STUDY TITLE:

Technology-Enabled Prevention Services for At-Risk Youth

PRINCIPAL INVESTIGATOR:

Name: [redacted]
Department: [redacted]

CO-INVESTIGATORS:

Name: [redacted]
Department: [redacted]

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Name: [redacted]
[redacted]

VERSION DATE:

December 3rd, 2020

RELATED STUDIES:

N/A

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	☒ Children (you must **complete Appendix A** in addition to this protocol document if you plan to enroll children) ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☐
Research has U.S. Federal government funding via direct award or a sub-award (e.g., NIH, NSF, other federal agencies or departments)	☐

1.0 Purpose and rationale of the study:

Anxiety disorders are the most common class of psychopathology among youth, with nearly a quarter of adolescents meeting 12-month diagnostic criteria.[1-3] Significant functional impairment is associated with youth anxiety disorders, such as problems with social relationships, performance in school, and physical health conditions.[4-6] The negative consequences of anxiety disorders follow youth into their adult lives, including increased risk for psychopathology, such as subsequent depression and substance use problems, and also significant functional impairment in the form of financial problems, poor health, and interpersonal problems.[7-9] There is evidence that anxiety prevention services can be effective for youth; however, the majority of effective services are primarily delivered face-to-face, decreasing the potential for scalability.[10-14] The few technology-enabled prevention services tested have not yet translated into significant effects on anxiety outcomes among youth.[15,16] Given the immersion of digital technology into the lives of this generation of teens, the potential of technology-enabled prevention services for anxiety to reach and engage at-risk youth is extremely promising.[17]

Novel approaches to increase engagement in and access to technology-enabled prevention services that prevent the development and impact of anxiety disorders among youth are needed. First, a technology-enabled prevention service needs to be designed that *includes adolescents in the design of the service*. Including adolescents in the design process to create services that meet their needs and fit within their daily lives will result in tools that teens engage with and use.[18] Second, a technology-enabled prevention service needs to be designed that *partners with community organizations*. Community organizations that serve youth provide a unique setting and infrastructure in which to embed technology-enabled prevention services. Utilizing community organizations, especially those programs that primarily serve underserved youth, increase scalability and access to mental health care. Third, technology-enabled prevention service needs to be designed that *explores underlying mechanisms*. While past technology-

enabled prevention services for youth have used evidence-based psychological strategies, they have not used an optimization strategy to evaluate which strategies are the most potent in driving the intervention effects. A widely accessible and available technology-enabled prevention service co-designed by teens and community partners has the potential to reach and engage large populations of youth in need of prevention programs to prevent the deleterious effects of youth anxiety disorders.

The **goals specific to this grant** are to employ user-centered design methods to engage adolescents, providers, and community partners into the iterative design and evaluation of a technology-enabled prevention service for anxiety among youth.

Specific Aim 1: To work with youth and a community organization that serves underserved youth to iteratively design a technology-enabled prevention service for anxiety. The co-design process will involve user-centered design workshops with youth at risk for anxiety psychopathology from the community-based [redacted]" teen program and their staff. Based on the feedback elicited from the design workshops, the PI will work with a software development team to adapt the technology-enabled prevention service. The PI will then conduct usability testing in the laboratory and in the field on the adapted prototype to iteratively refine features (with the software development team) to ensure that the prototype is usable and useful for at-risk adolescents in community settings.

Specific Aim 2: To conduct an 8-week randomized pilot trial evaluating the adapted technology-enabled prevention service for anxiety among 80 youth with elevated anxiety from a community organization that serves underserved youth. We will use a 2^3 factorial experimental design for the pilot trial. The goals of the trial are to a) evaluate the feasibility and acceptability of the technology-enabled prevention service for anxiety designed in Aim 1 with adolescents in a community setting (**Aim 2a**), b) estimate the effects of the intervention components on anxiety symptoms, as well as on the psychological (i.e., avoidance, cognitive biases, and emotion dysregulation) and engagement targets (**Aim 2b**), and c) estimate if the targeted psychological and engagement targets mediate the relation between the intervention components and anxiety symptoms (**Aim 2c**).

Specific Aim 3. To form and convene two advisory boards comprised of local and national members, as well as to partner with a Teen Investigator on these activities. We recently received seed grant funding through Northwestern's Alliance for Research with Chicagoland Communities (ARCC) to form and convene diverse advisory boards, one teen-based and one adult-based, with varying perspectives to oversee and provide feedback on the delivery, implementation, community impact, and scale-up of a technology-enabled prevention service for youth anxiety. The goals of these boards are for members to provide input on what can be done to advance the delivery and implementation of the technology-enabled prevention service for teen anxiety, as well as provide high-level guidance on community impact and on subsequent scale-up efforts in other settings that serve underserved youth. We will also recruit 1 Teen Investigator from the [redacted] teen program to work with us in preparing and leading the advisory board meetings, as well as helping with data analysis and dissemination of data from the board meetings. Upon consultation with the IRB reviewer, there is agreement that the activities related to Aim 3 (i.e., the teen and adult advisory boards, as well as the role of the Teen Investigator) are not considered human subjects research, nor is there research intent for these activities; thus, there is no NU IRB requirements for this type of material.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Study 1a. We will recruit 10 adolescents aged 12-18 years from the [redacted] led by the teen services staff within the [redacted] to participate in two 75min **design workshops**. Adolescent participants will have total Spence Children's Anxiety Scale- Short Version (SCAS) scores > 1 SD above the mean (i.e., $\geq$ 23).[47] We chose this cutoff point because individuals with SCAS scores in this range are at increased risk of anxiety

problems.[47] In addition, exclusionary criteria for youth include: (a) current or past diagnosis of anxiety disorder; (b) current psychotic disorder; (c) not owning a smartphone with internet service; and (d) inability to provide assent and obtain verbal guardian consent.

Study 1b. We will recruit 10 adult (18 ≥ years) staff members working with [redacted] teen services to participate in two 75min **design workshops**. No exclusionary criteria will be included, in that we will invite each staff member to participate in the design workshops. Participation will be completely voluntary.

Study 2a. We will recruit 10 adolescents aged 12-18 years from the [redacted] program to participate in one 60-minute **laboratory usability session**. Adolescent participants will have total Spence Children's Anxiety Scale- Short Version (SCAS) scores > 1 SD above the mean (i.e., ≥ 23).[47] In addition, exclusionary criteria for youth include: (a) current or past diagnosis of anxiety disorder; (b) current psychotic disorder; (c) not owning a smartphone with internet service; and (d) inability to provide assent and obtain verbal guardian consent.

Study 2b. We will recruit 10 adult (18 ≥ years) staff members working with [redacted] teen services to participate in one 60-minute **laboratory usability session**. No exclusionary criteria will be included, in that we will invite each staff member to participate in the laboratory usability session. Participation will be completely voluntary.

Of note, the current protocol will be revised in a subsequent modification to reflect additional project information, including participant-facing materials, for the later phases (i.e., the 8-week **usability field trial** [Study 3]) and the 8-week **randomized pilot trial** [Study 4]).

3.0 Sample Size:

Ten participants typically identify 95% of usability issues. For 80 participants, we will be able to detect an effect of $d = .65$ based on two groups with 80% power at a type I error rate of .05 using an independent t-test. Accordingly, the maximum numbers of participants to be included in studies are:

Study 1a: 10 adolescents aged 12-18 years
Study 1b: 10 (adult 18 ≥ years) [redacted] teen services staff
Study 2a: 10 adolescents aged 12-18 years
Study 2b: 10 (adult 18 ≥ years) [redacted] teen services staff

4.0 Recruitment and Screening Methods:

Study Recruitment. We will work with [redacted] staff to recruit youth for the research study. This will involve distributing flyers throughout the [redacted] and also the [redacted] communication staff posting about the study via [redacted] s digital media outlets (e.g., twitter, website, etc.; see advertisement text document). [redacted] staff will also recruit adolescents via word of mouth, indicating the research opportunity involves helping Northwestern researchers and developers create a digital program to assist youth to deal more effectively with anxiety and stress. They will also indicate that they would be paid for their time and need their parent or guardian's verbal consent to participate. Importantly, [redacted] staff will broadly disseminate information about the study to all adolescent members aged 12-18 years. [redacted] staff will not single out, or approach, adolescents they believe to be experiencing mental or emotional health issues. Interested adolescents will be given a flyer with more information and directed to include their parent/guardian in contacting the research team and/or accessing the hyperlink for the brief screening survey. If eligible for the study, the adolescent will be asked to provide their email along with their parent/guardians' email, and we will send an email to introduce the study and setup a phone call with the parent/guardian and adolescent.

Adolescent Eligibility Screening Process for Study 1a and 2a. Identical to approved screening survey methods used in [redacted], interested adolescents will be directed to take a brief online screening survey or contact the research team with the permission of their parent or guardian.[37] The first page of the survey will contain an online parental consent form describing the contents, purpose, and duration of this brief, anonymous screener. Text will indicate that the purpose of the study is to recruit adolescents for a workshop/usability session of which the goal is to help with the design and testing of a smartphone application (app) designed to assist youth to understand and deal more effectively with emotions, like stress and anxiety. If parental permission is provided, the second page will contain an online adolescent assent form with identical information as the parental permission form. The following survey will include three areas of criteria to determine eligibility (i.e., aged 12-18 years, correctly answering the data quality-check question, and scoring 22 or below on the SCAS). Ineligible participants will be directed out of the survey and thanked for their time. Online parental permission and online adolescent assent will be attained, but to protect the anonymity of the adolescents, we will not collect written documentation of adolescent assent or parental consent for this brief screening survey. Importantly, there is no more than minimal risk involved in completion of the brief online survey and adolescents' answers will remain completely anonymous (no IP addresses will be automatically logged in REDCap).

Those eligible will be asked if they remain interested in the research opportunity that involves helping Northwestern developers create a smartphone app to assist youth to deal more effectively with stress and anxiety. This request will indicate that they would be paid for their time and need their parent's consent to participate. Those interested will be asked to click a hyperlink within the survey that will redirect them to separate survey hosted on REDCap and the adolescent will be asked to provide her/his email along with their parent's email. There will be no link between the answers to the brief screening survey and the survey asking for parent and adolescent email.

We will contact the parent and adolescent via email to tell them more information about the study. If the parent and adolescent indicate interest in hearing more about the study upon contact, we will then setup a phone call with both the parent and adolescent to go over the study procedures and the consent and assent forms and answer any questions or concerns they may have prior to agreeing to participate in the study. In this process, the parent/guardian and adolescent will be fully informed of all activities related to the investigation, the types of assessments and procedures, the right to discontinue participation at any time for any reason, and the potential risks associated with study procedures addressed in the parental permission/assent forms. Once the forms are reviewed, all questions/concerns are addressed, and the adolescent confirms interest in participating in the study, we will document the verbal informed consent/assent and documentation will be securely stored in a locked cabinet at the Center for Behavioral Intervention Technologies (CBITs). If the parent and adolescent are not available at the same time, we will first talk to the parent to attain verbal parental permission over the phone, and then get in contact with the adolescent to attain verbal assent after parental permission is received. Eligible and consented adolescents will be scheduled for the workshop at the [redacted].

5.0 Research Locations:

The adolescent and staff design workshops (Study 1a & Study1b) and laboratory usability session (Study 2a & Study 2b) will be conducted at the [redacted]. [redacted]y has developed a youth development program called [redacted] This program is specifically designed for teens, and by teens, that focuses on the social-emotional and academic development of youth. The [redacted] is a social service system for seven communities west of Chicago, which includes socioeconomically diverse neighborhoods with variant access to mental health resources. The [redacted] anchors social service and public safety services under the directorship of [redacted] and strategically targets community partners and youth development programming. Director [redacted] leads the [redacted]

program, supporting the associated teen services staff. As a recent extension of social service, the [redacted] just started deploying mental health services to children, youth, and adult patrons of their [redacted]. All in-person sessions for Studies 1-4 will take place in a private room within the [redacted] to ensure participant confidentiality and privacy. Required permissions and approvals will be obtained at that location prior to project deployment.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

N/A

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

N/A

8.0 Procedures Involved:

Note: We are currently planning for the described study procedures to occur in person as proposed (5-year timeline beginning July 1; see Table 3 Timeline); however, in the event this is not possible given the current pandemic, all in-person procedures in Studies 1-4 will be conducted remotely over Zoom. Precautions will be taken to protect the meeting from being accessed by others, such as password-protecting the meeting and not allowing entry into the meeting until the host arrives. We will record the Zoom sessions and store those recordings on the secure server hosted by Northwestern University. Participants will be compensated in electronic Visa gift cards for their efforts.

Study 1a. Ten adolescents will be asked to complete two individual *design workshops* lasting around 75min. The first design workshop will involve the method of 'zine-making.' In zine-making, we will ask adolescents to draw, write, and/or collage several 'snapshots' of their experiences regarding feeling stressed/anxious and managing that anxiety, resulting in the creation of a small story of adolescents' most recent experiences with stress and anxiety. The second design workshop will use the HCI 'think aloud' method. In this exercise, we will provide adolescents a phone with the original adult IntelliCare apps installed on it (or ask them to download the apps on their own smartphone if remote). We will ask them to verbalize their thoughts while they navigate through the IntelliCare program to complete a set of tasks. The data collected will be to help inform the design of the digital tool for anxiety prevention, and how it can be integrated into the current lives of adolescents. At the end of each of the 75min sessions, adolescents will be thanked, comprehensively debriefed, and given $25 for their participation ($50 total if both sessions are completed).

Study 1b. We will recruit 10 adult (18 ≥ years) staff members working with [redacted]'s teen services to participate in two, 75m design workshops. We will invite all staff members to participate in the research opportunity and underscore that their participation is completely voluntary. Interested staff will be scheduled individual sessions at the [redacted]. Staff will be asked to complete a two-session, individual *design workshops*. The first design workshop will utilize the HCI method of zine-making. We will ask the staff to draw, write, and/or collage several 'snapshots' of their current workflow at the [redacted], and how a digital intervention for youth anxiety could be incorporated into this workflow at the [redacted] The second design workshop will use the HCI 'think aloud' method. In this exercise, we will provide staff a phone with the original IntelliCare coaching dashboard installed on it (or ask them to download the dashboard on their own smartphone if remote). We will ask them to verbalize their thoughts while they navigate through the coaching dashboard to complete a set of tasks. The data collected will be to help inform the design of the coaching platform associated with the digital tool for adolescent anxiety prevention, and how it can be integrated into the current workflows of [redacted] teen services staff. At the end of each of the 75min sessions, staff will be thanked, comprehensively debriefed, and given $25 for their participation ($50 total if

both sessions are completed).

Study 2. Laboratory usability testing will evaluate the usability of the apps and coaching dashboard prototypes. As 10 participants typically identify 95% of usability issues, we will recruit 10 new adolescents aged 12-18 years and 10 teen services staff to participate in 60-minute laboratory sessions.[52] Adolescents will be enrolled in waves of 3-4, and staff will also be enrolled in waves of 3-4. The "think aloud" method will be used, in which adolescents and staff will be asked to verbalize their thoughts when using the functioning prototypes of the IntelliCare apps (for adolescents) or coaching dashboard (for staff) to complete specific tasks (e.g., attain a badge in Thought Challenger; check adolescents' progress on dashboard). This process will be used to identify problems early in the design process, such as features leading to user confusion, error, or dislike.[53,54] The PI will work iteratively with the waves of adolescents and staff to address the problems identified by prior groups before the next group tests the refined prototypes. Adolescents and staff will be administered the System Usability Scale (SUS)[55] to obtain quantifiable measures of usability. Sessions will be recorded and observation notes will be taken. Screen capture software will be used to record progression through the tasks. At the end of the 60min session, they will be thanked, comprehensively debriefed, and given $25 for their participation. See Table 3 for our working timeline.

Table 3. Timeline

Study	Activity	Year 1		Year 2		Year 3		Year 4		Year 5	
		1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Studies 1-3: Design Workshops & Usability Testing	Adapt IntelliCare to Youth Digital Prototype	X									
	Design Workshops and Refinements	X	X								
	Usability Laboratory Testing and Refinements		X	X							
	Usability Field Trial and Refinements			X	X						
	Finalize Digital Prototype for Pilot Trial				X						
Study 4: Pilot Trial	Recruit and Enroll Adolescent Participants					X	X	X	X		
	Deliver the Intervention					X	X	X	X		
	Conduct 6-mon Follow-up Assessments						X	X	X	X	
	Analyze Trial Data									X	X
	Write and Submit NIH R01 Grant							X	X	X	X
	Submit Manuscripts and Conference Abstracts	X	X	X	X	X	X	X	X	X	X

9.0 Research with Vulnerable Populations (if children are the ONLY vulnerable population you plan to enroll, do NOT complete this section -- instead fill out Appendix A)

Children are the only vulnerable population; see Appendix A.

10.0 Incomplete Disclosure or Deception:

N/A

11.0 Consent Process:

Brief Online Screening Survey (Study 1a, Study 2a)

Identical to approved screening survey methods used in [redacted], the first and second page of the survey will contain an online parental permission form and an online adolescent assent form describing the contents, purpose, and duration of this brief, anonymous screener. The online adolescent assent form will be available only if parental consent is given. Text will indicate that the purpose of the study is to recruit adolescents for a workshop (for Study 1a)/usability session at the [redacted]y (Study 2a), of which the broader goal is to help with the design and testing of a smartphone application (app) designed to assist youth to understand and deal more effectively with stress and anxiety. Text will also indicate that survey answers are anonymous and will be kept completely private. The text encourages adolescents to talk about the survey with their parents or a trusted adult, and for both the adolescent and parent to visit the webpages provided giving information about our center and institution. Lastly, the text indicates

participation is completely voluntary and that the adolescent will be asked to provide their email, along with their guardian/parent's email if eligible for the relevant study. If the parent does not agree for their child to participate in the study or if the adolescent does not agree to participate, the adolescent will be directed to the end of the survey. Further, if the adolescent indicates they are out of the age range of 12-18 years, do not answer the automation preventative question confirming they are a real person, or score 22 or below on the SCAS, they will also be directed to the end of the survey. Online parental permission and online adolescent assent will be attained. To protect the anonymity of the adolescents, we will not collect written documentation of adolescent assent or parental consent for this brief screening survey. Importantly, there is no more than minimal risk involved in completion of the brief online survey and adolescents' answers will remain completely anonymous (no IP addresses will be automatically logged in REDCap).

Consent and Assent Process for Adolescent Studies (Study 1a, Study 2a)

If the parent and adolescent indicate interest in hearing more about the study upon email contact, we will setup a phone call with both the parent/legal guardian and adolescent to go over the study procedures and the consent and assent forms and answer any questions or concerns they may have prior to agreeing to participate in the study. We will send the parental permission and adolescent assent forms via email prior to the scheduled phone call for parent-adolescent dyad to review. The adolescent and parent will also have the opportunity to read through the forms at the beginning of the phone call if they have not done so already. During the scheduled phone call with both the adolescent and parent, they will be fully informed of all activities related to the investigation, the types of assessments and procedures, the right to discontinue participation at any time for any reason, and the potential risks associated with study procedures addressed in the parental permission/assent forms. During this discussion, we will emphasize it is very important to us that they understand the procedures, risks and benefits, and other consent components prior to providing their consent/assent. We will also encourage the parents and adolescents to ask questions on anything that is not clear. After which, we will ask the parental/guardian if they are willing for their child to participate in the relevant study and document their verbal parental permission. Next, we will ask the adolescent if they are interested in participating in the relevant study and document their verbal assent. If the parent and adolescent are not available at the same time, we will first talk to the parent to attain verbal parental permission over the phone, and then get in contact with the adolescent to attain verbal assent after parental permission is received. Once the permission and assent forms are reviewed, all questions/concerns are addressed, and the parent/guardian and adolescent confirm permission/interest to participate in the study, we will schedule the study session at the [redacted]. If adolescents aged 18 years provide their permission to participate, they will be asked to provide their signature on the consent form. The verbal parental permission forms and adolescent assent forms and documentation will be securely stored in a locked cabinet at the Center for Behavioral Intervention Technologies (CBITs). Finally, in compliance with HRP-090 and 091, participants will be provided the opportunity to receive copies of the signed and dated consent and assent forms.

Consent Process for the Staff Studies (Study 1b, Study 2b)

Staff affiliated with the [redacted] will be provided with a paper consent form at the beginning of the one-on-one session. The researchers will allow time for staff to read the form and will offer to address any questions or concerns that the staff may have before they sign the consent document. Participants will be informed of the optional nature of this study, that all questions are optional, and that the session will be audio and video-recorded. Participants will be informed that participation in this study is not a job requirement, and given the opportunity to ask any questions. The amount of time devoted to this process will be approximately 5-10 minutes at the beginning of the session. If participants are willing to take part, they will be asked to sign and date the consent form.

On the consent form, participants will have the option to provide optional consent to be contacted for future projects. However, any future projects would involve their own consent processes, and their consent to be contacted will not affect their participation in the current project. Finally, in compliance with HRP-090 and 091, participants will be provided the opportunity to receive copies of the signed and dated consent form.

12.0 Waiver of Participant Signature on Consent Form:

Online parental permission and online adolescent assent will be attained for the brief online screening survey, but to protect the anonymity of the adolescents, we will not collect written documentation of adolescent assent or parental consent.

Verbal parental permission will be attained for adolescent studies, but to decrease barriers to adolescent participation, we will not collect written documentation of parental consent. Verbal adolescent consent will also be attained for adolescents aged 17 years or younger at the same time as verbal parental permission is being attained, or after if the teen is unavailable during phone call with the parent.

13.0 Waivers and Alterations of Consent Information:

N/A

14.0 Financial Compensation:

Study 1a. Adolescents will be given $25 cash per design session ($50 total).
Study 1b. Adult staff will be compensated $25 cash per design session ($50 total).
Study 2a. Adolescents will be given $25 cash for the laboratory usability session.
Study 2b. Adult staff will be compensated $25 cash for the laboratory usability session.

15.0 Audio/Video Recording/Photography

Video and audio recordings are necessary for coding the qualitative data. Only the first names of the participants will be used in recordings to respect their privacy. All audio and video-recordings will be uploaded and stored in the Northwestern University digital secure data storage following the completion of all sessions and deleted from the recording device. Following IRB policy, data will be kept 3 years after the completion of the study. The audio recording will be transcribed before coding. The transcription of audio files may be conducted by one or more of the following NU transcription vendors:

GMR Transcription https://www.gmrtranscription.com/
Wordsworth https://wordsworthcoop.com

Files may be shared via secure access to FSM servers or through vendors' proprietary web-based applications for secure file management. Qualitative coding will be conducted on the transcripts using thematic analysis. From the analysis, we will identify core themes that will help inform the design and deployment of the digital intervention prototype designed to help adolescents better manage anxiety. We will include an optional element in the adolescent and parent permission forms, as well as in the staff consent forms, that ask permission for use of video-recordings and/or audio-recordings in scholarly presentations or publications.

The specific events that will be recorded for each study are as follows:
Study 1a: Individual adolescent in-person workshops will be audio- and video-recorded.
Study 1b: Individual staff in-person workshops will be audio- and video-recorded.
Study 2a: Individual adolescent in-person laboratory usability sessions will be audio- and video-recorded.
Study 2b: Individual staff in-person laboratory usability sessions will be audio- and video-recorded.

16.0 Potential Benefits of this Research:

There are no direct benefits for participants who take part in this study. One potential benefit is that the knowledge gained from this study may contribute to a better understanding of adolescent anxiety and may help inform development of effective technology-enabled prevention services for youth. Further, results from this study will pave the way for future studies to test an optimized technology-enabled prevention service, with the idea that it will be a highly potent, available, and accessible service for at-risk youth. We believe the benefits outweigh the minimal risks involved in study participation, especially considering the likelihood and protections in place.

17.0 Potential Risks to Participants:

General Risk. Precautions will be taken to minimize participant risk in the proposed study. Adolescent and staff participants (and adolescents' parents) will be fully informed of all procedures related to the investigation, the types of assessments and procedures, and the potential risks associated with these procedures. They will be given an opportunity to have any questions answered to their satisfaction and then will be asked for their verbal informed assent/consent statements prior to participating in the project. Further, adolescent and staff participants (and adolescents' parents) will be reminded that they can discontinue their participation at any time for any reason without penalty or prejudice. The specific risks involved in the proposed investigation are enumerated below; procedures related to limiting risk are outlined in the Section 18.0.

Risks Associated with the Design Workshops, Usability Testing, and Pilot Trial Procedures. In regard to the design workshops, usability studies, and self-report measures, there are no foreseeable risks associated with these procedures. Some participants may be mildly uncomfortable answering some questions (e.g., indicating how often they are "fearful of embarrassment"); however, evidence also suggests that some participants may derive benefit from the self-assessment.[1]

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

Protection Against Risks

Informed Consent and Assent. Informed assent and consent forms conforming to the requirements of, and approved by, the human subjects review board at Northwestern University will be approved prior to any data collection. Informed consent and assent will be collected from adolescent (and their parents) and staff participants prior to study sessions. A similar process will be used for consenting adolescent participants (and their parents) as for staff participants. The informed adolescent assent / parental consent, and staff consent will be verbally collected over the phone. Interested adolescents (and their parents) and staff participants will be sent the consent and assent forms prior to the consenting session for them to review. During the consenting process, participants will first be given a brief introduction of the study and then will be given time to read the consent/assent forms. Adolescents will read an informed assent form and parents will read an identical informed consent form to allow their child to participate in the study. Staff will read an informed consent form. The informed consent/assent forms will delineate study procedures, limits of confidentiality, risk and benefits of the study, information pertinent to compensation schedule, and indicate that participants may discontinue their participation at any time without penalty or loss of benefits. For staff participants, additional discussion will focus on the voluntary nature of the studies, and that participation in the study is not a requirement of their job. All participants will be given contact information for the project PI and Co-Is and the Northwestern IRB compliance coordinators that they can use should they have any concerns or questions about the conduct of the study. After participants review the informed consent/assent forms, the researcher will address any questions that may arise. In addition to addressing participant questions, the researcher will execute a step-by-step plan to ensure that they fully

understand their rights and protections as participants in a research study. This includes verbally reviewing each of the elements detailed above (e.g., confidentiality; right to withdraw; voluntary participation) and providing clarification regarding any words or phrases on the forms that participants did not understand. At this time, participants will be asked if they would like to provide their permission to participant in the study. If so, a researcher will fill out the verbal consent/assent forms for the adolescent participants and their parents. All research personnel will be comprehensively trained in human subject protections, including successful completion of the applicable sections of the Collaborative Institutional Training Initiative.

Procedures to Ensure Confidentiality. Participants' confidentiality will be carefully protected. Research material obtained from participants will be self-report measures (collected via the secure data acquisition and management software of REDCap), transcripts from design and usability studies, and app use metrics. Breach of confidentiality is unlikely, as all data forms will be coded by arbitrary study number and stored in a locked filing cabinet in a locked office (i.e., double locked). Assent and consent forms with identifying information (names) will be filed separately from actual study data in a separate locked filing cabinet. As a part of the consenting process, parents will be informed that they will not have access to the adolescents' data. All interviews will be audio recorded, and the workshops and laboratory usability studies will be video recorded. Audio and video recordings will be deleted immediately upon completion of the study. Only trained members of the research team will have access to participant data; all personnel will be carefully trained in the ethical conduct of research, including requiring all personnel to complete the online Collaborative Institutional Training Initiative tutorial. Scientific presentations and publications will not contain any information that could be used to identify a particular individual.

Procedures to Ensure Subject Safety. No direct questions assess for self-harm or suicidality; however, we have developed procedures to ensure safety of participants. Participants who express suicidal ideation, other forms of serious threat to themselves or others, or report instances indicative of abuse or neglect at any point in the project will receive ideographic, ethically, and legally indicated courses of action. This includes assessment of seriousness of danger, referral for immediate crisis management (e.g., hotlines, crisis centers, hospitals), and contacting emergency psychiatric teams or law enforcement authorities as necessary. A detailed step-by-step protocol is available in the Center for Behavioral Intervention Technologies (CBITs) for dealing with such crises, in which all personnel are comprehensively trained before playing any role in data collection. The first step in this protocol is consultation with clinical psychologist Co-I [redacted] or clinical psychiatrist [redacted] during remote sessions, or the research team's clinical psychologist or licensed social workers that are on-site at the [redacted] All necessary steps will be taken to ensure the participant's safety, up to and including calling emergency services to go out to the participant's location (or come to the on-site location if in person) to perform a safety check and hospitalize the participant if necessary. If a participant becomes fatigued or distressed during any of the assessment procedures, they will be reminded that they may discontinue at any time, for any reason, without penalty or prejudice. As part of the informed assent and consent procedures, all participants will be given referral information in case they become distressed during or after sessions.

Procedures to Handle Adverse Effects. The current study will utilize procedures already in place for ongoing research in CBITs designed to protect human subjects via the prevention and early identification of adverse effects. First, the PI and her research team will track all self-report and interview data to ensure the wellbeing of each participant. Participants whose responses suggest the presence of suicidal ideation will be interviewed by the PI and given an appropriate referral. In the case of responses suggestive of suicidal intent or harm to others, the individually tailored plans for participant protection described above will be immediately implemented.

Only comprehensively trained research assistants will be allowed to assist with the human subjects portions of the protocol. The PI will be readily available to adolescent and staff participants throughout the duration of the study. Importantly, CBITs has a clearly specified set of policies in which all research personnel are comprehensively trained prior to playing any role in data collection. Specifically, if a participant responds negatively, the procedure will immediately be stopped to assess for participant distress. Should the participant be distressed, the PI has already been trained in cognitive-behavioral methods of anxiety reduction (e.g., guided imagery, diaphragmatic breathing, cognitive re-structuring) and is prepared to use such methods to assist participants in returning to a more relaxed state. Participants evidencing adverse effects will not leave the research setting (or exit the phone call if it is remote) until they and the PI feel that they have returned to a relaxed state, as indexed by their self-report and direct observation. Any incidents that involve an adverse effect will be immediately reported to the IRB at Northwestern University. All participants will be provided with information about anxiety disorders as well as referral information for local providers with expertise in the treatment of such concerns.

Debriefing Procedures. In addition to these standard safeguards detailed above, a thorough debriefing for the current study will be employed in which participants will be comprehensively debriefed in a post-study protocol interview at the end of their session. Participants will first be given the opportunity to have any questions addressed. Then, the debriefing will focus on the ethical, educational, methodological, and participant satisfaction functions of participant debriefing consistent with published recommendations.[64-65] Consistent with the recommendation to give participants a sense of satisfaction for participating in research, participants will be informed of the potential public health significance related to effective preventive interventions readily available for youth. Participants will also be given the opportunity to ask any questions they have pertaining to the research project throughout the debriefing protocol.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

Principal Investigator, Dr. [redacted], and Co-Investigators, [redacted] will oversee safety of participants, with the understanding that any events researchers deem necessary to report to [redacted] will lead to a suspension of data collection. Such events would involve any feedback from participants indicating the session protocol contents are distressing or inappropriate, such as a participant objecting to the content of questions, or expressing distress resulting from engaging with the session. Should such an event occur, the research team will conduct an immediate review of (1) the event triggering the review, (2) the existing protocol, and (3) adjustments to the protocol going forward, for which all researchers conducting field work will be re-trained prior to resuming data collection.

With regard to monitoring of data quality and protected health information, all personnel involved with the proposed project will have the required human subjects and confidentiality training, which includes information about maintaining data integrity and security. All digital recordings will be deleted immediately upon completion of the study; in the interim, all recordings will be securely stored. Finally, during data collection, weekly research team meetings will be scheduled to review data collection progress.

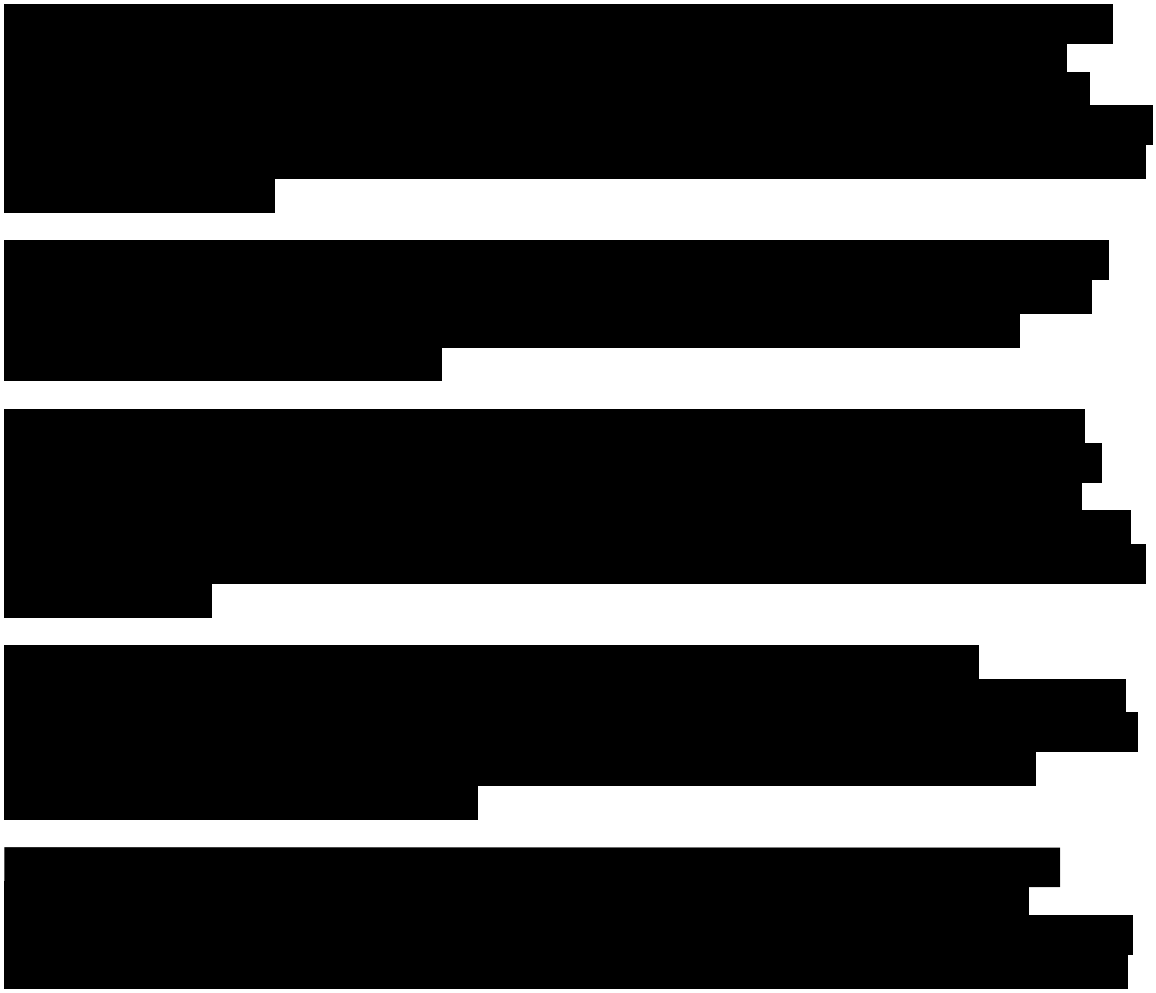
20.0 Long-term Data and Specimen Storage and Sharing:

Electronic and physical storage of data collected will be managed by the PI, Co-PIs, the research team conducting the study. When active analysis of data is complete, the electronic and physical data will be retained according to Northwestern University's data retention policies, up to and including destruction of data in the future.

De-identified study data may be shared for research purposes with collaborators outside of the research team at Northwestern University. Collaborators may include researchers at other institutions such as universities, foundations, research groups within companies, and/or government agencies for the purposes of improving science by aggregating datasets across projects or accessing specialized expertise such as machine learning and data mining. A data use agreement will be executed before study data is released to a researcher or organization that is not part of the study team. The data use agreement will specify what data will be transferred to another organization or research center. Some journals now require that data used in publications must be provided to the journal and may be made public. In those instances, we will provide a de-identified dataset to the journal. Study consent forms will explain the range of information that may be shared with collaborators.

21.0 Qualifications of Research Team to Conduct the Research:

The Center for Behavioral Intervention Technologies (CBITs) at NU conducts research to evaluate behavioral intervention technologies and technology enabled services. The People, Information, and Technology Changing Health (PITCH) lab at NU focuses on addressing problems related to how technology can improve collaboration and communication in healthcare. The Bridges Program at NU focuses on developing innovative implementation research methods to foster partnerships between community, service delivery, and research expressly addressing health and equity. The three research groups aim to improve the delivery of care through the better design, implementation, and evaluation of health services technologies for all.



[redacted]