-12 and consists of 30 items that measure Personal Adjustment, Internalizing Problems, and Self-Regulation. Dever et al. (2020) report evidence for the three-factor structure, as well as strong concurrent validity, predictive validity, and test-retest reliability. For each item, participants decide how often a statement is true for them and respond using a 4-point Likert scale (*Never* to *Always).*

For the study, four measures will be used pre- and post-intervention: the BESS, COPE, FBBA, and SEI. For the study, participants will answer 77 items. All measures are described below.

- **Social-emotional distress.** The BASC-3 BESS (described above; Kamphaus & Reynolds, 2015), which is part of the eligibility screener, will also be used for pre- and post-intervention assessments.
- **Knowledge of Self-protection Skills.** The Knowledge of Self-Protection Options (KSPO) was created by adapting the Forms of Bullying Bystander Actions (Jenkins et al., under review), which assesses bystander intervention options. The items assess different types of self-protection skills (e.g., direct intervention, protect emotions, and reporting to adults), which will be taught during IVY.
- **Self-efficacy for Protecting Self.** The Self-Efficacy for Protecting Self (SEPS) scale was created for the purpose of this project to measure participants' perceptions that they would be able to protect and defend themselves in future victimization experiences. It was modeled after other self-efficacy for intervention scales (e.g., intervening in bullying [Andreou et al., 2005] and cyberbullying [Bussey et al., 2015]. The SEPS consists of 9 defending options that were drawn from the KSPO (described above). Response options range from 1 (*I cannot do this well at all)* to 7 (*I can do this very well*).
- **Knowledge of Coping Skills.** Coping skills will be measured using the Brief COPE (Carver, 1997), which is a multidimensional scale that assesses a range of adaptive and maladaptive coping strategies. There are 28 items that measure problem-focused coping, emotion-focused coping, and avoidant coping strategies. Though the original Brief COPE is intended for adults, researchers have adapted it for use with adolescents (e.g., Yuan et al., 2017; Yusoff, 2011). The authors of the scale report that most alphas were above .60, and exploratory factor analysis supported the hypothesized factor structure.

1.4 Describe what data will be collected during the study and how that data will be obtained.

Data will be collected through several surveys both pre- and post-test using electronic surveys via qualtrics. The measures are described above.

2.0 Study Timelines

2.1 Describe:

- *The duration of an individual subject's participation in the study.*

  10 weeks. One week of data collection before and after the 8 week intervention.

- *The duration anticipated to enroll all study subjects.*

  Enrollment for the foundation-funded project will occur during September 2023-April 2024.

  Enrollment for the NIH-funded project will occur during August 2024-May 2025.

3.0 Inclusion and Exclusion Criteria

3.1 Describe how individuals will be screened for eligibility.

Participants will be sixth-, seventh-, and eighth-grade students who have experienced peer victimization.

3.2 Describe the criteria that define who will be included or excluded in your final study sample.

No restrictions will be placed on gender or race, though attempts will be made to balance the groups in relation to these demographic characteristics (e.g., avoid groups that have one or two girls and six boys).

To be eligible for the study, the students must 1) be a middle school or high school student (via parent report), 2) have access to a computer with webcam and a private space for each meeting (via parent report), 3) and report distress from victimization by peers that has occurred in the past month

3.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

Individuals who are not yet adults (infants, children, teenagers) will be included in this study.

4.0 Recruitment Methods

4.1 Describe when, where, and how potential subjects will be recruited.

The intervention will be delivered virtually via a HIPAA-compliant Zoom meeting. Since the intervention will not occur at a single school and everything will be completed through virtual meetings, youth can be recruited from anywhere.

Describe the source of subjects.

Via advertisements in the outlets mentioned above (local social media groups) or through contacts with local middle schools.

Participants will receive a $75 gift card if they complete the pre-test, 8 week intervention, and post-test. They must be present for at least 6 of the 8 sessions. They will receive an additional $25 gift card if they also complete the post-intervention focus group. Partial completion will not be compensated, nor will early withdrawal from the study.

5.0 Withdrawal of Subjects

5.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Subjects will not be withdrawn from the study unless they choose to not complete the survey during the data collection process. Participants may be asked to discontinue if they are too distressed by the topic that it would not be healthy for them to continue.

5.2 Describe any procedures for orderly termination.

If subjects are terminated, their data will be deleted and they will not be included in the planned analysis.

5.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

If subjects wish to withdraw, their data will be deleted and they will not be included in the planned analysis.

6.0 Risks to Subjects

6.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. For each of these risks, describe in detail how the risks will be minimized.

There are risks involved in this study beyond those expected in other therapy groups and research involving psychological tests. However, group sessions will cover sensitive information, such as

recalling events of peer victimization, that may produce minimal distress. This information is noted in the informed consent so that participants are aware of the sensitive nature of the study. Given the sensitive nature of the IVY intervention, it is likely that the participants may feel distressed or uncomfortable when discussing or recalling events when they were the target of peer victimization. Sharing their victimization stories is encouraged during one session, but it will not be required. There is risk that group members may share experiences or events that could be considered harassment or abuse. To alleviate any distress caused by the intervention, counselors will be available to individuals after the sessions. The phone number for the National Suicide Prevention Hotline as well as other victim resources, will be presented to the participants. Participants may also terminate their time in the study at any time without penalty.

6.2 If information about the study's actual purpose will not be completely or accurately described to study subjects, or in any way be withheld, obscured, masked, or blinded from study subjects (e.g., you want to avoid participation bias or priming prospective subjects), you are required to describe here that you will: (a) as part of the consent process provide subjects with a statement to the effect that subjects may not be made aware of some features about the study, such as its exact purpose, study questions and materials, or subjects' responses that you would like to collect, and that subjects will be provided with additional information about the study at the end of their participation or at any time they withdraw, (b) debrief subjects at the end of their participation or at any time they withdraw, and (c) provide the IRB with a copy of all materials that will be used to debrief subjects.

No information is withheld, obscured, masked, or blinded from subjects.

6.3 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

There is a chance that engaging in the online sessions could risk privacy if the participant does not have a private place to log in to their sessions. Using a private room without anyone else in the room will be emphasized to both parents and participants

7.0 Potential Benefits to Subjects

7.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

The goal of the study is to potentially alleviate some of the distress the participants are experiencing. Participants will learn a variety of skills for coping with emotional difficulties, as well as strategies for how to protect themselves in the future. Through learning these skills, the hope is for participants to thrive academically and socially despite the challenging circumstances they have faced.

7.2 Indicate if there is no direct benefit. Do not include benefits to society or others. Also, payment to research subjects for participation in studies is

not considered a benefit so do not list payment to research subjects in this section; if a recruitment incentive will be offered, described this in section 13 under Recruitment Methods.

The direct benefit is described in section 16.1. The goals of the intervention is for the subjects to feel reduced distress and learn skills to dealing with future victimization.

8.0 Data Management and Confidentiality

8.1 Describe the data analysis plan, including any statistical procedures or power analysis.

An initial indication of changes in the outcome variables will be explored. A repeated measures ANOVA will be used to assess change in pre- and post- outcome measures. The small sample size may limit the power to detect statistically significant differences (Thompson, 1996; Valentine & Cooper, 2003); thus, effect sizes will also be calculated. Based on a large meta-analysis of over 800 meta-analyses in education, Hattie (2009) categorized a small effect as .20, medium as .40, and large effect as .60. If there is missing data (e.g., a participant dropped out), scores will be deleted list-wise.

8.2 Describe any procedures that will be used for quality control of collected data.

Missing data is the most salient issue with quality of the data. Participants will be asked to complete all questions on the surveys. To reduce attrition in the intervention over time and missing data in the pre- and post-intervention surveys, several strategies will be employed. First, to incentive attendance, compensation will be provided to participants that attend at least 6 intervention sessions and complete the post-intervention surveys. This will be made clear in the consent and assent documents. Second, reminders will be sent the day before each session to remind the participant and their parent about the day and time of the session. Third, to overcome barriers to access, the intervention will be scheduled at a time that is deemed appropriate by the school based on student schedules and the academic calendar. These strategies are in line with previous research on attrition and treatment adherence (Nock & Ferriter, 2005; Snell-Johnson et al., 2004).

8.3 Describe the steps that will be taken to secure the data (e.g., information security and privacy training, authorization of access, authentication for access, password protection, encryption, physical and administrative controls, certificates of confidentiality (or "CoC"; see our CoC link), and separation of identifiers and data) during storage, use, transmission and sharing.

One dataset that connects names, id numbers, and responses will be stored on a password protected computer. All other data will be identified using a study-specific ID number. For the virtual participants, best practices for telehealth will be followed. A HIPAA-compliant videoconferencing software will be used. The physical address of the participant and the name and phone number of a safety contact will be verified before each session. An alternate phone number will be gathered in case of technology problems. All participants will have access to resources for crisis counseling should the need arise between sessions. Caregivers will have the ability to contact the PI for non-crisis concerns.

8.4 Describe how data or specimens will be handled study-wide: e.g.,

- *Who will extract data or link data/specimens?*
    - Research staff
- *What information will be included in that data or associated with the specimens?*
    - Data include demographic information and responses to survey questions.
- *Where and how data or specimens will be stored?*
    - Data will be collected using Qualtrics then responses will be downloaded and stored on a password-protected OneDrive folder.
- *How long the data or specimens will be stored?*
    - At least 7 years
- *Who will have or otherwise be provided with access to the data or specimens, including for future research or data sharing?*
    - Only the PI, project GA, and post doc will have access to the OneDrive folder.
- *Who is responsible for receipt or transmission of the data or specimens?*
    - PI Jenkins
- *How will data or specimens will be transported?*
    - Not applicable
- *When will identifiers, linking keys or data be destroyed or disposed.*
    - After all day have been collected and cleaned.

9.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

9.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*

A data safety and monitoring plan was developed to ensure that appropriate protocols were in place since children are the primary target population. Dr. Lyndsay Jenkins (PI) will be responsible for all aspects of the project, including design, data collection, and use of data. Dr. Jenkins will be responsible for monitoring data to ensure the safety of participants. Data will be collected at the beginning and end of the study, approximately 10 weeks between data collections. All data will be collected via Qualtrics that only the PI will have access to. Responses will be viewed within 48 hours of survey completion to examine for any distress the participant may express. A descriptive analysis will be conducted as the data come on. At the end of the experimental group, statistical tests will be conducted to ensure that the intervention did not cause excessive distress, particularly we will examine if the internalizing distress score shows an increase of distress more than 10 points on the Tscore scale. If more than 5 participants show an increase in their Tscore for internalizing distress, the waitlist control group will not begin until the team has had a chance to interview the participants to determine if it was the intervention that caused the increase in distress. Unanticipated problems involving risks to participants will be promptly reported to the IRB. The PI will review the progress of the project and data being collected to ensure that potential adverse effects are identified, and if they occur it will be

reported to the IRB. Any action recommended by the IRB to the PI will be implementing immediately.

According to NIH regulations, an adverse event (AE) is drug reaction is also known as a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events (SAE) are those that can cause disability, are life- threatening, result in hospitalization or death, or are birth defects. There are no components of the intervention that involve medication or other events that are medical in nature, so it is extremely unlikely that disability, life-threatening injuries, hospitalizations, deaths, or birth defects could occur.

Though AE and SAE are very unlikely, since we will be working with minors and the topic of past trauma may come up, there is a chance that a child may report abuse. The research assistants involved in this study are mandated reporters in the State of Florida. Any statements given by children that may be a report of abuse will be documented and the research assistant will report to the PI. If necessary, these reports will be given to the appropriate reporting agency and documented with the IRB.

Additional steps we will take include:
· The investigators will carefully monitor for iatrogenic impacts of the research.
· The PI will ensure that assent (from minors) is obtained prior to performing any research procedures and that all participants are eligible to participate (based on IRB-approved eligibility criteria).
·The investigators will ensure that all study procedures are conducted in strict accordance with the IRB-approved research protocol.
· Additional details are delineated in the Human Subjects section of this grant.

10.0 Provisions to Protect the Privacy Interests of Subjects

Before completing this section, refer to the special instructions below about use of study participants' health information.

10.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

The importance of confidentiality within the group will be emphasized, as will the importance of attending the sessions from a private location, preferably with headphones. Participants will not be required to share private information in the group setting. On the surveys, they will be encouraged to answer all questions.

10.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

We have built in "ice breaker" activities that encourage participants to get to know and become comfortable with other group members. We will stress the importance of confidentiality throughout the intervention process.

10.3 Indicate how the research team is permitted to access any sources of information about the subjects.

Research team will have access via the data set stored on the OneDrive password protected file, as described above.

11.0 Compensation for Research-Related Injury

This section is required for any study that may involve: (1) any harm or discomfort for which the probability or magnitude is greater than those that may be ordinarily encountered by healthy persons in daily life or during the performance of routine physical or psychological examinations or test; (2) a clinical trial; (3) a FDA-regulated product(s) (e.g., drugs, devices, biologics, nutritional supplements or combination products); and/or (4) is funded by any federal department or agency:

11.1 Describe what specific arrangements and referrals will be made in the event a subject experiences a research related injury.

Any injury resulting from participation in this study will be reported to the Institutional Review Board and funding agency (if applicable.

11.2 Describe the available compensation in the event of research related injury.

The Institution has no policy or plan to pay for any injuries that you might receive as a result of participating in this research protocol.

12.0 Consent Process

12.1 Indicate whether you will you be obtaining consent, and if so describe:

- *Where will the consent process take place*
    - Online/electronically
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
    - *No*
- *Any process to ensure ongoing consent.*
    - Consent is provided for the length of the intervention only, no follow up is needed.
- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
    - *The role of the individuals listed in the application as being involved in the consent process.*
        a. *Either Lyndsay Jenkins, Sonya Kaminski, or Madison Woodall may be involved in the consent process of meeting with parents or assent process for meeting with children. The meeting will take place via Zoom.*
    - *The time that will be devoted to the consent discussion.*
        a. *15 minutes*

- *Steps that will be taken to minimize the possibility of coercion or undue influence.*
    a. *It is clear in writing that they are not required to participate and choosing to do so will not impact their relationship with us or FSU.*
- *Steps that will be taken to ensure the subjects' understanding.*
    a. *The consent and assent forms are written in simple jargon free language.*
    b. *A zoom meeting will be held to answer any questions they might have.*

13.0 Process to Document Consent in Writing

13.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

We request that the written documentation be completed electronically via DocuSign. The parent will sign the form electronically, then it will be sent to Dr. Jenkins to sign. DocuSign will automatically send the completed form with both signatures to both parties (parents and Dr. Jenkins). Dr. Jenkins will download all completed consent forms and store them in a OneDrive folder. Only Dr. Jenkins and project staff have access to the OneDrive folder.

13.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

13.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

Consent and assent forms are attached, but the text will be put into Qualtrics.

14.0 Setting

14.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*

Local Tallahassee social media groups (e.g., Tally Moms) and local schools.

- *Identify where research procedures will be performed.*

All research will be performed virtually. The intervention will be delivered virtually via HIPPAA-compliant Zoom meetings.

15.0 Resources Available

15.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*

Using online recruiting makes it difficult to ascertain the number of potential subjects; however, reaching parents directly via social media or through schools makes it feasible to obtain the number of youth needed for the study. Exact size of the potential subject pool is difficult to ascertain.

- *Describe the time that you will devote to conducting and completing the research.*

The PI is dedicating approximately 4 hours per week to this project. The GAs are dedicating 10 hours (foundation-funded project) or 20 hours (NIH-funded project) each per week. There is also a research post doc, Sonya Kaminski, who is dedicating 15 hours per week to the project. Sonya's start date is January 2024.

- *Describe your facilities.*

Project staff will use their personal or FSU provided laptops, Qualtrics and Zoom are free from FSU. The project is funded through a foundation grant.

- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*

The PI is a licensed psychologist and is available to assist if needed. If the PI feels that the participant would benefit from individual counseling, referrals to free and fee-based counseling will be made. There will also be a list of mental health resources provided to all participants (See attached "mental health resources" document).

- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

The GAs and post doc will involved in refining the intervention, therefore are inherently familiar with the protocol. They have completed the CITI training and also have general counseling training from their doctoral program as well.