PROTOCOL TITLE:

Design Opportunities for Mental Health Technologies for Youth

PRINCIPAL INVESTIGATOR:

[redacted]

CO-INVESTIGATORS:

[redacted]

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1.0 Purpose of the study:

The overarching goal of this research is to develop the next generation of digital mental health (DMH) tools and services that are effective, implementable, and scalable that will treat and prevent anxiety in youth. The specific goal of the proposed project is to conduct a preliminary study to better understand how adolescents experience anxiety, ways adolescents manage their anxiety, and about their technology use. This study will provide initial data that will allow for proof of principal and a foundation for further research. An important aspect of developing these tools is the relevance to the users and how the tools fit into their current routines of life; this is particularly important for adolescents, who are avid users of technology. Consequently, in this project, we plan to conduct interviews with adolescents to learn about how they use technology, their feelings around anxiety, and what management strategies they use the most. We are also interested in the best ways to implement digital tools for youth anxiety into community organizations. Thus, we also plan to conduct interviews with staff members affiliated with the community-based organization of the [redacted] to provide insight into how to best implement this type of technology in their everyday workflow.

2.0 Background / Literature Review / Rationale for the study:

Adolescence is a key phase of life where several mental disorders become apparent. Specifically, the transition from childhood into adolescence is marked by dramatic increases in morbidity and mortality, primarily associated with increases in a range of mental health disorders, substance use, and consequences of risk taking and poor decision-making. In fact, the majority of mental health problems begin before the age of 21 [1], and poor mental health during adolescence often has ongoing negative impacts on adult life. The World Health Organization notes that anywhere from 10-20% of children and adolescents worldwide are dealing with mental health issues [2]. In the US, mental health issues, and depression and anxiety in particular, pose significant risk for other forms of psychopathology, and are characterized by significant functional impairment across multiple domains [3]. Despite these alarming statistics, surveys consistently find that the majority of adolescents suffering from mental disorders do not receive treatment of any sort [4], highlighting the need for innovation in the delivery of services to this important developmental period.

Technological innovations, especially in mobile computing (e.g., smartphones) and online social networks, are transforming the daily lives of adolescents, and adolescents are amongst the most ubiquitous users of personal digital technology [5]. Furthermore, the social capabilities of internet enabled devices tap into core adolescent motivations in powerful ways [6]. This raises the question of how digital technology might be used to address the mismatch between the burden of adolescent mental health disorders, and their access to and utilization of treatment services.

To date, there have been a number of digital mental health tools that have targeted internalizing disorders in youth [7]. While controlled studies have demonstrated various degrees of efficacy, none have been successfully implemented in real world settings. This is consistent with digital mental health research in other age groups, which has also shown efficacy in controlled settings, but has consistently failed in real world implementation. This failure has at least 3 causes: 1) consumer-facing tools are cumbersome to use and do not fit into the fabric of user's lives; 2) the services are poorly

designed and do not fit into the workflows of already existing services; and 3) there has been little attention to the design of implementation plans that are essential for successful, real-world deployment. In the case of digital services targeted towards adolescents, there is a fourth salient factor, which is that the services need to be adapted to the specific developmental capacities and motivations of that age group.

Consequently, we need to develop technologies and services that will help address the mental health issues in this population. In particular, if we want these tools and services to be impactful and sustainable, we need to design them in partnership with the users who will be using them and in settings where they will be deployed. In this project, we will utilize user-centered approaches to start engaging adolescents and community partnerships in the process of designing and implementing digital mental health (DMH) tools and services for youth.

3.0 Inclusion and Exclusion Criteria:

Study 1. Fifteen adolescents aged 12-17 years, who endorse elevated anxiety symptoms indexed via the well-validated measure of *Spence Children's Anxiety Scale-Short Version (SCAS)* will be eligible for the study [8]. Youth participants will have total SCAS scores > 1 SD above the mean from a large, represented sample of youth who took the SCAS short version measure (i.e., ≥ 23). Youth will be recruited from the [redacted]. Adolescents who are not fluent in English will be excluded from the study. Adolescents whose parents are not fluent in English, and thus not able to provide meaningful parental permission, will be excluded from the study. The following populations will be excluded from the study: a) Adolescents unable to provide assent; b) Pregnant women (where the activities of the research may affect the pregnancy or the fetus.); and c) Prisoners or other detained individuals.

Study 2a. We will recruit 10 adult (18 ≥ years) staff members affiliated with Rush University who work on the partnership between Rush University and [redacted] aiming to integrate mental health care into the [redacted]. The following populations will be excluded from the study: a) Adults unable to provide consent; b) Pregnant women (where the activities of the research may affect the pregnancy or the fetus.); and c) Prisoners or other detained individuals.

Study 2b. We will recruit 10 adult (18 ≥ years) [redacted] staff members who work with youth through the youth programs at the [redacted] (see Section 5.0 for more details). The following populations will be excluded from the study: a) Adults unable to provide consent; b) Pregnant women (where the activities of the research may affect the pregnancy or the fetus.); and c) Prisoners or other detained individuals.

4.0 Sample Size:

The maximum numbers of participants to be included in the study are 15 adolescents for Study 1, 10 adults for Study 2a, and 10 adults for Study 2b.

5.0 Research Locations:

The interviews for the proposed study will be conducted on the phone with youth and staff at the [redacted] 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]. The interview sessions for Study 1 will take place over the phone in a private room to ensure participant confidentiality and privacy. The sessions for Study 2a and 2b will take place over the phone, with the call administered within a private room at Northwestern University to ensure participant confidentiality and privacy.

6.0 Multiple sites:

NA

7.0 Reliance Agreements/Single IRB:

NA

8.0 Procedures Involved:

Study Overview. Interviews will be conducted with 15 youth and 20 staff from the youth programs at the [redacted] To better understand adolescent technology use and their experiences around anxiety, we will conduct individual interviews that include open-ended questions with the youth in the study. To better understand the workflow of the [redacted] youth staff, the organizational objectives and constraints, and staffs' typical interactions with adolescents around stress and anxiety, we will conduct sessions with the [redacted] staff and Rush staff who work on the partnership between Rush and the [redacted]. Data from these sessions will include transcripts of the sessions. These data will be analyzed to inform the creation of a digital program designed to help support adolescents in managing their stress and anxiety. The data will also inform the implementation of that program into community-based organizations.

Study 1. We will work with [redacted] staff to recruit youth for the feedback session. We will also distribute flyers throughout the [redacted] and share study information via the [redacted] digital outlets (e.g., twitter, website, etc.) to recruit youth. Interested adolescents will be directed to include their parent/legal guardian in emailing the research team or accessing a brief (approximately 5min), online screening survey (hosted on Qualtrics) through a hyperlink to determine eligibility. 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 feedback session, of which the goal is to help with the development of a smartphone application (app) designed to assist youth to understand and deal more effectively with emotions, like stress. Two questions will be included to assess parental comprehension of the form (please see the updated screening

survey). If parental permission is provided and comprehension questions answered correctly, the second page will contain an online adolescent assent form with identical information as the parental permission form. If the comprehension questions are not answered correctly, parents will be directed out of the survey and thanked for their time. The following survey will assess three areas of the eligibility criteria (i.e., aged 12-17 years, correctly answering the data quality-check question, and SCAS scores ≥ 23) [8]. 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 Qualtrics).

Those eligible will be asked if they remain interested in the research opportunity that involves helping Northwestern developers create an online program 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 Qualtrics 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.

Consistent with previous prevention programs, no information regarding participants' "at risk" status (i.e., moderate anxiety symptoms) will be provided to the adolescent or parent. Direct provision of such information may unnecessarily activate negative expectancies about likelihood of developing future problems. Instead, we will contact the parent and adolescent via email to tell them more information about the study without explicitly noting participant status (please see Parent teen email)" for introduction email text. If the parent and adolescent indicate interest in hearing more about the study upon email contact, we will then setup a phone call with both the parent and adolescent to go over the study procedures, study eligibility, 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 parental consent 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 discuss the study procedures and assess adolescent interest in study participation. Eligible adolescents, whose parent provides permission, will be scheduled for the feedback session at the [redacted].

The 75min individual, one-time session will involve an interview on the telephone with eligible adolescents. At the beginning of the session, a researcher will go through the

assent process with the adolescent that is identical to the parental consent process described, verbal assent will be collected over the phone, and the adolescent will be sent a list of mental health resources at the end of the interview. The interview will ask the adolescents open-ended questions about how they use technology, their experiences with anxiety, and anxiety management. Please see "SRCD Youth Session Script _6.8.20" document for more details regarding the interview. At the end of the session, adolescents will be thanked, debriefed, and given a $25 Visa giftcard for their participation in the session.

Study 2a. We will recruit 10 adult (18 ≥ years) staff members affiliated with Rush University who work on the partnership between Rush University and [redacted], which aims to integrate mental health care into [redacted]. We will send the staff members an email explaining the research opportunity. Interested staff will be scheduled for sessions over the phone.

Staff will be asked to complete one telephone-based interview session. The interview questions will ask staff questions about their workflow, use of technology in their job activities, and about youth's needs around anxiety. The data collected will help inform best practices of implementing mental health care services into a community-based organization. At the end of the 60m session, staff will be thanked, debriefed, and sent $20 via Hyperwallet for their participation in the session.

Study 2b. We will recruit 10 adult (18 ≥ years) staff members working with the youth programs from [redacted]. We will send the staff members an email explaining the research opportunity. Interested staff will be scheduled for sessions over the phone.

Staff will be asked to complete one telephone-based interview session. The interview questions will ask staff questions about their workflow, use of technology in their job activities, about youth's needs around anxiety. The data collected will help inform how the support services for the digital prevention program can be integrated into the existing workflow of [redacted] youth programs. At the end of the 75m session, staff will be thanked, debriefed, and sent a $25 Visa giftcard for their participation in the session.

9.0 Incomplete Disclosure or Deception:

NA

10.0 Recruitment Methods:

For Rush, we will get in contact with the project lead, [redacted] from Rush University, and she will provide an email list for all Rush staff who work on the partnership between Rush University and the [redacted]. For the [redacted], we will obtain an email list from the director of social services and public safety services, [redacted], at the [redacted] of all staff who work primarily with youth at the [redacted]. We will send an email to staff affiliated with Rush University and a separate email to the staff affiliated with the [redacted] staff explaining the research opportunities. Those interested will be asked for a phone number to contact them to tell them more about the study and to schedule their session.

We will work with [redacted]ns and the [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] 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 12-17 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.

11.0 Consent Process:

Study 1: Brief Online Adolescent Screening Survey

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 and parental comprehension questions are answered correctly. Text will indicate that the purpose of the study is to recruit adolescents for a feedback session, of which the goal is to help with the development of a smartphone application (app) designed to assist youth to understand and deal more effectively with emotions, like 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 feedback session. Two questions are included to assess parental comprehension of the form. If the parent does not agree for their child to participate in the study, does not answer the comprehension questions correctly, or if the adolescent does not agree to participate, they will be directed to the end of the survey. Further, if the adolescent indicates they are out of the age range of 12-17 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 Qualtrics).

Study 1: Adolescent Feedback Study Session

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. 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. The parent will also be given the opportunity to read through the forms if they have not done so already. After which, we will ask the parental/guardian if they are willing for their son/daughter to participate in the study session and document their verbal parental permission. 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 discuss the study procedures and assess adolescent interest in study participation. If it becomes apparent that the parent/legal guardian is not able to provide informed permission due to a language barrier, they will be thanked for their time and excluded from the study. 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 for their child to participate. Once the 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 telephone interview. At the beginning of the session, a researcher will go through the assent process identical to the parental consent process described, verbal assent will be collected, and the adolescent will be sent the list of mental health resources at the end of the session. The verbal parental permission form and verbal adolescent assent form and documentation will be securely stored in a locked cabinet at the Center for Behavioral Intervention Technologies (CBITs).

Study 2a: Interview Session

Staff affiliated with Rush University will be sent the consent form over email and asked to read the form at the beginning of the session. The researchers will allow time for participants to read the form and will offer to address any questions or concerns that the participants may have before the participants provide their verbal consent over the phone. Participants will be informed of the optional nature of this study, and that all questions are optional, and that the session will be audio-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 provide verbal consent to participate in the study.

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.

Study 2b: Interview

Staff affiliated with the [redacted] will be sent the consent form over email and asked to read the form at the beginning of the session. The researchers will allow time for participants to read the form and will offer to address any questions or concerns that the participants may have before the participants sign the consent document. Participants will be informed of the optional nature of this study, and 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 provide verbal consent to participate in the study.

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.

12.0 Financial Compensation:

Study 1. Similar to study compensation strategies employed in previous studies at the community-based organizations facilitated by our collaborators at Rush University, adolescents will be compensated a $25 Visa giftcard for their participation at the end of the 75min telephone session.

Study 2. Adult participants in Study 2a will be compensated $20, via the University's vendor, Hyperwallet, for their 60m telephone session, and adult participants in Study 2b will be compensated $25, via a Visa gift card, for their 75m telephone session. For those participants compensated using Hyperwallet, this virtual payment can be used for online purchases or can be transferred to the participant's personal bank account. For those who decide to transfer the funds to their bank account, they are required to provide their name, address, and email address. This information will remain confidential and de-identified, and they will not receive spam from Hyperwallet. Additionally, there is a $1.50 bank (wire) fee that is deducted from the card for bank transfers; the research team will pay this fee by loading $21.50 on the card for participants who choose to transfer the funds to their personal bank account. For those who receive a Visa gift card, they will be sent the electronic gift card via email.

13.0 Audio/Video Recording/Photography

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 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 from the sessions using thematic analysis. From the analysis, we will identify core themes that will help inform the future design and implementation of a 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 audio-recordings in scholarly presentations or publications.

The specific events that will be recorded for each study are as follows:
Study 1: Individual adolescent telephone interviews will be audio-recorded.
Study 2a: Adult staff telephone individual sessions will be audio-recorded.
Study 2b: Individual adult staff telephone interviews will be audio-recorded.

14.0 Potential Benefits to Participants:

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 preventive and treatment interventions for youth. Further, results from this study will pave the way for future studies to design and implement a digital intervention prototype in community settings, with the idea that it will be a highly potent and scalable intervention for at-risk youth. We believe the benefits outweigh the minimal risks involved in study participation, especially considering the likelihood and protections in place.

15.0 Risks to Participants:

The overall level of risk posed by this study is minimal. There are no foreseeable risks associated with these assessment procedures. Some participants may be mildly uncomfortable answering some questions; however, evidence also suggests that some participants may derive benefit from the self-assessment. There are no other obvious physical or psychological risks above and beyond those of normal daily life for those involved in this study. Based on our previous experience, the likelihood of these risks is low, as is the seriousness.

16.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

Only research team members will be able to access information about the participants. Digital data gathered in the field (audio recordings) will be uploaded and stored on Northwestern computers and servers following the completion of the sessions and deleted from the recording device. All paper-based data (consent forms, paper artifacts, etc.) will be kept in a locked cabinet at the Center for Behavioral Intervention Technologies (CBITs). All data collected from Qualtrics will be de-identified and stored on Northwestern computers and servers. The online surveys will take advantage of Qualtrics' fully anonymous data recording (i.e., no IP addresses will be automatically logged) and secure SSL encryption to promote anonymity. Participant data will be coded with randomly generated identifier numbers; responses will never be linked to a participant's name or any other identification information. All participant identifiable

information (i.e., email and phone number) will be separately stored on Northwestern computers and servers. All data presented will be done in aggregate form without any personal identifiers. Following IRB policy, data will be kept 3 years after the completion of the study.

17.0 Data Monitoring Plan to Ensure the Safety of Participants:

Principal Investigator [redacted] and Co-Investigator [redacted] will oversee safety of participants, with the understanding that any events researchers deem necessary to report to Drs. [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.

18.0 Data, and if applicable, Specimen Banking:

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.

19.0 Data Sharing:

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.

20.0 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 PITCH lab at NU focuses on addressing problems related to how technology can improve collaboration and communication in healthcare. The two research groups aim to improve the delivery of care through the better design, implementation, and evaluation of health-related technologies.

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