Feasibility Trial of a Single Session of Crisis Response Planning for Youth at High Risk for Suicide

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PRINCIPAL INVESTIGATOR:

STEPHANIE GORKA, PHD

THE OHIO STATE UNIVERSITY, COLLEGE OF MEDICINE

DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL HEALTH

CO-INVESTIGATORS:

LAUREN KHAZEM, PHD

THE OHIO STATE UNIVERSITY, COLLEGE OF MEDICINE

DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL HEALTH

HEATHER WASTLER, PHD

THE OHIO STATE UNIVERSITY, COLLEGE OF MEDICINE

DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL HEALTH

STUDY LOCATION(S):

THE OHIO STATE UNIVERSITY

INSTITUTE FOR BEHAVIORAL MEDICINE RESEARCH

460 MEDICAL CENTER DRIVE

COLUMBUS, OH 43210

LIST OF ABBREVIATIONS

AE	Adverse Event
ASQ	Ask Suicide Screening Question
CITI	Citi.gov Human subjects training
CO-I	Co-Investigator
CRP	Crisis Response Planning
DIAMOND-KID	The Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders Child and Adolescent Version
EMA	Ecological momentary assessment
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
OSU	Ohio State University
OSUWMC	Ohio State University Wexner Medical Center
PHI	Protected Health Information
PI	Principal Investigator
SAE	Serious Adverse Event
TAU	Treatment as Usual

1.0 Background/Scientific Rationale

Suicide is a serious public health issue and a common cause of death. In the US, the prevalence of suicide has risen in the last two decades, particularly amongst youth[1]. Recent reports reveal that 10% of high school students have made a suicide attempt and 22% have considered suicide[2]. There is an urgent need for better access to suicide prevention and this need is reflected in the national prioritized agenda for suicide research.

Effective multi-session outpatient therapies exist for suicide prevention; however, less than one-third of youth who experience suicidal thoughts engage in regular treatment[3]. Accordingly, there has been a shift in focus towards ultra-brief risk management strategies that are highly transportable and easily scalable to reach more individuals in need. Along these lines, recent studies led by our group have shown that a single session of crisis response planning (CRP) reduces suicidal behavior by up to 76%, while also rapidly reducing the severity of suicidal ideation and number of psychiatric inpatient days in high-risk populations[4].

During CRP, therapists and individuals collaboratively develop a personalized plan for managing acute periods of intense affective arousal to mitigate risk during real-world crises. Most prior studies investigating the effectiveness of CRP have been conducted in adults, such as military personnel[4-6]. Prior studies have also largely involved in-person, face-to-face administration of CRP. However, youth experience significant barriers to in-person treatment including financial costs, transportation issues, stigma/shame, concern for lack of anonymity, and difficulty navigating the mental health treatment system[7]. Novel virtual care technologies offer accessible and cost-effective intervention delivery options that have shown to be effective in promoting health in youth[8-11]. There is an untapped potential for virtual approaches to engage high-risk youth who typically do not receive treatment but could significantly benefit. Thus, the primary goal of this study is to adapt and pilot test a virtual chat-based CRP protocol for youth at high-risk for suicide.

CRP will be adapted by utilizing a virtual chat-based platform. Given that CRP has never been tested in youth, we will use a 3-arm design to disentangle the effects of CRP from the virtual platform. A total of 90 youth, ages 14-18, who screen positive on the Ask Suicide-Screening Questions (ASQ) will complete a study screen and 2-weeks of daily ecological momentary assessment (EMA) designed to capture baseline mood and suicidal thoughts and behaviors. The EMA will also measure real-time use of various emotion regulation strategies. Participants will then be randomized to one of three treatment arms: 1) in-person CRP; 2) virtual CRP; or 3) virtual crisis risk management (control). Changes in mood, suicidality, and behavior will be assessed using an additional 2 weeks of daily EMA. At the end of the protocol 10 individuals per treatment arm (30 in total) will be randomized to complete an in-depth interview to assess feasibility and acceptability of the intervention and the research protocol. Questions rooted in a theoretically driven implementation science framework will be used to identify intervention-related facilitators and barriers to guide adaptation and implementation of the intervention. The Specific Aims are as follows:

2.0 Objectives/Aims

Aim 1. Assess the feasibility and acceptability of traditional and virtual CRP in adolescents. Hypothesis 1: Virtual CRP will be rated as more feasible and acceptable compared with traditional CRP and the control intervention.
Aim 2. **Examine whether a single session of CRP changes suicide risk in adolescents.** Hypothesis 2: Both versions of CRP will be associated with changes in frequency and severity of suicidal ideation and behavior compared with the control. Virtual CRP will be equally as effective as traditional CRP at reducing suicide risk suggesting virtual CRP is a promising scalable intervention adaptation.
Exploratory. **Identify mechanisms of CRP treatment success.** Explore common mechanisms related to CRP treatment success, including treatment-related increases in emotion regulation capacity, by capturing complementary constructs at the screen and via EMA. This exploratory aim will shed light on the developmental specificity of identified processes to guide future mechanistic adaptations.

Study duration. Participants will remain enrolled in the study for 5-6 weeks which includes the virtual screening session, two weeks of pre-intervention EMA, the single-treatment intervention, two weeks of post-intervention EMA, and online follow-up session.

3.0 Eligibility

3.1 Inclusion Criteria

Participants will be required to be: (a) 14-18 years old at the time of assent/consent; (b) their legal guardian is willing and able to give parental permission (if under 18 years old), (c) able to give informed assent/consent (as applicable); and (d) endorse current desires to make a suicide attempt as defined as answering “yes” to item #3 on the Ask Suicide Screening Question (ASQ) tool.

3.2 Exclusion Criteria

Exclusion criteria will include: (a) factors that would interfere with data interpretation including serious medical or neurologic conditions; (b) current severe substance use disorder; (c) lack of access to a personal smartphone and; (d) lack of fluency in English.

3.3 Excluded or Vulnerable Populations

No individuals will be allowed to participate in the study if they are less than 14 years of age or older than 18 years of age. This age range was chosen to focus on high-risk high-school aged-youth.

4.0 Subject Enrollment

- We propose to recruit 90 youth who are acutely suicidal from Nationwide Children's Hospital (NCH), the Ohio State University Wexner Medical Center (OSUWMC) system, local high schools, and the surrounding community through word-of-mouth referrals, posted flyers, and PeachJar. PeachJar is a service through Columbus City Schools that sends out flyers via email to parents of kids in the school system. No information about parents of children will be provided to research staff; the flyer will be shared through PeachJar administrators. For those who are recruited through OSUWMC and NCH, no medical records will be reviewed.
- Participants will be recruited through advertisements and social media. We will also use print ads and word-of-mouth referrals.
- Advertisements will include a QR code that when scanned will direct interested individuals to the study's online Recruitment Survey on REDCap. If the individual chooses, they will complete the online survey that assesses for initial eligibility criteria.
- Study staff will determine potential participants' eligibility for the research.
- If an individual meets this initial eligibility criteria on the survey, trained clinical research staff or investigators will call the individual and complete a phone screen to further assess eligibility for the research study.
- Following the completion of the phone screen, potentially eligible individuals will be scheduled for a virtual screening session and have a copy of the parental permission and assent forms or consent form (dependent upon age) emailed to the interested individual and legal guardian (if under 18 years old).
- If the individual is under 18 years old, at the beginning of the virtual screening session, participants and their legal guardian will provide informed assent and parental permission. If the individual is 18, a legal guardian will not be present and consent will be obtained. Specifically, once the procedures are explained to them in detail, participants will be given ample time to read the parental permission and assent forms or consent form, formulate questions, and ponder the responses. Participants will have time between initial contact and the scheduled screening session to discuss participation with people of their choice. We will emphasize to participants and their legal guardian (if under 18) the voluntary nature of their participation in the study. Participants will also be told that they are free to drop out of the study at any time for any reason.

  Online Screening Sessions: For individuals under 18 years old, parental permission and assent will be collected via REDCap software. The authenticity requirements involve Remote Signing, Username & Password. During the phone screen, if participants are found to be eligible, they will establish a password with study staff. The study staff will enter the passcode in the participant's REDCap record. Participants and their legal guardian are provided a link to sign the assent and parental permission forms in REDCap. Participants and their legal guardians are then asked for the password, which is cross referenced with the password

already on file in the REDCap project. The completed parental permission and assent forms will be downloaded and stored in the PI's laboratory in a locked cabinet and locked office. A copy of the signed parental permission and assent forms are provided by REDCap.

If the individual is 18, the procedures above will be followed except that a legal guardian will not be present and only consent will be obtained.

- After obtaining informed consent or parental permission and assent, a trained staff member will perform a clinical assessment of suicidal thoughts and safety, treatment history, and administer a small battery of self-report questionnaires. Initial eligibility for the research will be documented in the research record. Screening visit data from participants who consented to participate in the study, but are not eligible, will be saved. Final determination of participant eligibility will be made by the PI or the PI in consultation with research staff.
- Eligible participants will download the Metricwire app at the end of the screening session. The next day, participant will complete clinical assessments four times a day for 14 days via smartphone technology.
- Participants will then be randomized to either in-person CRP, virtual CRP, or standard crisis risk management (the control intervention). All treatments take approximately 30-minutes to 1-hour.
- Immediately after the intervention, participants will continue to compete clinical assessments four times a day for 14 days via the same smartphone technology.
- At the end of the 14-day post-intervention window, participants will complete a short battery of questionnaires and a brief clinical assessment of suicidal thoughts and safety, conducted by clinically trained research staff. 10 participants from each study arm (a total of 30 participants) will also be randomized to complete a brief qualitative interview that assess the feasibility and accessibility of the corresponding treatment interventions.
- Participants not engaged in mental health treatment services will be provided our mental health services referral list.
- Participants who turn 18 while enrolled in the study will be required to sign the most up-to-date consent form in order to continue participating in the study. If the participant does not sign the consent form after turning 18, they will be withdrawn from the study.
- Termination Criteria: Participants may be terminated for any of the following: (a) completion of study; (b) participant request to exit or withdraw consent; (c) development of a systemic, medical, neurologic, or psychiatric illness requiring treatment that would exclude participation; and (d) non-compliance with study protocol requirements.

5.0 Study Design and Procedures

Participants. A total of 90 individuals with active suicidal thoughts and/or urges will be recruited. In order to capture individuals at high risk for suicide, participants will be required to endorse current suicidal ideation and intent, defined as answer "yes" to question 3 on the Ask Suicide-Screening Questions Survey (ASQ)[12]. Exclusion criteria are listed above.

Recruitment. Participants will be recruited from the community and the OSUWMC and NCH. We will use a wide variety of recruitment methods including online and in-person advertisements and word-of-mouth referrals. More specifically, collaborators at NCH clinics will distribute approved flyers. For those who are recruited through OSUWMC and NCH, no medical records will be reviewed.

Entry Assessments. Inclusion/exclusion criteria. Potential participants will be screened using a battery of questionnaires and a brief clinical interview that assesses for treatment history, suicidal thoughts, and safety. Exclusionary criteria will be those that would interfere with data interpretation (e.g., serious medical or neurologic conditions, current severe substance use disorder, lack of access to a personal smartphone, and lack of fluency in English). If interested participants meet eligibility criteria and provide parental permission and assent, they will be enrolled in the study.

Study Overview. This study is a mixed methods randomized control trial combining clinical interviewing, EMA data collection, brief one session intervention, and qualitative interviews (Fig. 1). Participants will first complete a virtual screening visit that includes collecting informed consent or parental permission and assent, assessment of study eligibility, clinical interviews, and questionnaires. For individuals under 18 years old, after a legal guardian provides parental permission, they will not be present during study activities and not have access to the participant's data (unless limits to confidentiality apply).

The following day after the screening visit, the 2-week pre-treatment ecological momentary assessment (EMA) data burst will begin. EMA prompts will be delivered four times per day during non-school hours and capture mood, suicidal thoughts and urges, behavior, and volitional emotion regulation strategies. The timing of these surveys will be set based on the participant's schedule. However, the total range of time that EMA prompts will be sent is between 7am to 10pm. Each prompt will include an option to request to speak to study staff. Information regarding if a wellness check was completed, changes in suicide risk, and adverse events will be documented by study staff as applicable.

At the end of the 2 weeks of pre-intervention EMA, participants will be randomized to one of three treatment arms: 1) traditional, in-person, Crisis Response Planning (CRP); 2) virtual CRP; or 3) virtual crisis risk management (treatment as usual [TAU]/control). All interventions will be a single, 30 minute-1-hour, session. The following day after the intervention, the post-treatment EMA data burst will begin. The prompt structure and items will be identical to the pre-treatment protocol, though new items capturing real-world use of the intervention plan (all 3 arms) will be included. At the end of the post-intervention EMA protocol, participants will complete follow-up questionnaires, a clinical assessment of suicidal thoughts and safety, and a qualitative interview (if randomized).

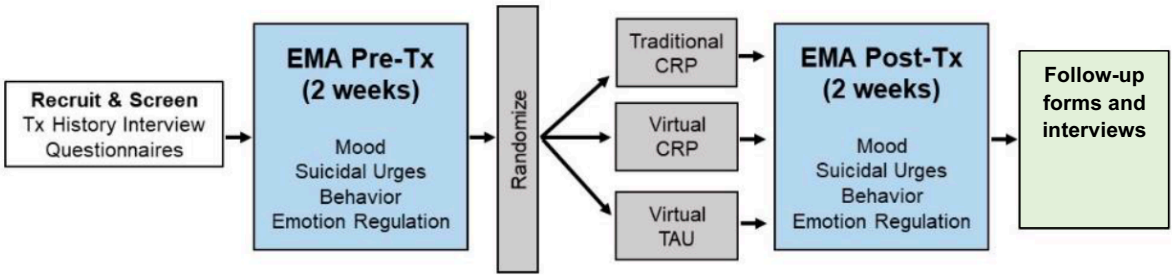

Figure1.

Initial Clinical Interview Assessments. At the screening session, trained study staff will conduct the following clinical interviews: Columbia Suicide Severity Rating Scale (C-SSRS)[13], Antidepressant Treatment History Form (ATHF), Psychiatric Treatment History Form, and Lethality Rating Scale (LRS; *this form will only be completed if participants report history of past suicide attempt*)[14]. If alcohol and substance use is reported on self-report forms, the Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND)[15] alcohol use and substance use disorder modules will be completed to assess for exclusionary criteria.

Initial Self-Report Assessments. At the screening visit, participants will complete the following self-report measures (see Table 1):

Baseline Demographic and Health Measures: Contact Information Form, NIH GUID Information Form, Demographic Questionnaire, General Health Questionnaire, Pubertal Development Scale (PDS)[16], and Treatment Preference Questionnaire.

Baseline Measures of Psychiatric Symptoms and Personality: Regulation of Emotion Systems Survey[17], Beck Depression Inventory (BDI-II)[18], PHQ-9 modified for adolescents[19], Beck Anxiety Inventory (BAI)[20], Anxiety Sensitivity Index (ASI)-3[21], Beck Hopelessness Scale for Children (BHS-C)[22], Pediatric Loneliness Scale, Short UPPS-P Impulsive Behavior Scale (SUPPS-P)[23], Timeline Follow-Back (TLFB; past 30 days)[24], Alcohol Use Disorders Identification Test (AUDIT)[25], Drug Abuse Screening Test – Adolescent Version (DAST-A)[26], Cannabis Use Disorder Identification Test (CUDIT)[27], Snaith-Hamilton Pleasure Scale (SHAPS)[28], the Personality Inventory for DSM-5 Faceted Brief Form (PID-5)[29], Intolerance of Uncertainty for Children (IUS-C)[30], The Child PTSD Symptom Scale (CPSS-5) self-report[31], Insomnia Severity Index (ISI)[32], Peer Relationships Questionnaire[33], and Family Relationships Questionnaire[34].

Baseline Measures of Suicidality: ASQ[12], Self-Injurious Thoughts and Behaviors Interview–Revised Self- Report (SITBI-R)[35], Beck's Scale for Suicidal Ideation (SSI – past week)[36], and Suicide Cognitions Scale –Revised (SCS)[37].

Randomization Procedures. At the end of the pre-treatment EMA, we will use stratified block randomization to assign youth to one of the three treatment interventions. Biological sex and history of suicide attempts will be our strata to ensure balance across the groups, consistent with adult CRP studies. Suicide attempt history has three levels: no prior attempts, one prior attempt, and 2+ prior attempts as data indicate that individuals with multiple suicide attempts have higher levels of pathology compared to individuals with single attempts and no attempts[38]. A computerized randomization scheme will be used to minimize the potential for bias in condition assignment. The same randomization procedure will be utilized to assigned 10 participants from each treatment arm to complete the qualitative interview at the end of the study.

Treatment Conditions. Descriptions of CRP (in-person and virtual) and the control condition are described and summarized in Table 2 below. We will obtain parental permission and assent at the screen to record intervention sessions. All interventions will be reviewed, scored, and discussed during clinical supervision.

Component	Description	CRP	Control
1. Suicide Risk Assessment Interview	Semi-structured interview of risk factors, suicide ideation, and history of suicide attempts		X
2. Narrative Suicide Risk Assessment	Therapist invites participant to share the events, symptoms, and contextual factors leading up to and surrounding recent suicidal crisis	X	
3. Supportive Listening	Therapist expresses concern and support	X	X
4. Warning Signs	Identify clear "warning signs" that individual is in a crisis	X	
5. Self-management Skills	Collaboratively identify "some things you can do on your own that will help to distract you or to feel less stressed"	X	
6. Reasons for Living	Identify "positive things in in our lives, or what is worth living for"; "tell me a story about these reasons for living"	X	
7. Social Support	Identify those who have "helped you during times of stress in the past, and who you feel comfortable contacting now when in crisis"	X	
8. Self-Guided Safety Plan	Complete a standard safety plan worksheet independently		X
9. Crisis Resources	Therapist provides phone numbers of professional sources of help	X	X
10. Referral to treatment	Therapist assess treatment plan and makes appropriate referrals to professional resources	X	X

Table 2.

CRP Intervention. Participants can be assigned to either in-person (traditional) CRP or virtual (chat-based) CRP. The protocols will be nearly identical with appropriate technology-related adaptions (see below). The CRP session will last 30 minutes-1-hour. Consistent with the published protocol[39,40] the session will include the following standard suicide intervention strategies: supportive listening, provision of crisis resources, and referral to a mental health professional (if not already established). The CRP active component involves a collaborative process in which the therapist invites the individual to share the events, symptoms, and contextual factors leading up to and surrounding the participant's recent suicidal crisis. Next, the individual and therapist identify the participant's personal warning signs for an emotional crisis, self-management coping skills, reasons for living, and sources of social support. These components are written, by the participant on an index card (in-person) or virtual whiteboard (virtual). The CRP document serves as a concrete reference for individuals in the real-world.

Virtual CRP Adaptations. The virtual CRP protocol will include all elements of the evidence-based, traditional CRP. Dialog between the therapist and participant will transpire via the Doxy.me chat window (without video). The dialog will be semi-structured

and include pre-developed text/prompts and an overarching framework for chat-based interaction. The therapist will lead the participant through the CRP development using the Doxy.me whiteboard feature that allows for participants to simultaneously view an editable document. At the end of the session, this document can be saved to the participant's computer and/or phone for future reference.

Virtual Crisis Risk Management (Control). Standard crisis risk management will serve as the control condition, similar to PI Gorka's R01 (2021H0039). The virtual intervention will also take place via Doxy.me. The session will last 30-minutes - 1-hour and include several of the basic risk management components listed above (Table 2). Following a semi-structured suicide risk assessment (i.e., C-SSRS[13]), participants will be asked to complete a self-guided safety plan worksheet independently (The Stanley-Brown Safety Plan[41]). The Stanley-Brown Safety Plan was previously identified as a "best practice" by the Suicide Prevention Resource Center/American Foundation for Suicide Prevention Best Practices Registry for Suicide Prevention[42] and has been utilized across clinical suicide studies[43].

The worksheet will be shared via Doxy.me and briefly reviewed by the therapist. The control intervention meets the expectations for standard risk management, though by design it lacks the engaging and collaborative aspects of CRP.

Doxy.me is a widely used telemedicine platform that has been used across the medical field and in research studies. The platform is HIPAA, General Data Protection Regulation (GDPR), The Personal Information Protection and Electronic Documents Act (PIPEDA), and Health Information Technology for Economic and Clinical Health (HITECH) compliant[44].

Post-Treatment EMA. The day following the intervention, the 14-day post-treatment EMA data burst will begin. The EMA items and structure will be almost identical to the pre-treatment protocol outlined above. However, several additional items will be included assessing how frequently the CRP (and control plan) is being used and its perceived effectiveness. Participants will rate on a 10-point scale to what extent they engaged in specific parts of their safety plan and how effective the plan was at changing their emotional experience. Similar to the pre-treatment EMA, each prompt will include an option to request to speak to study staff. Information regarding if a wellness check was completed, changes in suicide risk, and adverse events will be documented by study staff as applicable.

Post-Treatment Follow-up Session. At the end of the EMA period, participants will complete a clinical assessment of suicidal thoughts and safety (C-SSRS). If randomized, participants will also complete a virtual qualitative interview that will be recorded. Topics to be assessed during the qualitative interview will include comfort of use, clarity of the protocol, likelihood of use, and perceived usefulness. In addition, participants will complete a battery of questionnaires to measure the acceptability and feasibility of the interventions as well as change in behavior and psychiatric symptoms:

Follow-up Self-Report Questionnaires: Beck SSI-past week, BDI, BHS-C, ASQ, SCS, Pediatric Loneliness Scale, PHQ-A, BAI, ASI-3, IUS-C,

Regulation of Emotion Systems Survey, ISI, TFLB, AUDIT, DAST-A, CUDIT, System Usability Scale (SUS; for those who complete virtual treatments only)[45], CRP Form (for those who complete CRP only), Client Satisfaction Questionnaire (CSQ-8)[46], and Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) Combined Form[47].

SAFETY PLAN. If a participant reports severe suicide ideation during a survey, an automated email alert will be sent to the research team via email and text message. Severe suicide ideation is defined as a score of 7 or higher on item 26 ("How strong is your intention to kill yourself right now?") where the possible range is 0-10. A score of 8 or higher represents a value that is approximately two standard deviations above the mean suicide ideation score reported in a community sample of suicidal individuals and approximately half of a standard deviation above the mean suicide ideation score reported in a psychiatric inpatient sample. These procedures have been used in prior studies by PI Gorka. When an automated alert is received by the research team, a member of the research team will contact the participant to conduct a risk assessment to clarify the nature of risk using the same procedures outlined above, review the participant's safety plan, and determine if the participant is at imminent risk to harm himself/herself, thereby warranting further evaluation for possible hospitalization and/or activation of emergency services (e.g., wellness check by law enforcement).

Self-report Data Processing. All measures will be self-entered, checked for discrepancies, and cleaned. Analyses will assume that 'missingness' occurred at random, with data imputed when necessary.

6.0 Expected Risks/Benefits

Based on prior studies by PI Gorka, a majority of actively suicidal participants are anticipated to benefit from the crisis response planning and crisis risk management interventions provided as part of the study.

6.1 Diagnostic/Assessment/Therapy Audio Recordings Procedures and Breach of Confidentiality: The diagnostic interviews (and questionnaires) may be time consuming and boring to some individuals. However, these are necessary to determine eligibility for the study and test hypotheses. In addition, questions about suicidal behavior, substance use, and audio recordings of therapy sessions may be considered sensitive by some participants. The collection of such data poses a potential risk of loss of confidentiality around sensitive information such as psychiatric status, history of substance use, etc. Information pertaining to psychiatric treatment or medical care will be protected in accordance with 42 CFR Part 2 and HIPAA regulations as applicable. Participants will be informed in the parental permission and assent documents that confidentiality will be limited in cases where the participant reveals intentions to harm themselves or others, and

the investigator feels that the proper authorities may need to be notified to prevent the occurrence of harm to the participant, or others (see additional details below). Confidentiality may also be broken in instances of reported ongoing child or elder abuse, as per mandated reporting guidelines. Interviews will be conducted by trained study staff who will maintain confidentiality and all data from interviews and questionnaires will be assigned an ID number to conceal the identity of the participant. Loss of confidentiality is also possible during the online assessments, particularly if participants complete these tasks at home, near family members and/or roommates. Participants will be informed of this risk during the informed assent document and prior to all online assessments.

6.2 High-Risk Management Procedures: The PI and Co-Is have independently conducted multiple studies with acutely suicidal individuals and have considerable experience managing suicide risk. If a research staff member becomes aware that the participant is at imminent risk to harm themselves, the following questions will be asked to clarify the nature of risk (and to identify those at imminent risk requiring consideration for hospitalization): (1) Do you have a plan for killing yourself and do you intend to act on the plan?; (2) Do you have a desire to kill yourself that you believe you might act on?; (3) Have you already taken steps to act on your plan? If so, what steps have you taken? Once a participant is identified as potentially imminent risk, the researcher will conduct a more thorough assessment to include possible evaluation by an investigator, all of whom are clinical psychologists and psychiatrists, for possible hospitalization. In the instance where a participant is determined to be in imminent risk to harm themselves, the participant's legal guardian will be immediately notified and referred to their nearest emergency department. Our research lab is located one block away from OSU psychiatry inpatient and outpatient mental health facilities. If a participant is determined to be in imminent risk during an in-person visit, their legal guardian will be immediately notified, and research staff will escort the participant to one of these facilities for further evaluation.

7.0 Data Collection and Management Procedures

- Sources of material from human participants include: (a) informed parental permission and assent or consent, (b) screen form, (c) diagnostic interviews, (d) self-report questionnaires, (e) therapy session recordings.
- Each participant is given a unique number and there is a password-protected master key database separate from study data linking the participant with the code only accessible to OSU research team members. This file is a password-protected master key database, which links the participant with unique participant codes; it is stored on the password-protected server, described above, and kept separate from study data. The information in this file could be used to *indirectly* identify participants. The record linking participants to the research codes will be destroyed 6 years after completion of the study, thereby anonymizing the data.

- Therapy session recordings will be stored onto the audio recorder's internal memory. At the start of each interview, research staff will inform participants that the recorder is being turned on. After turning the recorder on, research staff will verbally notify the participant and ask him or her to verbally confirm that they are aware of the recorder being turned on. At the end of each workday, staff members will upload audio recordings to the encrypted, secured server within the PIs laboratory. Once the audio files have been successfully uploaded, staff members will delete the audio files from the audio recorder's internal memory. Staff members will confirm the successful deletion of audio files from the recorder's internal memory via visual inspection of the digital file list, which is displayed on a screen located on the front of the recorder. Audio recordings can then be accessed for review by the investigators via the same security procedures that are in place for accessing research data. Audio recorders will be locked when not in use using the same procedures required for security and storage of PHI.
- All research materials from participants will be labeled with the unique participant code (not participant name).
- Paper forms with the participant code will be kept in a locked cabinet where only official study staff has access.
- Only official OSU study staff have access to the data. If any member of the research study leaves, his or her access to the network and all files will be removed immediately, thereby terminating access to this file and other files associated with the study.

8.0 Data and Safety Monitoring

- We have developed a formal data safety and monitoring plan to ensure the ongoing safety of participants (as well as the integrity of the study). The plan involves weekly meetings that will be used to communicate any concerns or issues with safety, confidentiality, or progress.
- Weekly meetings of the research staff of this study will be conducted that will include review of accrual, consenting procedures, protocol adherence, adverse events, and quality control of all data obtained from the study in the previous week. All changes in protocol design will be reviewed by the OSU IRB before such changes in protocol design take place.
- All adverse events (AE) occurring during the study will be reported and reviewed by the PI. All AEs will be reviewed and as necessary, medically treated or referred to medical treatment as determined by the PI. If deemed necessary by the PI, a participant may be withdrawn from the study. AEs will be evaluated for serious adverse event (SAE) criteria. If an SAE should occur, it will be reported to the IRB. The initial report will be followed by a complete SAE report, sent to the IRB. If a participant withdraws from the study or the PI discontinues a participant's participation due to a SAE, the participant will receive follow-up medical care as necessary. Follow-up care will continue until the participant no longer requires hospitalization, the condition is stabilized with no future change expected, or the problem is determined to be unrelated to the study. The outcome of SAEs will be reported to the IRB.

9.0 Statistical Considerations and Sample

Aim 1. Assess the feasibility and acceptability of CRP in adolescents. We hypothesize that virtual CRP will be rated as more feasible and acceptable than traditional CRP and virtual TAU. To examine this hypothesis, we will address each of the questions listed in Table 3 (above). We will compare the 3 interventions on our measures of acceptability and feasibility including SUS, CSQ-8, IAM, and AIM scores; intervention usefulness ratings; enrollment and completion reports; and qualitative interview themes. We will further examine whether virtual CRP achieves well-defined benchmarks such as SUS scores ≥8064, CSQ-8 scores ≥2765, and IAM scores ≥1660. These data will be used to update and modify the virtual chat-based CRP protocol for future testing.

Aim 2. Examine whether CRP reduces suicide risk in adolescents. We hypothesize that both versions of CRP will be associated with greater change in frequency and severity of suicidal ideation compared with the control intervention. Virtual CRP will be equally as effective as traditional CRP at reducing suicide risk suggesting virtual CRP is a promising scalable intervention adaptation. To test our hypotheses, we will use flexible multilevel mixed models with treatment arm, time (pre vs. post), and the arm by time interaction. Suicidal ideation defined as Beck SSI total score and EMA suicidal ideation severity scores will be separate dependent variables. We anticipate an arm x time interaction that will be followed up using planned comparisons.

Exploratory. **Identify potential mechanisms of CRP treatment success.** We hypothesize that CRP increases capacity for volitional emotion regulation. We will measure pre- and post-treatment emotion regulation via: 1) self-report questionnaire; 2) dynamic shifts in affect (EMA); and 3) engagement in emotion regulation strategies (EMA). We will use a series of multilevel mixed models specifying treatment arm, time, and time by treatment arm factors on our emotion regulation outcomes.

Power Analysis and Sample Size Determination. Our sample size was selected pragmatically to identify issues related to study acceptability and feasibility. There is ample evidence to suggest that a sample size of 90 will achieve saturation on qualitative interviews and feasibility and acceptability outcomes (i.e., meaningful new themes are unlikely to emerge beyond this size). Our prelim data in adults (R01 sample) suggests that CRP is associated with a large reduction in severity of suicidal ideation (ηG2=.455), which would suggest sufficient power (>75%) for the present aims though the effects of this CRP protocol have never been examined in adolescents.

10.0 Regulatory Requirements

10.1 Informed Parental Permission, Assent, and Consent

Individuals 14-17 years old:

- During the initial meeting with study staff, the nature of the research project will be described to all potential participants and their legal guardian. A written summary, in lay terms, of the research project will be provided to the participants in the written informed parental permission and assent documents that the participants and legal guardians will review. The

documents will inform the participants of the voluntary nature of the study procedures, the purpose of the study, the procedures to be followed, the duration of the study, the risks associated with data collection, as well as the potential benefits to the community at large.

- We will specifically request that the legal guardian attend the first virtual lab visit, or prior to study participation if the legal guardian's schedule does not allow, to discuss with study staff the procedures with the opportunity to ask questions. After providing informed parental permission and assent, guardians will not be present during any study activities. Legal guardians will be informed that they will not have access to any of the participant's data.

Individuals 18 years old:

- During the initial meeting with study staff, the nature of the research project will be described to all potential participants. A written summary, in lay terms, of the research project will be provided to the participants in the written informed consent documents that the participant will review. The documents will inform the participants of the voluntary nature of the study procedures, the purpose of the study, the procedures to be followed, the duration of the study, the risks associated with data collection, as well as the potential benefits to the community at large.

All participants:

- Participants will also be informed of limits of confidentiality and mandated reporting guidelines. Of note, only individuals who are medically and psychiatrically stable will be referred and consented to participate in the study. Inability to provide informed consent or parental permission and assent is exclusionary. Informed consent, parental permission, and assent will be obtained by the PI or designated research staff and the participant will receive a copy of the signed consent, parental permission, and assent forms. Participants will be informed that they can discontinue participation at any time without penalty.
- Each member of the research team will complete the HIPAA and CITI human subjects trainings and will be trained in the research protocol and will have reviewed the informed consent document themselves.
- The informed consent, parental permission, and assent documents will be stored in a separate locked file cabinet from any other research files in a locked office. Only research staff on this specific research study will have access to the informed consent/assent documents.

10.2 Subject Confidentiality

- All data from participants will be marked with a research identifier number only and kept in locked cabinets. No data will have participant names on them, except for consent forms and payment forms, which will be stored separately from other questionnaires in a locked file cabinet. Paper records will be kept in locked file drawers in a locked room, to which only authorized

research personnel have access. Confidentiality of participant records is assured by assigning each participant with a research identifier number/code, and such data are stored in computer files (except for a single tracking file) without reference to name, or any other type of personally identifiable information (e.g., birth date, etc.). Data that may be reported in scientific journals will not include any information that identifies any person as a participant in this study.

- Location and storage of computer files: These files will be stored on a user-name and password protected local workstation.
- Single tracking file: This file is a password-protected master key database, which links the participant with unique participant codes; it is stored on the password-protected server, described above, and kept separate from study data. The information in this file could be used to *indirectly* identify participants. Only research study personnel directly involved with the project will have access to this file. If any member of the research study leaves, his or her access to the network will be removed immediately, thereby terminating access to this file and other files associated with the study. The record linking participants to the research codes will be destroyed 6 years after study completion, thereby anonymizing the data.
- **Limits of Confidentiality on Clinical Information.** Confidentiality is limited, however, when there is danger to oneself or others, or reports of child and elder abuse. If the participant is discovered to be acutely homicidal or actively suicidal during the evaluation period PI Gorka will be notified and an appropriate clinical decision for emergency psychiatric evaluation will be made, including an evaluation of the need for referral to the nearest emergency room for potential psychiatric hospitalization. Detailed information on the handling of suicide ideation is described above. If the participant discloses that a child is the subject of physical or sexual abuse, appropriate steps will be taken to ensure safety of the child, including contacting Department of Children and Family Services (DCFS). Participants will be made explicitly aware of mandated reporting guidelines prior to signing the assent or consent form. If it is determined that filing a DCFS report is necessary, the PI will be immediately notified. The PI (a clinical psychologist) will inform the participant of the report and assess expectations and reactions. The PI will provide acute clinical counseling, if warranted, and make appropriate clinical referrals.
- No PHI will be collected in this study. Identifying information includes the participants name and contact information (phone number, email address, home address). The reasons that we are collecting this information include: the participants name for the informed assent document, phone number and email address to contact them during the study period. No information from the participants' medical records will be recorded for research purposes.

10.3 Unanticipated Problems

- Any unanticipated problems (its occurrence, frequency or severity is new or greater than previously known or as expected based on participant

characteristics, including natural progression of disease). They are always unanticipated by definition and will be reported to the IRB within 5 business days of the PIs (or her team's) knowledge of the event.

11.0 References

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Table 1.

	Questionnaires	Online Screen	Pre-Treatment EMA (14 days)	Post-Treatment EMA (14 days)	Post-Treatment Follow-up
Clinician Administered	Antidepressant Tx History Form (ATHF)	**X**			
	Psychiatric Treatment History	**X**			
	C-SSRS	**X**			**X**
	LRS (as applicable)	**X**			
	DIAMOND/DIAMOND-KID AUD/SUD Modules (as applicable based on self-report forms)	**X**			
	Qualitative Interview (if randomized)				**X**
Self-Report Forms	Contact Info Form	**X**			
	GUID Info Form	**X**			
	Demographics Form	**X**			
	Health Questionnaire	**X**			
	PDS	**X**			
	PID-5	**X**			
	BDI	**X**			**X**
	BHS-C	**X**			**X**
	SSI – past week	**X**			**X**
	SCS	**X**			**X**
	SITBI	**X**			
	Pediatric Loneliness Scale	**X**			**X**
	ASQ	**X**			
	ASQ Follow-up				**X**
	PHQ-A	**X**			**X**
	BAI	**X**			**X**
	ASI-3	**X**			**X**
	AUDIT	**X**			
	AUDIT (*past month*)				**X**
	DAST-A	**X**			
	DAST-A *(past month)*				**X**
	CUDIT	**X**			
	CUDIT *(past month)*				**X**
	SUPPS-P	**X**			
	CPSS-5	**X**			
	IUS-C	**X**			**X**
	Regulation of Emotion Systems Survey	**X**			**X**
	SHAPS	**X**			
	Insomnia Severity Index	**X**			**X**
	Peer Relationships	**X**			
	Family Relationships	**X**			

	Treatment Preference Questionnaire	**X**			**X**
	TLFB *(past 30 days)*	**X**			
	TLFB *(since baseline)*				**X**
	EMA Survey (Pre-Treatment)		**X** (4 times/day)		
	EMA Survey (Post-Treatment)			**X** (4 times/day)	
	CRP form *(CRP groups only)*				**X**
	SUS *(virtual interventions only)*				**X**
	CSQ-8				**X**
	AIM, IAM, FIM Combined Form				**X**