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### A technology-augmented intervention to prevent peer violence and depressive symptoms among at-risk emergency department adolescents: Protocol for a randomized control trial

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#### Abstract

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**Background:** Peer violence and depressive symptoms are increasingly prevalent among adolescents, and for many, use the emergency department (ED) as their primary source of healthcare. Brief in-person interventions and longitudinal text-message-based interventions are feasible, acceptable, and may be effective in reducing peer violence and depressive symptoms when delivered in the ED setting. This paper presents the study design and protocol for an in-ED brief intervention (BI) and text messaging program (Text).

**Methods:** This study will be conducted in a pediatric ED which serves over 50,000 pediatric patients per year. Recruitment of study participants began in August 2018 and anticipated to continue until October 2021. The study will enroll 800 adolescents (ages13–17) presenting to the ED for any reason who self-report past-year physical peer violence and past-two week mild-to-moderate depressive symptoms. The study will use a factorial randomized trial to test both overall intervention efficacy and determine the optimal combination of intervention components. A full

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 $2\times2$  factorial design randomizes patients at baseline to 1) BI or no BI; and 2) Text or no Text. Peer violence and depressive symptoms improvements will be measured at 2, 4, and 8 months through self-report and medical record review.

**Discussion:** This study has important implications for the progress of the greater field of mobile health interventions, as well as for adolescent violence and depression prevention in general. This proposal has high clinical and public health significance with high potential scalability, acceptability, and impact.

#### Keywords

Depression; violence; adolescent; mHealth; text messaging; prevention

#### Introduction

Adolescents with a history of physical peer violence experience depressive symptoms at three times the rate of community peers [1–6]. Between 5–10% of adolescents in community samples reported past 30-day depressive symptoms [1, 2, 7] versus about 40% of adolescents with a history of peer violence [3–5, 8]. Depressive symptoms likewise increase the risk of involvement in peer violence [9–16]. If unaddressed, these concurrent problems lead to increased risk of mental health disorders, substance use, and other risky behaviors [6, 17–25].

The inter-related problems of peer violence and depressive symptoms are increasingly prevalent among adolescents, particularly among minority and low-income youth [26, 27]. Emergency departments (ED) are often the only source of healthcare for these at-risk teens [28–32]. Higher rates of peer violence (40–50%), depressive symptoms (20–40%), and other mental health issues are reported among youth in the ED, regardless of the reason for their ED visit, compared to youth in schools or pediatric clinics [5, 26, 33–37]. Youth with a history of peer violence and depressive symptoms are also more likely to have future ED visits for assault injuries [21, 22, 38]. ED screening for risk behaviors, including a history of violence, is supported as an important public health strategy [39–43].

Peer violence and depressive symptoms share common underlying mechanisms: deficits in cognitive reappraisal, emotional regulation, and self-efficacy skills [44–54]. These skill deficits are mutually reinforced by continued experiences of both peer violence and depressive symptoms [44, 48, 55, 56]. Cognitive Behavioral Therapy (CBT) and Motivational Interviewing (MI) based interventions can address these skill deficits and prevent future peer violence and depressive symptoms [57–59]. Intensive case management programs for assault-injured youth, initiated in the ED or in the hospital, may also be effective at preventing future physical peer violence [60, 61]. Multi-session CBT-based interventions decrease depressive symptoms and reduce incidence of major depression disorder, including among youth with a history of peer violence [62–70]. These interventions, however, require significant staff and time resources. At-risk racial, ethnic, and low-income youth are unlikely to access these preventive or therapeutic treatments due to both structural and personal barriers [7, 22, 71–74].

Brief in-person interventions and longitudinal text-message-based interventions, delivered in the ED setting to at-risk adolescents, are feasible, acceptable, and may be effective in reducing peer violence and depressive symptoms when theoretically-based, interactive, positive, and dynamically tailored [58, 75–81]. Text messaging is a particularly accessible intervention modality: over 90% of adolescents have a mobile phone, 95% report owning or having access to a smartphone, and adolescents are constantly communicating via text and other mobile messaging platforms [82–86]. Text message interventions may have lower costs after the development phase, and may circumvent common barriers to accessing preventive interventions such as stigma and transportation [85, 87–89]. Existing literature on text-messaging interventions is mixed regarding the need for human support (versus automated curricula), and the degree of tailoring and personalization needed [90–96]. If automated text messaging reduces peer violence and depressive symptoms, it could potentially be more easily disseminated than in-person interventions. Prior to dissemination, however, it is important to evaluate efficacy of these novel programs. [97, 98].

#### Methods

#### Overview

Our previously completed pilot randomized control trial iDOVE [59] consisted of a brief intervention (BI): a 20-minute CBT- and MI-based intervention during the ED visit; and an 8-week text intervention (Text): automated, tailored, two-way text-message curriculum started after the ED visit which reinforced cognitive appraisal, emotional regulation, and self-efficacy skills. The iDOVE pilot had excellent rates of recruitment (82% consenting) and retention (>90% completing 4-month follow-up). In the study, 96% of recipients responded to at least one of the daily text messages, with a mean response rate of 84% (47 of 56 days received a response). iDOVE compared BI and Text interventions to a control group showing promising effect sizes in reducing peer violence (d=0.46, p=0.01) and depressive symptoms (d=0.37, p=0.07) at 8 weeks among youth with moderate symptoms at baseline. Teens whose daily mood had not improved by Day 7 of the Text intervention had poorer outcomes at follow-up and reported the need for in-the-moment "live" text support [59].

Automated text-message-based mood ratings correlate strongly with longitudinal depressive symptoms [99]. In iDOVE, latent class modeling was used to identify distinct subgroups of participants who showed similar patterns of daily text-message-based mood ratings over the course of the intervention. These patterns helped identify a subgroup of participants who are not improving in response to the intervention, and identify the critical time at which the divergence between improvers and non-improvers was evident. This characterization shows that text-based daily mood ratings are a well-operationalized, feasible marker of need for additional, "adaptive" intervention. Based on qualitative feedback provided by pilot participants [77], the pilot randomized control trial iDOVE [59], and others' studies [100–103], more personalized text messaging with a human counselor may be helpful for participants showing no signs of improvement via Text. Texting with a live counselor is highly acceptable to youth, as illustrated by the exponential growth of Crisis Text Line [104, 105]. Use of human support is associated with improvements in outcomes in internet-based CBT prevention programs [106–109].

The primary aim of the current study, iDOVE2, is to test the efficacy of the components of iDOVE, an in-ED brief intervention (BI), automated text message intervention (Text), and adaptive, real-time texting (LiveText) components as developed in our pilot study, and to determine the most potent and parsimonious combination of these intervention components, using a factorial design, preventing peer violence and depressive symptoms among at-risk youth. The second aim is to examine the efficacy of the LiveText adaptive component among early non-responders (the subset of Text participants who do not show signs of improvement after 7 - 14 days). These participants will be re-randomized to either receive the supplementary LiveText intervention, or to continue with the standard Text intervention. Outcomes among the intervention groups will be compared to controls on peer violence and depressive symptoms over the course of follow-ups at 2, 4, and 8 months. A factorial design is a well-accepted strategy for optimizing behavioral interventions' components [110–112]. Factorial designs allow simultaneous testing of both main effects of, and interactions between, intervention components. Factorial designs also have high statistical efficiency, with a reduced number of experimental subjects needed compared to traditional trial design strategies [95, 111–113]. The  $2\times 2$  factorial design used in this application will allow us to efficiently unpack which, if any, elements are most efficacious, and thereby design the most simple intervention [111, 114].

Preliminary evidence shows intervention effects on changes in the putative participant-level mediators (cognitive reappraisal, emotional regulation, and self-efficacy skills). Formally testing whether changes in these mediators from baseline to 2-month follow-up mediate intervention effects on primary outcomes at subsequent follow-up time points will contribute to future efforts to design more effective preventive interventions [115, 116]. Examining whether baseline participant characteristics (gender, baseline violence and depression severity, substance use, prior counseling) moderate intervention effects can identify subgroups who stand to benefit most from the interventions. Finally, examining secondary effects (on other types of violence) may inform other adolescent violence prevention efforts.

#### Study design

iDOVE2 will enroll 800 adolescents (ages13–17) presenting to the ED for any reason who self-report past-year physical peer violence and past-two week mild-to-moderate depressive symptoms. The study will use a factorial randomized trial to test both overall intervention efficacy and determine the optimal combination of intervention components. A full  $2\times 2$  factorial design randomizes patients at baseline to 1) BI or no BI; and 2) Text or no Text. Text participants who do not show signs of improvement after 7 – 14 days (based on daily Text mood assessment) will be re-randomized to either 1) continue standard Text intervention; or 2) additionally receive LiveText, a more intensive text-message micro-counseling with a human interventionist. Peer violence and depressive symptoms improvements will be measured at 2, 4, and 8 months through self-report and medical record review. Figure 1 illustrates the study's timeline.

The research protocol and informed consent process was approved by the hospital system's Institutional Review Board. A National Institutes of Health (NIH) Certificate of

Confidentiality was obtained before initiation of the study. A Data Safety and Monitoring Board was assembled using the institution's Research Committee and two external members.

#### Recruitment

his study will be conducted at the primary Level 1 trauma pediatric ED in a Northeast city which serves over 50,000 pediatric patients per year. The patient population is diverse, with about 30% publicly insured, 30% Hispanic, and 40% non-White race. Recruitment of study participants began in August 2018 and anticipated to continue until October 2021.

A Research Assistant (RA) will be present in the ED seven days a week from 1:00pm – 9:30pm in accordance with ED volume. Every patient meeting screening inclusion/exclusion criteria will be approached. Potentially eligible participants will be identified from the electronic ED tracker. After obtaining verbal parent consent and verbal adolescent assent, RAs will administer a computerized screening/baseline survey on a touch-screen tablet. Surveys will be conducted using Research Electronic Data Capture (REDCap) [117], a secure, web-based application designed to support data capture for research studies. All screened patients will be given a small gift (USD \$1–2) as compensation for the screening. Computer-based assessments have been repeatedly shown to be more accurate than face-toface questionnaires about risk behaviors [118].

Inclusion criteria for screening include: age 13–17, English speaking, and parent/guardian present. Exclusion criteria for screening include: chief complaint of suicidality, psychosis, sexual assault, child abuse; in police or child protective services custody; in need of emergency psychiatric care or evaluation; and being unable to assent. Participants are eligible for full study enrollment if they self-report: past-year physical peer violence using a modified version of the Conflicts Tactics Scale 2 (CTS2) [118]; past-two week mild-to-moderate depressive symptoms using the Patient Health Questionnaire 9 (PHQ9) [119–121]; and owning a text-message-capable cellphone. The CTS2 is a validated measure (a=0.89–0.91) used in previous ED-based peer violence prevention interventions and asks about frequency of different types of physical victimization and perpetration [5, 58, 77, 122, 123]. To be eligible, participants must report 1 past-year on the CTS2. The PHQ9 is a standard, well-validated, clinically relevant screening tool for depressive symptoms [119–121]. To be eligible, participants must score between 5–19. This range accords with that used by other preventive intervention studies [5, 77]. Participants who meet enrollment criteria will complete a written informed consent process and a contact information form.

#### Randomization

Participants will be randomized into one of four groups based on the factorial design: 1) Yes BI but No Text ("BI only"); 2) No BI but Yes Text ("Text only"); 3) Yes BI and Yes Text ("BI+Text"); and 4) No BI and No Text ("Control"). Randomization will be stratified by sex and baseline depressive symptoms, both known moderators of outcomes, using a block randomization procedure. The team's biostatistician will generate the randomization scheme based on a stratified permuted block randomization procedure, with small, random sized

blocks (sizes 2–4). Study staff, except the RAs conducting recruitment and the Project Manager, will be blinded to randomization.

Depressive symptoms for randomization will be assessed using the Center for Epidemiologic Studies Depression scale-Revised (CESD-R), one of the most widely used assessments of depressive symptoms [124]. The CESD-R will be used for baseline and outcome measures instead of the PHQ9 score because of its greater validity and reliability. CESD-R cutoffs were chosen according to clinical cutoffs.

#### Intervention protocol

Each intervention component has been developed, iteratively refined, and piloted based on our theoretical model, existing CBT- and MI- based interventions, best practices for brief interventions and text-message interventions, expert consultation, and participant feedback [58, 64, 65, 76–78, 80, 119]. Congruent with our theoretical model, each component emphasizes cognitive reappraisal, emotional regulation, and self-efficacy skills.

Participants randomized to BI will receive a manualized, PowerPoint-guided, CBT- and MIbased intervention during the ED visit. Average ED visits are 3–5 hours, and the BI was developed to be about 20 minutes. As described elsewhere [59], the intervention provides feedback, encourages goal-setting and reflection regarding self-efficacy on peer violence and depressive symptoms, and gives a brief introduction to basic CBT concepts (e.g. the thoughts-feelings-actions triangle, cognitive reappraisal, emotional regulation skills) and their connection to both peer violence and depressive symptoms. All in-ED BIs will be delivered by Bachelor's level-RAs and audio recorded for fidelity. The audio files will be assessed for adherence (based on session content) and competence (based on the Cognitive Therapy Rating Scale [125] and the Motivational Interviewing Treatment Integrity Code [57]). These scales will be used to rate the first ten BI recordings from each RA and 20% of interventions thereafter.

Participants randomized to Text will be briefly (about 3 minutes) oriented to the textmessage system during the ED visit. For participants randomized to receive both interventions, the Text orientation will occur after completing the BI. The automated text message curriculum is tailored by gender and baseline peer violence level, as per text message intervention best practices [92, 95, 126–129]. Text content consists of: 1) Automated daily mood queries; 2) automated daily messages, tailored according to daily mood and baseline characteristics, that sequentially develop cognitive reappraisal, emotional regulation, and self-efficacy skills over the 8-week intervention; and 3) on-demand supportive messages which can be automatically pulled by the participant texting the keywords "stressed", "sad", "angry', or "happy". Text messages will be delivered to participants' own cell phones at the time of day that the participants prefer (outside of school hours), using an algorithm-guided automated text-message delivery system (programmed by GoMo Health, Asbury Park, NJ). For any responses deviating from expected parameters (e.g. 1-5 or an on-demand keyword), participants will receive an automated text-message instructing them to call a 24/7 mental health hotline, talk to a trusted adult, or call 911 in case of emergency. Text responses will be reviewed daily by study staff and address any concerns. All participants will receive a brochure containing information about the thoughts-

feelings-actions triangle as an enhancement of standard care. Essentially, the Control group will only receive the brochure.

In addition to the standard Text curriculum, participants re-randomized into LiveText will also receive an automated message telling them they can get additional "live" support at designated times. The human text interventionist will be available to each participant once weekly, at different times of the day, to interact via text. The interventionist will provide the same basic content as Text in a more intensive and personalized format. Specifically, the interventionist will ask participants about current stressors (e.g. issues with school, relationships, friends/family), and then provide relevant reinforcement of cognitive reappraisal, emotional regulation, and self-efficacy skills drawn from the existing Text curriculum. Criteria to be re-randomized into LiveText are reporting no improvement in mood within 7–14 days of the Text program. No improvement in mood is defined as reporting a daily mood score below a 4 or not responding.

RAs will complete a one-day online MI training followed by instruction in the BI, Text, and LiveText protocols. RAs will also complete an 8-hour in-person training sequence, listening to audio tapes of exemplar sessions from our previous pilot trial, followed by active role plays, until the RAs reach 80% fidelity criterion. Training will be provided by the Principal Investigator, Co-Investigators, and the Project Manager.

Maximum compensation for the entire trial is \$140: \$20 at baseline, \$25 for 2-month followup, \$30 for 4-month follow-up, and \$40 for 8-month follow-up. Participants receiving Text will receive \$10 per month for two months to cover text messaging costs. Participants who alert of us to a change in contact information will additionally receive \$5.

RAs will be extensively trained to recognize and manage participant distress. If a participant reports suicidal ideation or meets criteria for severe depression in the screening/baseline survey or verbally discloses suicidal ideation or abuse in the ED, RAs will immediately notify the attending emergency physician. If mental health or other crises are identified during follow-up surveys or responses in text messages, the RAs will contact the Project Manager and a Co-Investigator who is "on call" to contact the participant, as per the study's crisis management plan. On-call Co-Investigators are licensed psychologists with expertise in adolescent trauma and psychopathology.

#### Measures

The assessment measures used in this study reflect high validity, reliability, and internal consistency and have been successfully used in prior protocols with ED-based research with adolescents [59, 77]. Primary outcomes are physical peer violence as described above using the modified Conflict Tactics Scale 2 (CTS2) [118] and depressive symptoms as described above using the Center for Epidemiologic Studies Depression scale-Revised (CESD-R) [124].

Secondary outcomes include other forms of peer violence. Adolescent dating violence will be assessed using the Conflict in Adolescent Dating Relationships Inventory, physical subset (CADRI), a scale with high validity and reliability for teen dating violence [130]. Relational

violence will be assessed using the Illinois Bully Scale (IBS), a validated self-report scale of bullying victimization and perpetration [131] with two additional questions from the Student School Survey (SSS) to assess cyberbullying [132]. Another secondary outcome is ED visits for peer assaults during the 12 months before and after enrollment, determined through chart reviews of enrolled patients.

**Mechanisms:** Cognitive reappraisal skills will be measured using the Emotional Regulation Questionnaire for Children and Adolescents, cognitive reappraisal subscale (ERQ-CA) which has strong construct and convergent validity [133]. Emotional regulation skills will be measured with the Self-Efficacy Questionnaire for Children, emotional selfefficacy subscale (SEQ-C) [134]. Violence self-efficacy will be measured using the Violence Self-Efficacy Scale [135].

**Potential covariates include:** use of psychological services using questions from the Child and Adolescent Services Assessment [136]; alcohol and other drug use using the short form of the NIDA-modified ASSIST [137]; and the presence of post-traumatic stress symptoms using the Primary Care-PTSD scale [138]. Although this study does not specifically target behavioral activation or social support in the intervention, these entities may be affected by a CBT-based intervention and will therefore measure social support using the Multidimensional Scale of Perceived Social Support (MSPSS) [139, 140]. Finally, sociodemographic variables including race, ethnicity, family poverty, and academic performance will be measured using the National Study on Adolescent Health [141], with additional questions on gender identity from the Gender Identity in U.S. Surveillance group [142].

#### **Analytic strategies**

Sample size was calculated with the goal of achieving sufficient power (>80%) to detect significant main effects of intervention components on peer violence and depressive symptoms, as well as the interaction between them [113, 143, 144]. These calculations accounted for theorized differences between BI, Text, and BI+Text groups, as well as theorized differences between LiveText and standard Text. Sample size was determined using the pwr package in R (cran.r-project.org). To our knowledge, with the exception of our prior pilot study [59], no single published study evaluates the effects of BI+Text on peer violence and depressive symptoms in youth, nor the differences between LiveText and standard Text on these outcomes. Consistent with expert opinion [145, 146], we therefore integrated several sources of evidence to determine an expected effect size for the proposed iDOVE2 study. First, we considered the between group differences on peer violence and depressive symptoms in our pilot (d=0.46 and d=0.37 respectively) [59]. Second, we considered other published trials of brief interventions for peer violence and depression, which includes a study of a brief computerized intervention for violence amongst teens (RR=0.70 at 6 months) [123]. Third, we considered meta-analytic evidence from Hetrick and colleagues on CBT-based adolescent depression prevention, indicating a standardized mean difference of -0.31 at 3 months [147]. Other studies suggest that the difference between LiveText and standard Text will be in the small-medium range (d=0.25) [106–109]. Taken together, given effects at least as large as those presented above, and an alpha level of

0.05, a total sample size of 800 participants would be required in order to have sufficient (80%) power to test the longitudinal effect of the intervention and its components on peer violence and depressive symptoms amongst the intent-to-treat sample, as well as to complete the planned subgroup analyses. This sample will also be more than sufficient (power >80%) to detect medium effect size for moderator ( $\hat{t}=0.15$ ) and mediator outcomes ( $\hat{t}=0.09$ ), even conservatively accounting for up to 20% attrition. All analysis will be conducted on the intent to treat sample, thus including all participants randomized at baseline.

After study recruitment has been completed, as a preliminary step, we will assess potential between-group differences in baseline characteristics (demographics and socio-economic status, including sex and gender; baseline peer violence; baseline depressive symptoms; and other psychosocial factors) using graphical methods and non-parametric and parametric tests as appropriate (e.g., Wilcoxon rank-sum test for skewed data, t-tests for normally distributed continuous data, and chi-squared tests for categorical data). Any variables not balanced by randomization will be controlled for as covariates in subsequent analyses. The distribution of outcome variables will be assessed, and if needed, transformed prior to subsequent analyses.

After study follow-up has been completed, to test the efficacy of the main iDOVE2 components on the primary outcomes (peer violence and depressive symptoms), we will use a series of mixed effects longitudinal regression models, in which the outcome at each follow-up (2, 4, and 8 months) is simultaneously regressed on time, BI, Text, BI x Text, time x BI, time x Text and time x BI x Text, controlling for baseline value of the outcome. Note that each effect estimate will maintain the power associated with all 800 subjects [110–113]. As per best practices for analysis of factorial design, for example, the main effect of the BI component will be tested by comparing the mean of the outcome variable for the 400 subjects who receive BI (i.e., those in "BI only" and "BI+Text") versus the mean of the outcome variable for the 400 subjects who do not receive BI (i.e., those in "Text only" and "Control" groups). Models will include a random intercept to adjust for correlated responses over time within participant and will adjust for any variables not balanced by randomization.

The effects of potentially co-varying symptom complexes (for example, PTSD symptoms) will also be explored on the primary outcomes using a similar analytic approach to that described above. Should outcome variables be skewed, and attempts to transform towards normality unsuccessful, we will examine intervention effects on median outcome values at follow-up adjusting for baseline using a series of quantile regression models. As a secondary analysis, we will examine efficacy on incidence of other forms of peer violence (physical dating violence, bullying, and ED visits for assault), using a longitudinal regression model implemented with Generalized Estimating Equations with robust standard errors. Specifically, we will regress the probability of physical dating violence, bullying, and ED visits for assault, respectively, on time, BI, Text, BI x Text, time x BI, time x Text and time x BI x Text, using a logit link function.

We will examine the efficacy of the embedded adaptive intervention using a similar analytic approach to that described for the first aim. First, we will compare responders (with reduced physical peer violence and reduced depressive symptoms) and non-responders, as well as treatment groups (LiveText vs. standard Text), with respect to baseline variables, including

demographics and baseline values of the outcome. Any variables not balanced by randomization will be treated as covariates in the regression models. Then, using a series of mixed effects regression models (as described above), we will estimate effects of group on outcomes over time. Specifically, a series of mixed effects models will estimate the effects of condition on peer violence and depressive symptoms over time. At the broadest level, we can estimate the LiveText effect by recoding the text effect such that it is a two-level variable (LiveText vs. standard Text). Similar to the recoding for main effects in Aim 1, we will be able to combine all LiveText participants into a single analytic group. Thus, the model will be able to estimate the effects separately for the LiveText and standard Text conditions and, as described above, is adequately powered to do so.

We will examine potential mediators and moderators of the intervention effects on both primary outcomes. Potential moderators include gender, baseline violence, baseline substance use, delinquency, and use of mental health counseling services. These will be explored using a series of regression models similar to those described in Aims 1 and 2. Models will include main effects of intervention component (for Aim 1) and group (for Aim 2), moderator, time and the interactions between them. A variable will be considered a moderator if the interaction between intervention component/group and the moderator is significantly different from zero. Potential mediators of the intervention effects include cognitive reappraisal skills, emotional regulation skills, and self-efficacy, and will be assessed using a series of multiple mediation models with bootstrapped standard errors. For example, mediators of the intervention effect on peer violence at follow-ups will be assessed using a multiple mediation approach, in which all potential mediators are tested simultaneously using a product of coefficients method [144], with bootstrapped standard errors (5000 samples with replacement). We will estimate the path coefficients (a path: effects of intervention components on changes in mediators from baseline to 2 months and b path: effects of changes in the mediators on peer violence at later follow-ups), as well as the indirect effect of intervention (ab path: effect of intervention components on outcomes through the mediators). Interest is in estimating the path coefficients, effect sizes, and confidence intervals. A similar approach will be used for identifying mediators of intervention components on depressive symptoms.

In our prior work, we have retained 85–90% of participants at 12-month follow-up. In the case that a participant drops out of the program, we will attempt to gather follow-up information. If a participant refuses to be contacted or otherwise loses contact with the research staff, we will censor the data at the point of loss. Our analyses will focus on the intent to treat sample, meaning that all participants randomized will be included in the analysis, regardless of the amount of data they contribute. Analysis will use estimating equations and maximum likelihood (ML) approaches to produce estimates of the regression parameters. One advantage of a ML approach is that it makes use of all available data without requiring imputation of missing values. ML estimates have been shown to be consistent when missing data is related only to covariates and observed values of the outcome [148]. As it is possible (although not testable) that missingness may be related to the missing outcome itself (e.g., not random), we will run a sensitivity analysis to explore the robustness of our findings to other assumptions of the missing data.

For data collection, we will specifically use REDCap [117]. The REDCap system provides secure, web-based applications that can be used for research and operational support purposes. It provides an intuitive interface for users to enter data with real-time validation rules (with automated data type and range checks) at the time of entry. It also allows automatic extraction of information from the electronic health record. These systems offer easy data manipulation with audit trails for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap servers are housed in a local data center at Lifespan and information transmission is encrypted. REDCap was developed specifically to conform to HIPAA Security guidelines, and has been extensively used by our research team in prior work.

#### Results

iDOVE2 is funded from March 2018 – February 2023 by the National Institute of Child Health and Human Development (R01 HD093655) with recruitment planned to continue until October 2021. The study is currently registered on ClinicalTrials.gov (ID: NCT03626103). Preliminary findings will be published in journals within one year of study completion, per NIH guidelines.

#### Discussion

#### **Design considerations**

As iDOVE2 was developed, we considered alternatives. Detailed below is our rationale for the present design:

Why past-year peer (non-partner) physical violence? Our work and others' shows that peer physical violence perpetration and victimization are highly overlapping [20, 149]. Moreover, teens with *any* past-year physical fights (not just those with acute injury) are high risk for future injury and depressive symptoms [6, 150, 151]. Our work and others' supports using the ED visit as a moment to screen and intervene with at-risk patients [39–43, 152]. Dating (partner) violence and non-physical violence (bullying/cyberbullying) are related but distinct types of adolescent violence with different underlying mechanisms and consequently, will not be used as inclusion criteria [151, 153–155]. We will, however, measure them at baseline and follow-ups.

Why not an app? Although mobile applications ("apps"), such as games have promise, their utility is limited in our at-risk population. Almost all adolescents (~90%) have mobile phones with text-messaging, versus only ~70% with smartphones (capable of mobile application deployment) [82, 83, 156]. Text-message behavioral interventions have high rates of being read and retained, and higher acceptability and feasibility than app-based health interventions among adolescents [157, 158]. Additionally, the cost of developing an app for both iOS and Android platforms, and keeping it updated, may limit long-term ability to disseminate the intervention.

Why no peer networking? Although social interactions increase engagement in many types of behavioral interventions [159, 160], given the sensitive nature of this intervention's topic, and the potential for violence retaliation among participants, social networking would not be appropriate for this intervention.

Why no parental involvement? From a developmental perspective, adolescent-focused interventions are most appropriate for this age group (13–17 year olds); our prior work supports parental acceptance of in-ED interventions for at-risk youth when content focuses on teens alone [33, 58, 77, 78, 161].

Why "LiveText" instead of a traditional booster, stepped care, or other intervention? For this age group, texting is a more appropriate preventive intervention for adolescents than a phone call or in-person session. Text interactions also have higher acceptability and feasibility, and may have higher efficacy than mixed-modality preventive interventions [162]. A structured text interaction, reinforcing Text and BI content, is strongly supported by the previously articulated needs of iDOVE pilot participants [77, 78, 80], as well as others' studies [100–102].

Why deliver the adaptive intervention only to Text participants? Daily assessments of mood may, in and of themselves, influence ability to identify and regulate emotions [163, 164]. Without this daily Text assessment of non-Text participants, we cannot reliably identify whether non-Text participants show signs of "no improvement," and could not reliably re-randomize them.

How does iDOVE2 relate to in-person counseling? The iDOVE2 intervention is purposefully designed as a supplement to, rather than substitute for, usual care. It is explicitly a preventive, not therapeutic, intervention. We will conduct exploratory analyses examining whether the intervention increases use of in-person counseling, and whether use of in-person treatment moderates effect.

#### Impact and future directions

The development and validation of technology-augmented preventive interventions is still in its infancy. Although text-message interventions are highly accessible to adolescents, a potential challenge is sustainability, especially when patients are recruited from the ED, where patients may have higher rates of changing their number or losing a cell phone plan [165]. Additionally, given the large cumulative burden of traumatic life events and mental health problems in this population, a stepped-care intervention may be more appropriate than simpler, "one-size-fits-all" interventions [166, 167]. This study therefore has important implications for the progress of the greater field of mobile health interventions, as well as for adolescent violence and depression prevention in general.

At the completion of this study, we hope to have defined: 1) The efficacy of the iDOVE2 intervention components, 2) the relative efficacy of the LiveText intervention with human counselors, and 3) mediators and moderators of intervention effect. Depending on study results, we will either have a simple, validated intervention addressing a major adolescent public health issue, or scientifically important information about how and why the individual

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iDOVE2 intervention components were not successful. If the study results are positive, the expected next step would be an effectiveness trial. If the study results show a null effect of all intervention components, the data will nonetheless inform future intervention development efforts. This study therefore represents an important contribution to the literature on violence prevention for at-risk youth.

This proposal has high clinical and public health significance, testing the efficacy of an intervention with potentially high scalability, acceptability, and impact. It is innovative in determining which, if any, intervention components have efficacy, and for whom. If all or part of the intervention components show efficacy, the next step would be to determine effectiveness and ease of dissemination[98]. Regardless of efficacy, this will advance the NIH-wide objectives of improved understanding of personalized intervention mechanisms [168, 169]. Accessible, easily disseminable interventions for these at-risk teens are a public health imperative to prevent future violence and related disorders [6, 17–25].

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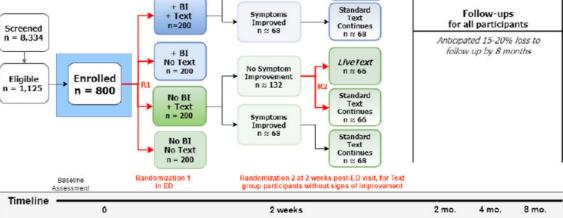
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LiveText n 🕫 66 No Symptom Standard Text Improvement n ≈ 132 Continue n ≈ 66

# Follow-ups for all participants



+ BI

+ Text n=200

