STUDY TITLE: BULLYDOWN: DEVELOPING A BULLYING PREVENTION PROGRAM THAT TRANSCENDS PHYSICAL BOUNDARIES

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1. RESULTS OF PREVIOUS RESEARCH

An estimated 20-24% of middle school students bully their peers 'regularly' or more often each semester.[1] Bullying involvement is associated with externalizing problems (e.g., alcohol use) for bullies and internalizing behaviors (e.g., depressive symptomatology)[2-4], and suicidal ideation and behavior for victims.[4,5] Efforts to reduce bullying perpetration, thereby also reducing victimization, are critical.

Existing bullying prevention programs have only a modest impact in elementary school settings and even less of an impact in middle schools.[6-12] Reasons for this include varying implementation fidelity as well as the reliance on teachers to deliver proscriptive content, which may result in youth dismissing the messages as a way of rejecting authority and exerting control over their social selves.[12] Approaches that avoid adult involvement and integrate less proscriptive language may have more success.

In the era of Covid-19, approaches that harness the power of technology are ever more relevant. We believe text messaging is one such approach as it provides novel opportunities to "go where youth are": Nearly all (91%) of the nine in ten teens who own cell phones use text messaging,[13,14] and usage is high across race, income, and rural vs. urban settings,[13] Content can be written to be approachable and not sound as if it is being delivered by an authority figure. Importantly, emerging evidence suggests that text messaging-based programs can affect behavior change.[15-18]

2. STUDY PURPOSE AND RATIONALE

This R21 proposal is an extension of our development work with BullyDown, a text messaging-based bullying prevention program designed for middle school students.[19,20] Guided by the Social-Emotional Learning (SEL) model,[21-25] the intervention content and program features have been iteratively refined within ongoing feedback from middle school youth from across the country. The program was then beta tested with 22 middle school students in Illinois. Nine in 10 said they liked the program, and all intervention participants said that it equipped them with skills needed to not bully others in the future. Although the sample size is too small to be anything but descriptive, rates of bullying dropped from 3 youth to 1 youth in the intervention while no change was noted in the control group (2 youth at both baseline and follow-up).

Building upon our promising findings, we propose to further develop and then pilot test BullyDown in a randomized controlled trial (RCT) of middle school students. Our multidisciplinary team includes expertise in text messaging-based behavior change intervention development and evaluation (Dr. Ybarra), school-based evaluations of bullying prevention programming (Dr. Espelage), and the psychosocial challenges associated with bullying (Drs. Ybarra and Espelage). Together, we aim to:

Specific Aim 1: Finalize the BullyDown program. Feedback from the beta test suggest that some program features could be better described and implemented. We also will update program content to acknowledge the growing infusion of technology in the classroom, and the online interactions that it requires. Currently, almost all youth in the United States are engaging in some type of online schooling experience because of Covid-19 restrictions. Even when these are lifted, however, technology will continue to be a central feature of the way education is delivered.

To finalize the content, we will first conduct focus groups (FGs) to understand how young people are interacting with each other online, their opportunities for positive and negative communications, and whether and how teachers fit into this picture. Once the intervention content is updated, we will have youth review the messages in Content Advisory

Teams to ensure that they are understandable and salient. We also may test the program in a beta test with 15-20 middle school youth.

Specific Aim 2: Pilot test the 7-week BullyDown primary prevention program for feasibility and acceptability in an RCT of 150 middle adolescents. Youth will be randomly assigned to either BullyDown, a 4-message-per-day program, or an attention-matched control group talking about 'healthy lifestyle' topics (e.g., exercise). Our main outcome measures will be feasibility (e.g., recruitment and enrollment rates) and acceptability (e.g., positive program appraisal) at intervention end. The behavioral outcomes we will measure to motivate power analyses for a future R01 include: (1) bullying perpetration, (2) other aggressive behavior directed towards peers, and (3) bystander behavior in the past 30 days at 3-month post-intervention. We also will examine behavioral indicators at intervention end to observe proximal effects.

Given the limited impact of existing school-based interventions and the time associated with implementing them during school time, more efficient and effective intervention methods are needed. Programs that can be delivered to youth in middle adolescence, typically of middle school aged, irrespective of whether they are attending school physically or virtually may be especially relevant as school boundaries become more fluid. BullyDown addresses this critical need by providing a scalable program that could be quickly and cost-effectively disseminated nationally. If efficacious, we will test the intervention in an R01-funded RCT. Future endeavors could include adapting the program for Spanish-speaking youth and dynamically tailoring content to reported bullying behaviors.

3. RESEARCH PROTOCOL

3A. DESCRIPTION OF STUDY POPULATION, INCLUSION AND EXCLUSION CRITERIA

Study Sites. Dr. Espelage has a strong relationship with the Chatham County School District (See Letter of Support). There are 8 middle schools in the District, with a combined enrollment of 712 7th graders. The schools are diverse in terms of race and income: 47% are racial/ethnic minority (e.g., 31.5% are Black) and 69% are receiving free or reduced cost lunch. We will randomly select three schools. Should a school choose to opt out, we will randomly select another from the remaining five schools. Note that, while enthusiasm for the program is high, it is against district policy to allow principals to provide Letters of Support.

Should additional sites be needed, we will draw upon local Boys & Girls Clubs. The Boys & Girls Club of America (BGCA) includes over 4,000 clubs in the U.S. and serves approximately 4 million young people. Local clubs affiliated with the BGCA provide young people with a safe, supervised, and constructive environment during non-school hours. The organization serves a diverse population of young people with a large representation from low-income backgrounds. The Boys & Girls Clubs of Durham and Orange Counties serve students in the cities of Durham and Chapel Hill. The clubs are diverse in terms of race and income: 85% are African American, 6% Hispanic, 3% are White, 3% are Asian, 2% are Multiracial, and 1% are American Indian/Alaskan Native. About 62% of students are experiencing financial hardship, 1% have disabilities, and 4% are English Language Learners.

We also may recruit 13-14 year olds using advertisements on social media, such as Facebook and Instagram.

Youth eligibility criteria. The inclusion criteria for youth matches the anticipated profile of users when the program is publicly available in the future. Participants will: be enrolled in one of our partner schools, be in middle school (i.e., 7th or 8th grade) or between the ages of 12-14 years of age, be English-speaking, own their own cell phone, intend to have the same cell phone number for at least 3 months (this may or may not apply, depending on the number of youth who meet this criterion), provide informed written assent, and have parental permission. Non-English speakers and youth who do not have the reading ability to complete the screener are not eligible.

Youth recruited via social media additionally must be 13 years of age or older due to the Children's Online Privacy Protection Act.

Justification for eligibility criteria. Excluding Spanish youth: Only 11% of students in the Chatham County School District are English language learners, suggesting that more than 600 of the 7th graders will be English-speaking.

Requiring cell phone ownership: If we gave youth phones, findings would not be generalizable (e.g., community-based organizations are unlikely to provide cell phones). **National data suggest that low income youth are as likely as higher income youth to have cell phones.**[13] Our District contact estimates that almost all students have a cell phone. Similarly, Dr. Espelage recently conducted FGs with low-income middle school students and most had a cell phone. As

such, we are not reifying the digital divide with this criterion.

3B. SAMPLE SIZE

We will include ~60 youth in focus groups, ~70 in content advisory teams, 15-20 youth in a beta test if time allows, and 150 in a randomized controlled trial.

For the focus groups, we will enroll about 60 youth to take part in the online discussion. The groups will be stratified by characteristics that we posit will contribute to a sense of shared experiences and/or affect the likelihood of being a perpetrator of bullying. This may include sex, race/ethnicity, among others. We will endeavor to purposefully sample youth so that at least 50% are racial/ethnic minority, at least 50% are receiving free or reduced cost lunch, at least 30% report bullying perpetration and 30% report bullying victimization (note that there may be overlap such that a youth is both a bully and a victim). Actual distributions of youth who screen eligible may result in different ratios. We anticipate partnering with about 7 schools and about 2 BCGA Clubs. We will work with school administrators and Club Directors to determine the optimal school participation for each research activity.

3C. DESIGN AND DESCRIPTION OF METHODOLOGY

Recruitment and enrollment protocol.

In person recruitment.

Recruitment and enrollment will be similar for each of the three research activities. Chatham County Public School administration has agreed to dedicate classroom time for us to recruit youth from middle schools. We also will recruit from local Boys & Girls Clubs and via social media.

First, research staff will visit classes or Clubs to briefly describe the study activity and encourage youth who are interested to complete the screener. If youth are still being taught at home, as they are now in July 2020, the screener will be a brief online survey. If youth are back at their brick and mortar school or Club, the screener will be either online or paper and pencil. The screener will disguise the qualifying criteria so that those interested in participating will not know the "right" answers. Dr. Ybarra's team has found this to be particularly important in technology-based interventions where students are especially keen to take part in the study.

Next, youth who are eligible will be invited to an enrollment meeting where the study activity will be discussed, any questions will be answered, and an enrollment packet will be distributed. Research staff will present the study in small groups during times that do not interfere with academic commitments (e.g., during break, lunch). The packet will include the parental permission and youth assent forms; it may also include a cover letter from the school principal or the Club Director as well, depending on the District supervisor's choice.

Based upon previous experience, we anticipate more youth will be eligible than is our target recruitment number for the pilot RCT (~50 youth per school). As such, youth will be randomly selected to participate among those who are eligible. A list of candidates will be generated by the study software program and students will be contacted sequentially.

Youth who are interested in taking part in the study will receive an enrollment packet that includes both youth assent and parental permission forms. If youth are distance learning, these forms will be available online. If they are back in their brick and mortar setting, the forms will be printed. Research staff will ask youth to bring back their signed parental form and their signed youth assent form within two weeks. We may also have an online version.

The benefit of an online screener and enrollment is that youth can complete both activities whenever it is convenient for youth. If we conduct the screening and enrollment processes in the schools or Boys & Girls Clubs, we may try to contact youth who are absent on the day of the particular research activity up to four times. In the case of enrollment, youth who cannot be contacted, as well as those who choose not to participate by either youth or parental choice will be replaced by the next student on the random list of candidates. If the school or Boys and Girls Club does not have internet, youth will complete a paper-and-pencil screener , which will then be data entered by study staff.

Once youth assent and parental permission have been obtained, an enrollment confirmation text message will be sent to their cell phone to confirm the validity and compatibility of their cell phone number with the intervention software program. If challenges arise with receiving the text message, research staff will solve the issue.

For those who are enrolled through the Boys and Girls Club, we may use a passive parental permission protocol. In this case, we will hand the permission forms directly to the parents.

Social media recruitment.

Participants may also be recruited primarily through social media, such as Instagram (IG) and Facebook (FB).

We will not ask youth to refer their friends because this has the potential to create problems with randomization (i.e., if one is randomized to the intervention and the other to the control).

All youth who view the social media ad and want to learn more will click on it, linking them to the project website. There, they will read a description of the study activity and, if interested, complete an eligibility screener. Participants will not be required to register to complete the screener; this step will be similar to a contact form.

We will be requesting a waiver of parental permission. Children who complete an online screener that suggests they may be eligible will be contacted by research staff to schedule an enrollment telephone call. Over the telephone, study staff will confirm the candidate's eligibility, explain the study, and obtain verbal assent to participate, including a decisional capacity assessment.[90]

Research staff may use an external telephone provider, such as Google Voice, to communicate with participants, including telephone enrollments. We anticipate transitioning these communications to our internal participant management system when human resources allow.

Enrollment

For those in the new beta test and RCT, youth will then complete the online baseline survey. They will not be enrolled in the study activity until the baseline survey is complete, at which time they will be randomized. To facilitate self-completion, youth in the RCT will receive an invitation text message with a unique URL to access the survey. This allows participants to complete the survey at a time and place convenient for them.

Other activities

Focus group participants will have a pre-FG online survey to complete. They will be able to complete it on their own (e.g., at home). If they are attending the brick and mortar school or Club, they also will be able to complete the survey at school in the computer lab or at the Club on laptops there if they would prefer.

Special cases:

Focus groups: We will collect assent post-hoc from youth in the focus groups who had parental permission to take part but did not provide their own informed assent. To do so, we will send an email and text message to them that reads:

Hi [Name] – It's [RA] from BullyDown. Thank you again for taking part in the focus groups! Your feedback was great. We forgot to get your permission to take part in the online discussion before you started. We apologize. Please click on this link and tell us whether you agree. If you have questions, please email: Michele@innovativepublichealth.org. Thank you!

Those who do not complete an online assent form will be sent a reminder:

Hi [Name] – It's [RA] from BullyDown again. Just a quick reminder – please click on this link and tell us whether you agree for us to use your answers from the discussion groups. If you have questions, please email: Michele@innovativepublichealth.org. Thank you!

Those who respond, will receive this message: Thank you for letting us know. Have a great rest of your week!

For those who do not respond, we will return to the schools with paper assents and ask youth to complete them then.

We will destroy the focus group data from youth who do not provide assent.

Beta test: Based upon the enrollment experience and our plan to ensure text buddies in the intervention arm are paired with people at different schools/settings, it may be difficult to fully randomize all new beta test participants. In this case, we may randomize some youth to the intervention or control group, and then purposefully assign other youth to the intervention.

Retention strategies.

In her 36-school longitudinal study, Dr. Espelage had a retention rate of 88% at 12 months.[98] Our BullyDown beta test

had a 100% retention rate at one-month post-intervention follow-up. We anticipate a similarly strong retention rate at 3 months post-intervention end in the current study. To achieve this, we propose:

Incentives. All youth recruited via schools or Boys and Girls Club via active parental permission will receive $5 for returned parental permission and youth assent forms irrespective of whether permission was granted.

Research participants in the FGs and CATs will each receive $30 for their participation. The FG participants will receive $15 for each day they participate. CAT participants will receive $15 for returning their feedback on the text messages and $15 for taking part in the online discussion. Youth in the beta test will receive $25 after they complete the Intervention end survey. Those in the RCT will receive $15 for each survey they complete for a total of up to $45. Incentives will be fulfilled with Amazon gift cards because they can be distributed online, monitored to ensure that they have been used, and reissued if necessary. These incentives are separate from the incentive provided for the returned parental permission form.

Each school and Club may be given a $500 stipend for their participation each year; all organizations taking part in the RCT will be given the stipend. Teachers will not receive any compensation or incentive directly.

Changed phone numbers. We have found stability of cell phone numbers to be high in Ybarra's other text messaging-based programs. We expect the same will be true for BullyDown. In fact, none of the participants in the beta test dropped out because of non-working or changed phone numbers. If participants are non-responsive to program prompts, we will reach out to them via text, email, and telephone. If that is unsuccessful, a member of the research team will visit the school or Club to check on the participant. During the enrollment phase, we will explain to participants the importance of recording the project phone number somewhere convenient for them so they can contact us if they change their cell phone number.

Assertive follow-up. For each data collection period, we will send automated reminders to youth who have not completed the survey via text messaging. We will engage in personalized outreach if the survey is not completed within a week of the initial invitation. If youth are attending brick and mortar school or BCGA Club, we also will schedule in-school and in-Club data collection so that youth have multiple opportunities to complete the survey, especially if they were absent on a particular day. To maximize data, we also will include youth in the 3-month post-intervention survey even if they have missed the intervention end survey.

Specific Aim 1: Finalize BullyDown content.

Updating content to reflect current school interactions and realities (n=60). Current messages focus primarily on in-person scenarios. We will build upon the development work described above by updating the content so that it better reflects online as well as offline peer interactions. To do so, we will conduct FGs to obtain youth voice about their current experiences with peers online. While it is unlikely that schools will remain online indefinitely, technology is continually being infused into classroom exercises and so we anticipate online interactions to persist even in post-Covid-19 school curriculum.

FGs will be stratified to promote a sense of shared experiences. Stratification characteristics may be sex, race/ethnicity, among others. To promote a diversity of experiences, we will purposefully recruit youth with a variety of bullying experiences. More information can be found in Recruitment and Retention.

FGs will be conducted over multiple days on CiPHR's highly interactive, bulletin board-style, password-protected website. This online data collection space has been fully vetted for acceptability and feasibility among adolescents in Ybarra's previous projects with adolescents.[51-57] We will ask participants to log on 2-3 times per day at their convenience and respond to moderator questions and comments from other participants.

Example questions include: Now that you are going to school online, how has this changed the way you talk with other kids in your class? How does bullying look different now than when you went to school in-person? Share an example of how someone was bullied in class this past week. What did other kids do? What did your teacher do? Questions will be updated to reflect the academic setting when we are in field.

Krueger and Casey[58] recommend 3-4 FGs per participant category. Online FGs can accommodate more participants, such that they typically include about 20 participants. Because one or two FGs are needed to match a commensurate sample size as in-person FGs, we plan to conduct about three FGs. We expect coding stability and theoretical saturation, the point at which emerging ideas are repetitive and do not substantively alter the themes developed from initial interviews, to be achieved after the two FGs. If saturation has not occurred, we will conduct additional FGs.

Please see **Data Analysis** for more information.

We will monitor the Boards closely for inappropriate behavior but anticipate that the online format will facilitate the feeling of a safe place and ability to be open and honest about one's experiences.

Dr. Ybarra will review the current content and identify opportunities to update it based upon the FG data. We anticipate examples and scenarios will be expanded to refer to online interactions more directly. To remain within the 4 message per day frequency, an additional week of messaging may be added, based upon how many messages can be simply adapted versus added. Once a draft is ready, Dr. Espelage will review and provide feedback. Ybarra will integrate the feedback and then send the revised content back to Espelage for review. This process will be iterative until they agree that the relevant themes have been well integrated.

Integrating lessons learned into the content**.** Several participants in the beta test expressed confusion regarding the interactive Text Buddy feature. Further probing revealed that some of this was related to feelings of discomfort about discussing bullying with students they went to school with. Nonetheless, beta test participants sent between 0-52 messages to their Text Buddy, suggesting its acceptability potential. To improve the experience, we will expand the instructions for the Text Buddy feature and include more concrete prompts about what Buddies can talk about with each other (e.g., Maybe text your buddy and talk about what you think it would be like if you stood up for a friend being bullied at school tomorrow). We also will match youth with someone at a different school/setting and make sure that they are aware of this so they do not worry they are talking with a classmate they may know.

Drafting attention matched control content. In the beta test, the control group received two messages a week focused on thanking them for being in the study. As has been done in Dr. Ybarra's other interventions (e.g., R21 CA135669; R34MH109296), we will draft attention-matched content to well position this R21 for a competitive R01 submission. To ensure that youth in both arms receive the same 'attention,' content will address healthy lifestyle topics unrelated to bullying (e.g., fitness, nutrition).

Confirming adapted content for acceptability in Content Advisory Teams (CAT; n=~70). The content will next be reviewed by a CAT comprised of ~24 students. Each CAT member will have one week to review the messages and provide feedback through an online platform. Next, an online group discussion will elicit reactions to the messages and program design. Possible questions include: How well do these messages speak to the experiences you and your friends have around bullying? How clear do you find the messages? How could we say things differently to make the messages more understandable? Once feedback from the CAT has been integrated, a second 24-member CAT of different students will confirm that the content has been improved. For instance, in a previous intervention development Ybarra's team led, the second CAT noted that we included too many emojis, which we had added based upon feedback from the first CAT. Having two different groups review the content also ensures a wider range of opinions and feedback. The control content will be reviewed by a ~24-member CAT.

Conducting a beta test to confirm the protocol, including the software functionality and surveys. Before rolling out the RCT, we may conduct a beta test to pilot the recruitment, enrollment, data collection, and randomization procedures, as well as to identify final opportunities to improve the content. In most cases, five is a sufficient number of testers to identify any issues. Here, we propose 15-20 youth so that ~10 youth will test the functionality of the intervention program and ~5 the functionality of the control program. Usability data will be collected weekly via text messaging from participants. We may send questions weekly via text messaging, or by phone for non-responders, about the program experience. At the end of the beta test, we may conduct one-on-one interviews to identify any additional experiential issues that need to be addressed before the RCT is launched.

Pilot RCT of BullyDown (n = 150)

Randomization and group assignment. Once youth complete the baseline survey, they will be randomly assigned to either the intervention (n = 76) or the control (n = 74) group. We will use a computerized minimization technique, as originally described by Taves[59] and more recently reviewed by others,[60-62] to balance the sample on youth key indicators. These may include sex, school or Club, and bullying perpetration history. Treatment assignment will be generated and maintained at a password-protected Internet website monitored by Dr. Ybarra.

Contamination. Studies across participant populations and behavioral targets report that contamination is uncommon and does not affect study outcomes.[63,64,65,66] Give this, and to be efficient with R21 resources, students will be randomized at the individual rather than school or Club level. As we have done previously,[63,64] we will ask questions at intervention end that are specific to the BullyDown content. If indicated, we will include the number of correct exposure

questions as a proxy for contamination in multivariate models.

Data collection. Measures will be collected online at baseline, intervention end, and 3 months post-intervention end. All participants, regardless of study condition, will complete assessments at each time point. Youth will be able to complete the surveys on their own (e.g., at home). If they are attending the brick and mortar school or Club, they also will be able to complete the survey at school or Club in the computer lab if they would prefer. To facilitate self-completion, youth will receive an invitation text message with a unique URL to access the survey. This allows participants to complete the survey at a time and place convenient for them. Alternatively, they can sign up for one of the survey sessions at school or Club that the research staff will schedule with the school or Club administration. To avoid unintentional influence that school and Club staff may have on youth survey answers, only research staff will be present in the computer lab during survey administration.

3D. MEASUREMENTS AND STUDY INSTRUMENTS

Most of the proposed measures below were used in the beta test, suggesting the survey length can be feasibly completed by adolescents in middle school or between the ages of 12-14 year of age. Measures are as follows:

Table 3. BullyDown assessment measures

Main Outcome measures (intervention end)	Acceptability	We will measure intervention acceptability and tolerability[67] with a combination of open-ended questions (e.g., "What aspect of the program did you like the least?") and questions that form a scale of intervention acceptability (e.g., I liked my Text Buddy; α = .87). Participants will estimate the number of messages they received in the past week and percent that they read. The program will record the number of weekly level-up questions answered, and the number answered correctly, as well as the number of Text Buddy and Forever Friend messages sent.
	Feasibility	We will monitor the number of eligible/ineligible youth, the number of parental permission forms received, the number of youth invited but who decline to take part, and the retention rate.
Preliminary behavioral outcome measures (Intervention end and 3-month follow-up)	Bullying perpetration	Bullying will be queried by type (e.g., relational, physical), mode (e.g., online, in-person), and place (e.g., at home, at school).[68] Youth who endorse any question at a frequency of 3 times or more in the past 30 days (to reflect repetitive behavior) will be coded as engaging in bullying.
	Other aggression	Youth who report engaging in the above bullying perpetration items, but less frequently so, will be coded as engaging in aggressive acts.[68]
	Bystander behavior	Youth will be asked if, in the past 30 days, they have seen or heard about (e.g., as a rumor) someone being bullied. Those who say yes will be asked what they did in response. Options will include: nothing, telling an adult, talking to the victim, and standing up to the bully.

Exogenous variables include: 1) **SEL components**: Communication – youth will be presented with four different scenarios and asked to identify whether it reflects passive, aggressive, or assertive communication. Causey & Dubow's Self-report Coping Measure will be used to measure stress coping and problem-solving. Both are 8-item subscales with acceptable reliability (α = 0.84 and α = 0.84, respectively). Problem-solving asks youth how often they, for example, "Change something so things will work out." Empathy will be assessed with the 5-item Empathy subscale in the Teen Conflict Scale (α = .62).[69] Respect for diversity will be measured with the 4-item Support for Cultural Pluralism subscale of the Inventory of School Climate (α = 0.68).[70] Identifying bullying will be measured by showing participants various "features" and asking them to identify those that reflect bullying (i.e., repetitive, with differential power, intent) Attitudes towards bullying and aggression will be measured with the 4-item University of Illinois Positive Attitudes toward Bullying Scale (α = 0.81).[71] Bystanders' intentions will be measured with the 5-item University of Illinois Willingness to Intervene scale (α = .62).[72] Anger and hostility will be measured with the University of Illinois Anger Scale (α = .81; e.g., "I got in a physical fight because I was angry").[73] Hostility will be measured with the Symptom Checklist-90 subscale, which is a 6-item scale (α = .87).[74] Impulsivity will be measured with the 4-item Impulsivity subscale from the Teen Conflict Survey (α = .62).[75,76] 2) **Peer victimization:** Victimization questions that mirror the bullying questions described will be asked of all youth. Those who say they have been victimized in at least one way 3 or more times in the past 30 days, by someone with more power than them, will be coded as being bullied. Those who report less frequent victimization and/or an aggressor with equal power will be coded as a victim of other aggressive acts. 3) **Exposure to domestic violence** will be measured using an item from the Juvenile Victimization Questionnaire (JVQ).[77] This well-

validated survey question has been used successfully in Dr. Ybarra's Growing up with Media survey, which included youth as young as 10 years old.[78] 4) **Exposure to community violence**: Four JVQ questions will measure exposure to community violence (e.g., Have you ever seen someone get attacked or hit on purpose?).[77] 5) **Alcohol use:** We will use the YRBS question to measure alcohol use in the past year and in the past 30 days.[79] 6) **Literacy** will be measured with the Comprehension subscale of the Stanford Diagnostic Reading Test[80]. It was designed to be used by students with low literacy and has high internal validity (α = .84-.90)[81]. And 7) **Demographic characteristics**: Sex assigned at birth, gender identity, sexual identity, age, grade, cell phone number, and number of people living in the home; length of time using text messaging, length of time with current cell phone number, and average text messaging frequency. **Data analysis is described in Statistical Design and Power.**

The reliance on youth self-report bears discussion. We have carefully considered the potential benefits and drawbacks of including teacher report. We decided not to because middle adolescents, those who are 12-14 years of age and typically in middle school, teachers see their students for one class a day. They are unlikely to know everything that occurs during a student's day and whether they are bullying or being bullied in other classrooms. We decided not to collect parent report because parents rarely know about their child's bullying behavior.[82]

Scientific rigor of the experimental design, methods, and analyses. The rigor of the proposed study is high. For example, random assignment eliminates the possibility of youth being purposefully assigned to a particular study arm. The attention-matched control will reduce the likelihood that behavior change, if detected, is due to the 'attention' youth received by the daily text messages. Program fidelity will be high as the sending of messages is automated and the same for each student.

3E. STATISTICAL DESIGN AND POWER

Specific Aim 1: Finalize the BullyDown program.

Transcripts of the FGs will be entered into Dedoose (formerly EthnoNotes),[85] a mixed methods analysis program. Codes will be generated based on the first FG, reexamined, and refined through constant comparison with the second FG.[86] A codebook will be created with codes, brief descriptions, and illustrative quotations.[87] Codes will be both generated inductively and derived from our initial research questions (e.g., how youth interact with their peers and their teacher online). Dr. Ybarra's project coordinator and Dr. Espelage's graduate research assistant will code both FGs. To assure inter-coder reliability, we will calculate a kappa value and accept a minimum of 0.75 as the criterion for adequate agreement between coders.[88] After coding is complete, we will extract themes using an iterative process to highlight evidence contradictory to our conclusions as well as the modal response.[89] The analysis will result in a report that describes the findings and advises how to integrate them into program content.

Specific Aim 2: Pilot test the 7-week BullyDown intervention for feasibility and acceptability in an RCT of 150 adolescents either in middle school and/or 12-14 years of age.

The **feasibility** of the BullyDown intervention will be determined by our recruitment and retention rates. If at least 75% of eligible studies assent and 80% complete the survey at 3-months post-intervention, we will deem these data points as supportive of a hypothesis of feasibility.

The **acceptability** of program features (e.g., badges, Text Buddy) will be measured using 5-point Likert scales; average scores of 4 or more will be supportive of acceptability.[90] Youth engagement with the program will be examined to identify potential trends in greater intervention impact (e.g., for those who use the Text Buddy feature).

Post-intervention one-on-one interviews to illuminate the intervention experience will be analyzed using a thematic approach,[91] as our aim will be more descriptive in nature, with a lower level of interpretation needed than is afforded by grounded theory or other qualitative analytical techniques.[92]

Analyses examining **behavioral outcomes** will be primarily intended to inform power analyses for the larger R01. Data will be treated as intention-to-treat and complete case. We will conduct sensitivity analyses (e.g., missing = bullying behavior) to understand how this may affect our findings. Missing data that are not the main outcomes will be imputed.

Baseline covariates will be examined to determine whether randomization performed as intended. Any that are significantly imbalanced across study arms will be included in multivariate analyses.

We will use logistic regression to analyze outcomes (e.g., bullying perpetration, other aggressive behaviors; bystander behavior). Once gross estimates of intervention effect have been calculated, covariates will be added to examine

whether they appear to mediate the relation between group assignment and the outcome. Three conditions must be met in order to claim that mediation is present:[93-95] (1) a predictor (e.g., experimental arm) is significantly associated with a mediator (e.g., TPP motivation); (2) The mediator is significantly associated with an outcome (e.g., pregnancy); and (3) when one controls for the mediator, the effect of the predictor on the outcome becomes non-significant. If this effect retains significant but is attenuated, partial mediation is indicated. A 10% or greater change in the point estimate will be deemed clinically significant. [96,97]

Sex as a biological variable. It is possible that males will respond to the program differently than females because it feels more individual and perhaps, in this way, will resonate more with males.[83] Conversely, perhaps because females text message at a greater volume than males,[36,84] the format of this program may resonate more with them. As such, sex will be explicitly examined as a potential moderator. To understand whether the intervention impact varies by sex, we will test an interaction term, i.e., experimental group X sex. If the term is statistically significant, then it will suggest that boys and girls are impacted differentially by the intervention.

To examine whether/how the intervention effect attenuates over time, we will use generalized estimation equations to analyze the data across follow-up periods using an identity link and exchangeable correlation structure. By entering an interaction term for experimental group X time, we can determine if the intervention is differently impactful at intervention end versus 3-months post-intervention.

Should Dr. Ybarra need statistical guidance, we will take advantage of Dr. Espelage's access to the biostatistics 'core' at the University of North Carolina (please see Budget Justification).

Power analysis

Because the behavioral outcomes data in this R21 will be used to inform the power analyses of the future R01, we respectfully suggest that a power analysis for this study is premature.

4. PROTECTION OF HUMAN SUBJECTS

Ethical considerations

The study will be conducted according to ethical principles stated in the Declaration of Helsinki (2013). IRB approval will be obtained before initiating the study. Assent and permission forms will take into consideration the well-being, free-will and respect of the participants, including respect of privacy.

Sources of Information.

RCT measures will be collected at baseline, intervention end, and 3-months post-intervention end in online surveys. All participants, regardless of study condition, will provide data at each time point. FG and CAT data will be collected online.

4.a. Potential Risks

The largest risk posed by participation in the study is inadvertent loss of confidentiality of one's bullying behavior or experiences. Confidentiality also may be lost if someone sees the participant's computer screen or intercepts his/her cell phone and reads the text messages. It is possible that survey questions or intervention topics may cause discomfort for some youth. It also is possible that conversations between Text Buddies will be harmful (e.g., bullying) in the RCT. Finally, it is possible that participants in the focus groups might be in the same online focus group as their bully.

4.b. Adequacy of Protection against Risks

The researchers take these potential risks very seriously. The PI will be responsible for all aspects of the project with respect to intervention design, data collection, and use of data. All aspects of the study will be approved by Pearl IRB, the Center for Innovative Public Health Research (CiPHR)'s OHRP-approved IRB of record prior to commencing data collection.

Informed Youth Assent and Caregiver Permission.

Youth assent and parental permission forms will receive final approval from the IRB before going into field. The assent information will be discussed with the participant by study staff either online, or at school or BCGA Clubs if youth are back in person. who are trained in Human Subjects Protections. Participants will be given the opportunity to ask any questions. They will be told that they can choose not to participate without any consequence. Given that children are a

vulnerable population, we also will be collecting active parental permission.

Because the study is low-risk, we will be sending the forms home for the parent and child to complete. To ensure that youth with language difficulties are able to understand the information they are being provided, the assent form will be written below the 6th grade level.

To further facilitate the ease of recording one's choice, we may offer the option to indicate one's acceptance or declination of youth assent and parent permission via an online form (i.e., that a clicked "yes" will be sufficient). Accordingly, we are requesting a waiver of documentation of youth assent and parent permission for those who complete an online form because the study involves minimal risk.

We will assent youth the same way that we are obtaining parental permission unless it is explicitly stated and documented otherwise.

Phone numbers for Drs. Ybarra and Espelage, and Pearl IRB will be listed in the assent and permission forms in case a participant or a parent has a question or would like to discuss the study or any concerns.

We may employ a passive parental permission protocol for youth recruited from the Boys and Girls Clubs, and also are requesting a waiver of parental permission for those recruited via social media. We are requesting this because:

1. The research involves no more than minimal risk to the subjects.
2. The waiver or alteration will not adversely affect the rights and welfare of the research participants.
3. It would not be possible to do this research with active signed parent/guardian permission. In the case of the Boys and Girls Clubs, only 50% of active permission forms given to eligible youth were returned. In the case of social media, obtaining parental permission would be logistically impracticable.
4. Due to the longitudinal nature of the research, identifiable private information is required to follow youth over time.
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation
6. For the Boys and Girls Club youth, participant selection is based on club membership and not exclusionary.

Youth who are recruited online will provide verbal assent during the enrollment call and again provide assent at the beginning of the baseline survey. Youth recruited via Boys and Girls Clubs who are enrolled using a passive parental permission protocol will have the opportunity to ask questions when the study activity is initially introduced to them. Because the forms will be handed directly to parents, they will have the opportunity to ask questions about the study at that time. If either caregivers or youth have questions subsequently, they can utilize the contact information provided on the form to reach Drs. Ybarra and Espelage.

Protection against Risk.

Reports will only use aggregated data. No report of individual data will be provided. The core research team will have monthly meetings, and more frequently when in field; and will utilize real-time Internet technology to monitor the progress of the study.

Research staff will help the participants set their phones to be password protected to limit access by others if they would like. We also will provide instruction on how to change their phone settings so that text messages do not scroll across the screen as an alert. Youth will be encouraged to only read messages when they are in a private space where they feel like they can engage with the content safely. We also will encourage youth to delete any messages that they do not want others to read.

Youth will be encouraged to complete the online surveys in a private space where no one can see their screen. They will be able to pause and come back to the survey later if they are not in a safe place.

Participants will be told in the enrollment meetings and in the assent form that some survey questions and program messages may make them feel uncomfortable. They will be encouraged to skip such questions or messages. They will also be told that they may withdraw from the program if they choose.

Because we are recruiting only about 7 youth per school into the male and female focus groups, respectively, we think it is very unlikely that a bully victim's buddy will be in the same focus group. Nonetheless, we will make it clear that participants can reach out to us at any time and stop their participation, including if they are uncomfortable with the other people who are taking part in the focus group.

Monitoring of Text Buddy Communication. Text Buddies are paired intervention participants who will be encouraged to text message each other about to discuss program content throughout the intervention. For example: "Talking about your bullying experiences with friends can be hard. Now that you're equipped with mad communication skills, try talking with your Buddy about the most recent time you saw someone bullied. What did you do? How did you feel? Text your Buddy and share."

Buddies will be paired based on sex and school / setting so that they will be at different schools / settings based upon findings from the earlier beta test. The software program will identify youth who match on these criteria and automatically pair them. Those who are not automatically paired will be flagged so that the research team can manually pair youth.

We posit that social support from a Text Buddy will positively influence youth over time. However, balancing this with the privacy needs of our participants, who likely do not want to exchange contact information with a stranger, is important. As such, all Text Buddy messages are routed through the study server, replacing the need for this exchange. Participant cell phone numbers will never be distributed to other participants. To send a message, participants will simply text the dedicated BuddyLine, the program phone number that participants will use to communicate with their Buddy. This message is sent directly to the program server, which identifies the intended recipient, and routes the message to the assigned Text Buddy. This methodology will also allow us to measure the amount of interaction between Buddies accurately; if participants texted each other directly, we would have to rely on self-report to measure frequency of contact. For analysis, we will keep a count record to reflect the number of messages sent by each participant.

Prior to the program start, we ask intervention participants to agree to a Text Buddy Code of Conduct that sets clear expectations for healthy interaction and support. We have closely monitored the interactions between Buddies during the beta test and did not see any inappropriate interactions. We also will block messages that contain specific key words (e.g., racial epithets, drug names, participant contact information such as social networking profile names) for review before they are sent through to the Buddy. Study staff **closely monitor** the Buddy interactions (16 hours/day) while in field. **Concerning message content is elevated to the PI within 24 hours.** Study staff are assigned to monitor the messages in real time from 8am – 10pm pacific standard time. Staff are able to receive text message alerts on their phone when a Buddy message is detected should they be away from their computer during their monitoring session. We note that across three projects that Ybarra's team has implemented this feature, never has there been a case of on buddy bullying another.

Providing resources and referrals. This is not a mental health intervention. Nonetheless, we will provide resources and referrals for youth. For example, we will have a resource page on the intervention website for youth who are upset or need help. The 24-hour crisis hotline, 1-800-SUICIDE, will be listed in case youth require immediate intervention. Those who are experiencing thoughts or feelings that are upsetting will be referred to the National Information Mental Information Center for assistance identifying a treatment provider. The National Mental Health Information Center is funded by the Center for Mental Health Services within the Substance Abuse and Mental Health Services Administration (SAMHSA). As one of SAMHSA's clearinghouses, the Center provides mental health information and treatment referrals to a varied audience throughout the United States and its territories, via the toll-free number (800-789-2647) and website (www.mentalhealth.samhsa.gov) that offers a service locator for finding local resources.

If someone articulates a plan to hurt themselves or others when monitoring Text Buddy messages or other participant program interactions, we will advise them to call 911 or go to their nearest emergency room. We also will provide the suicide crisis hotline. If crisis language is observed during monitoring, youth will be referred to Christina Patts, LICSW, for assessment and referral. Ms. Patts has extensive experience implementing this type of crisis contact for youth taking part in research studies. She is the clinician on call for Dr. Ybarra's Girl2Girl and Growing up with Media studies. She has also served as consultant for studies measuring child sexual and physical abuse.

Protecting privacy. Dr. Ybarra's team has conducted several online national surveys with very sensitive questions. There are many benefits to this methodology, including increased self-disclosure compared to interviewer-based data collection, and convenience and increased safety for the participant as s/he can decide when and where to best answer the survey. Participants will be given the option to complete the survey on their own, or at school or the Club if they are back in brick and mortar settings. Participants will receive a personalized link which they can click on to take them directly into the survey. To further ensure privacy, we also ask participants to complete the survey in a private place – and then ask again at the beginning of the survey to see if they are. If they indicate they are not, they are encouraged to pause the survey and come back to it later.

No names will be collected except on youth assent and parent permission forms. Study materials will be safeguarded as follows: informed parent permission and youth assent forms will be kept under double lock in filing

cabinets in separate physical locations. Secure UNC SOE server if not physically collected.

Secure electronic transmissions and storage of data. All data are password protected with strong encrypted passwords and is transmitted securely using SSL (TLS) 128-bit encryption across the Internet (HTTP). SSL provides front-end users with the assurance of access to a valid, “non-spoofed” site and prevents data interception or tampering with sensitive information. The 128-bit encryption is the preferred security level of government and financial institutions. To ensure against the remote possibility that an intruder gains access to stored data, all data stored are protected with strong passwords that are also encrypted, making use of any acquired data nearly impossible. Any Personally Identifiable Information (PII) is securely encrypted and stored separately from study data. All access to participant data is limited to access via a secure VPN network, making it impossible to access otherwise.

Data are located on our dedicated server in Liquid Web's secure SSAE-16 Compliant datacenter in Lansing, Michigan. Dedicated servers eliminate security issues involved with shared hosting environments where hundreds of websites and users reside on one shared web server, as well as ensuring both physical and network security.

Dedicated server facility security includes:

- 24/7/365 Manned Facilities
- CCTV Security Cameras Covering Inside, Outside and All Entrances of Data Centers
- Site Entrances Controlled By Electronic Perimeter Access Card System
- Sites Remotely Monitored By 3rd Party Security Company
- Entrances Secured by Mantraps with Interlocking Doors
- SSAE-16 & HIPAA Compliant, Safe Harbor Certified

Having a backup copy offsite is critical for protecting against data loss due to a catastrophic event (e.g., an earthquake). The datacenter is equipped with redundant tier 1 bandwidth, ensuring minimal latency and fast connections to all points of the global Internet. Datacenter access is strictly limited to technical staff. Electronic security systems control datacenter access and are accompanied by a full complement of motion-detecting security cameras that monitor the entire facility.

Our servers are equipped with daily backups to an external hard drive, as well as extensive server-hardening, firewall protection, brute force detection and evasion, Apache denial-of-service attack prevention/protection, and email virus filtering. In addition, the server is monitored by Liquid Web 24/7 to ensure 100% uptime and receives daily security audits and monthly vulnerability scans.

A description of the text messaging platform. To further promote data security, the BullyDown program is delivered through CiPHR’s proprietary platform that has been developed and improved upon over several research projects (e.g., R01 TW007918, R21 CA135669, R01MH096660 R34MH109296, R34MH108781, R01 HD095648). The system was developed using PHP, Javascript and Jquery programming languages and utilizes MySQL Databases running on a Linux (LAMP) based server. The system makes us of the Twilio gateway service's API to both send and receive text messages.

4.c. Potential Benefits of the Proposed Research to the Participants and Others

Extant research has demonstrated the link between incidence of school bullying and resulting adverse outcomes such as depression, anxiety, physical illness, school dropout, and suicide. Research also has identified a link between school bullying behaviors and high-intensity violence in schools (e.g., school shootings). To the extent that the BullyDown text messaging program is effective in reducing bullying in schools, we anticipate positive long-term societal effects for youth, including decreased need for delinquency and mental health services, enhanced positive youth development, improved academic achievement, and societal cost savings associated with these outcomes.

4.d. Importance of the Knowledge to be Gained

BullyDown will contribute to scientific knowledge in several important ways: 1) BullyDown will be delivered outside of school. By engaging with the content in a non-academic setting, youth may be more likely to apply their new behaviors across contexts, including bullying scenarios that take place online and other places where youth congregate. This also has the advantage of giving youth the opportunity to learn SEL components and interact with someone else in the program (i.e., a Text Buddy) without a potential perpetrator sitting in a desk nearby. It also bypasses situations when school-based programming is not viewed as "cool" by some students, resulting in their under-engagement in program activities, which

can implicitly reinforce negative social norms. 2) In school-based intervention programs, school personnel are often called upon to implement the content. To do so, they need to be extensively trained to maximize efficacy. Increasingly, financial resources for training are simply not available in US public schools. BullyDown is administered through text messaging, bypassing training and competition with professional development time. 3) Compared to in-person interventions which may be vulnerable to variable implementation fidelity, all youth in the program receive the same content in the same order, thereby ensuring fidelity. Also compared to "apps" that require a smart phone and data, all cell phones are text messaging-capable. 4) The meta-analytic results described above reflect the best-case scenario. Although all states require schools to implement bullying prevention programming, there is significant variation in what is mandated, resulting in a wide spectrum of programming offered in schools across the US. In the FGs we conducted in the BullyDown development process, very few youth talked about a comprehensive bullying prevention curriculum in their school. BullyDown can be delivered as a "booster" outside of school time that enhances whatever programming is being offered by schools. In doing so, one of the benefits of BullyDown is that it helps to ensure all youth are exposed to the basic tenets of a bullying prevention curriculum. 5) Given the focus on victimization that most of the current prevention programs have, our focus on perpetration is innovative.

4.e. Data and Safety Monitoring Plan

The PI will be responsible for all aspects of the project with respect to intervention design, data collection, and use of data. Pearl IRB will approve all aspects of the study prior to commencing data collection. Informed youth assent and parental permission will be obtained from all participants. Participants will have access to 24-hour referral information as well as phone numbers for the study administrators (i.e., PI and IRB).

Data Monitoring

The PI will be responsible for monitoring data to ensure the safety of participants. Additionally, the IRBs will be responsible for data and safety monitoring.

In order to ensure privacy for participants and to minimize risk, we will be using computer- and text messaging-based data collection procedures. This reduces the number of people who view the data and increases self-disclosure on sensitive topics. Access to the data will be password protected.

Each participant will be given a random unique identifier in the data set which will be stripped of all personal information to protect confidentiality. Datasets used for analysis will contain project identification numbers but neither names nor other identifying information such as email addresses. Identification information will be retained by CiPHR for the duration of the study and stored separately from the responses provided by subjects.

Collaborators will receive data stripped of personal identifiers. To ensure complete confidentiality, access to the key linking personal identifiers to usernames and passwords will be restricted to key personnel. Reports will not identify individual adolescents. Dr. Ybarra will oversee the data storage and reporting procedures. Upon completion of the analysis of the data collected in this study, records will be destroyed. Reports will only use aggregated data. The core research team will have weekly meetings utilizing real-time Internet technology to monitor the progress of the study.

Adverse Events

Dr. Ybarra will review the progress of the project and data being collected to ensure that potential adverse effects are identified, if they occur, and reported to both IRBs. This includes unanticipated problems involving risks to subjects or others. Any action recommended by the IRBs to the PI will be implemented immediately in order to minimize further risk. The adverse event report will further be communicated to other entities (e.g., NIH) in a timely manner as appropriate based on their policies. Dr. Ybarra will also be responsible for reporting to the project officer if the IRBs or any other entity temporarily or permanently suspends an NIH-funded trial. All notifications will be done via email immediately followed with a certified letter.

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