Digital Youth-Nominated Support Team (YST) Program

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Date of IRB Approval: February 22, 2024

Title: **Digital Youth-Nominated Support Team (YST)Program-**

Brief Title: Digital YST Program

Date: January 6, 2023

Sponsor: National Institute of Mental Health (NIMH)

Protocol Number: 2022-Oui-002
Version Number: 1.1

CONFIDENTIALITY STATEMENT

The confidential information in this document is provided to you as an Investigator or consultant for review by you, your staff, and the applicable Institutional Review Board (IRB) or Ethics Committee (EC). Your acceptance of this document constitutes agreement that you will not disclose the information contained herein to others without written authorization from Oui Therapeutics, Inc.

STATEMENT OF COMPLIANCE

This trial will be conducted in compliance with the protocol, International Council on Harmonization Good Clinical Practice (ICH GCP) and applicable state, local and federal regulatory requirements. Each investigational site must provide this protocol and the associated informed consent documents and recruitment materials for review and approval by an appropriate Institutional Review Board (IRB) or Ethics Committee (EC). Any amendments to the protocol or consent materials must also be approved before implementation.

Sponsor Protocol Approval Page

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PROTOCOL NUMBER:	2022-Oui-002
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We, the undersigned, have read and approve the protocol specified above and agree on its content.

Patricia Simon VP, Clinical	
	Date: 01/06/2023
Brian Keenaghan VP, Operations	
	Date: 01/06/2023

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the Statement of Compliance above.

PI or Clinical Site Investigator:

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1. PROTOCOL SUMMARY

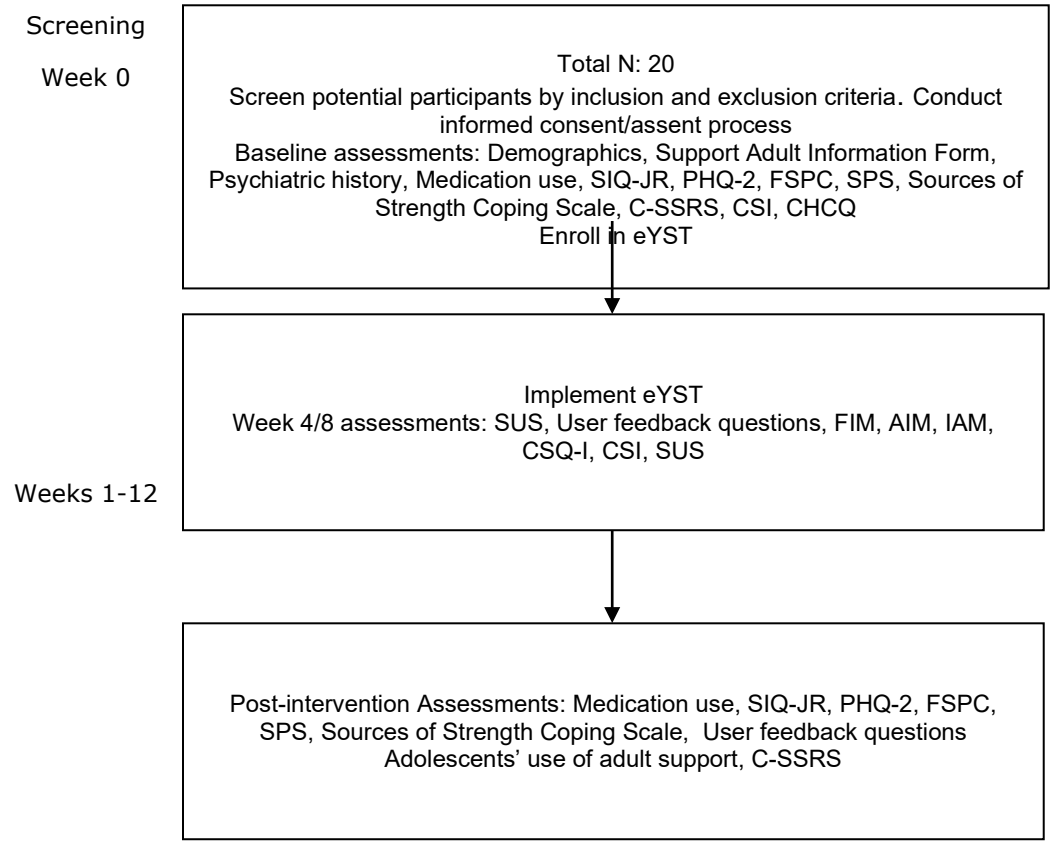
1.1 ABBREVIATIONS

AE	Adverse Event
AIM	Acceptability of Intervention Measure
EC	Ethics Committee
eCRF	Electronic Case Report Form
CFIR	Consolidated Framework for Implementation Research
CFR	Code of Federal Regulations
CHCQ	Chronic Health Conditions Questionnaire
COREQ	Consolidated Criteria for Reporting Qualitative Research Checklist
CSC	Clinically Significant Change
CSI	Cornell Services Index
CSQ-I	Client Satisfaction Questionnaire
C-SSRS	Columbia-Suicide Severity Rating Scale
ED	Emergency Department
EDC	Electronic data capture
ED-STARS	Emergency Department Screen for Teens at Risk for Suicide
E-REP	Enhanced Replicating Effective Programs
FDA	Food and Drug Administration
FIM	Feasibility of Intervention Measure
FSPC	Family, School, and Peer Connectedness

GCP	Good Clinical Practice
GP	General Practitioner
HIPAA	Health Insurance Portability and Accountability Act
IAM	Intervention Appropriateness Measure
ICH	International Council on Harmonization
IEC	International Electrotechnical Commission
IRB	Institutional Review Board
MedDRA	Medical Dictionary for Regulatory Activities
NIMH	National Institute of Mental Health
PHI	Protected Health Information
PHQ-2	Patient Health Questionnaire-2
PHQ-9	Patient Health Questionnaire-9
PI	Principal Investigator
PO	Program Official
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
RCT	Randomized clinical trial
SA	Suicide attempt
SAE	Serious Adverse Event
SI	Suicide ideation
SIQ-JR	Suicide Ideation Questionnaire Jr

SPS	Social Provisions Scale
SUS	System Usability Scale
TAU	Treatment as usual
YST	Youth-Nominated Support Team
YST-Is	Youth-Nominated Support Team intervention specialists

1.2 STUDY SCHEMA



1.3 SCHEDULE OF ACTIVITIES

Table 1. Schedule of Assessments

	Study Periods												
	Screening	Intervention											
Week (W)	W0	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12*
Informed Consent / Assent	Y, P, A												
Demographics, Contact, and Information Form	Y, P, A												
Medical Chart Abstraction (Completed by study staff)	Y												
Medication use	Y*												Y*
Chronic Health Conditions Questionnaire (CHCQ)	Y*												
Enrollment in eYST	Y, P, A												
Suicide Ideation Questionnaire Jr (SIQ-JR)	Y												Y
Patient Health Questionnaire-2 (PHQ-2)	Y												Y

	Study Periods												
	Screening	Intervention											
Week (W)	W0	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12*
Family, School, and Peer Connectedness (FSPC)	Y												Y
Social Provisions scale (SPS)	Y												Y
Sources of Strength Coping Scale	Y												Y
System Usability Scale (SUS)					Y, P				A				
User feedback questions					Y, P				A				A
Feasibility of Intervention Measure (FIM)					Y, P				A				
Acceptability of Intervention Measure (AIM)					Y, P				A				
Intervention Appropriateness Measure (IAM)					Y, P				A				
Client Satisfaction Questionnaire (CSQ-I)					Y, P				A				
Cornell Services Index (CSI)	Y*												Y*

	Study Periods												
Screening	Intervention												
Week (W)	W0	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12*
Columbia-Suicide Severity Rating Scale (C-SSRS)	Y												Y
Adolescents' use of 'caring adult' support (quality, amount)													Y
Measures Administered via eYST													
Presenting Concerns	Y*												
eYST Check ins		A	A	A	A	A	A	A	A	A	A	A	A

Y = Youth | **P** = Parent | **A** = Support Adult |
* = Parent Reported

2. INTRODUCTION

Suicide is the second leading cause of death among adolescents in the US (Heron, 2021). Adolescents hospitalized for suicide ideation (SI) or suicide attempt (SA) are at risk for future SAs (Miranda et al., 2014) and early mortality (Kapur et al., 2015); rates of death by suicide may be as high as 10% by 15 years post discharge (Kapur et al., 2015). Despite these known risks, many suicidal adolescents do not obtain recommended treatments after hospital discharge (Chung et al., 2017) because of barriers to access, stigma (Arora & Persaud, 2020; Moskos et al., 2007), and the unavailability of enough providers trained to deliver effective suicide prevention (Institute of Medicine (US) Committee on Pathophysiology and Prevention of Adolescent and Adult Suicide, 2002; Substance Abuse and Mental Health Services Administration (SAMHSA), 2020). Additionally, although suicide can be preventable when timely intervention is available (King, Arango, et al., 2019), few treatment interventions have been developed for adolescents and even fewer have demonstrated impact on morbidity or mortality. Thus, there is an urgent need to develop scalable suicide prevention methods.

Youth-Nominated Support Team (YST) is a three-month program that pairs adolescents, who are being discharged from a healthcare facility after a suicide attempt, with adults (known as support adults) whom the patient selects to become their support network (King et al., 2009). YST provides tailored education and ongoing support to these adults who, in turn, encourage youth to adhere to recommended treatments and make positive behavioral choices (King, Arango, et al., 2019). Although associated with reduced self-injury mortality and designated a promising intervention (Substance Abuse and Mental Health Services Administration (SAMHSA), 2020), YST is not readily scalable as it requires significant time commitment from mental health professionals, known as YST intervention specialists (YST-Is), and necessitates engagement and coordination from multiple personnel. To mitigate these limitations, we propose to build eYST, a digitized version of YST, which will streamline YST's operational processes.

2.1 BACKGROUND

2.1.1 Summary of Clinical Findings for Youth-Nominated Support Team (YST)

YST is a three-month psychoeducational, social support program for adolescents at risk for suicide, which aims to strengthen each adolescent's supportive network of adults (King, Arango, et al., 2019). YST is the only youth suicide prevention program that has been associated with reduced mortality and, specifically, self-injury mortality. YST's association with reduced mortality was not only statistically significant, but also clinically meaningful. With a conservative estimate based on the lowest end of the confidence interval, YST reduced mortality by at least 50%. Moreover, YST was associated with a more rapid reduction in SI and with obtaining more mental health treatment, a hypothesized mediator of improved outcomes. However, YST is not widely implemented, and few healthcare staff have formal training in this method. Thus, scaling YST (through eYST), while including features that track and support implementation fidelity, has the potential to save lives and reduce suffering among the many youth who are suicidal. eYST will reduce the need for provider time and help youth develop a robust support network.

Oui Therapeutics (through its telehealth business) and Dr. Cheryl King (the developer of eYST) are administering YST. Through a pilot study of YST in our telehealth business (with no digital automation), we have learned that health plans are willing to pay for YST, care managers

will refer patients to YST, parents will enroll their children in YST, and support adults will agree to participate in YST. We have also determined the need to increase efficiency by 1) digitizing components of the psychoeducational training delivered to youth, parents and support adults; and 2) reducing administrative burden on the YST-Is by automating the nomination and contact processes.

2.1.2 Overall Rationale for the Study

The purpose of this study is to digitize The Youth Nominated Support Team (YST) by developing eYST and conducting a single arm feasibility and acceptability trial. This intervention will be nationally scalable and accessible to suicidal youth and has strong potential to lead to a reduction in the youth suicide rate.

2.2 PRODUCT

2.2.1 Platform Overview

The product of this project will be a functional platform (called eYST) which will digitize and optimize the operational processes of the YST intervention. eYST will allow Oui Therapeutics to nationally scale YST with fidelity. The long-term goal of eYST is to markedly increase access of a proven intervention and deliver a digital and scalable solution that can be easily integrated with the existing infrastructure of behavioral health programs, ultimately aiding in reducing the likelihood of youth attempting suicide.

We will build eYST, which follows the key steps of YST (See Table 1). YST is a three-month psychoeducational, social support program for adolescents at risk for suicide, which aims to strengthen each adolescent's supportive network of adults. It is based in a conceptual model of social support that emphasizes how relationships with caring adults may positively impact adolescents' mental health by: 1) improving their connectedness; 2) providing helpful information/facilitating problem-solving; 3) framing experiences and problems in a constructive way; and 4) encouraging healthy behaviors (e.g., treatment adherence) (Substance Abuse and Mental Health Services Administration (SAMHSA), 2020). YST is also based in health behavior theories that emphasize attitudes and support related to treatment seeking (Gipson & King, 2012). Adolescents nominate caring adults in their lives to serve as support persons after hospitalization. These adults attend a psychoeducational session to learn about the youth's treatment plan, suicide warning signs, communicating with adolescents, and how to support the youth's treatment adherence and other healthy behaviors. They meet with the adolescent at least weekly to provide emotional support and encourage positive behavioral choices. YST-Is then provide nominated adults with weekly consultation for three months to address questions and concerns. Building on these findings, eYST includes automations in 6 parts of YST.

Table 1. Comparison of Traditional Youth Nominated Support Team (YST) implementation to eYST implementation.

	YST intervention specialists (YST-Is) tasks	**eYST tasks**

Launch	1. nintroduce parents and youth to program	1. iintroduce parents and youth to program via website (text/video)*
Nomination process	2. hhelp youth nominate up to 4 supportive adults 3. oobtain parent/guardian approval	2. hhelp youth nominate up to 4 supportive adults via website* 3. oobtain parent/guardian approval via website*
Initial Contacts with Nominated adults	5. eestablish contact 6. eexplain role of YST support adult 7. oobtain written informed consent 8. aassist with re-nomination if a support adult declines 9. ccomplete YST support adult information forms 10. sschedule psychoeducation session	5. eestablish contact via automated SMS text and email (sent at nomination) 6. eexplain role of YST support adult via website (text/video) and provide contact information of YST-Is for questions 7. ssupport adults opt into the study electronically 8. aassist with re-nomination if a support adult declines 9. hhelp adult complete YST support adult information forms 10. ssupport adult schedules telephone/video call
Psycho-education	11. dduring meeting provide psychoeducation covering suicide risk, emergency contacts, communication best practices (i.e., style of language) and frequency of contact 12. dduring meeting discuss youth's treatment plan	11. pprior to meeting provide and track completion of asynchronous psychoeducation via website text and videos covering suicide risk, emergency contacts, communication best practices (i.e., style of language) and frequency of contact 12. dduring telephone/video call YST-Is discuss youth's treatment plan
Support Check-ins	13. ccheck-in with YST support adult via telephone 14. ddocument check-in with support person	13. ccheck-in with YST support adult, scheduled via eYST platform, will occur weekly across the 12 weeks. With opportunities for additional check-ins if needed 14. ddocument check-in with support person automatically through eYST
*=done in the presence of a clinician/YST intervention specialist		

1) *Launch.* Video and text content on the website introduce parents and youth to YST in the presence of a clinician.
2) *Nomination.* Video and text content on the website explains the qualities of appropriate, and inappropriate, support adults. Youth enter the names and contact information, if they

have, for possible support adults into eYST. Parents approve support adults via the website and complete any missing information for them.

3) *Initial contacts with nominated adults.* Once the parent approves the nominated adults, an automated SMS text and email is then sent to each support adult. These messages contain a link to a program introduction that explains the role of the support adult. After the support adult opts into the study, they schedule a telephone/video call with the YST-Is through eYST.
4) *Psychoeducation.* Prior to meeting with the YST-Is, support adults will review brief introductory psychoeducation videos and related text content (e.g., adolescent mental health information) on the website. After completion of psychoeducation is confirmed, the YST-Is will have a telephone/video call with the support adult to discuss the youth's individualized treatment plan, communication with adolescents, and strategies for encouraging the youth's treatment adherence and healthy behaviors.
5) *Support check-ins.* Support persons will provide information about how their check-ins with the youth are progressing (see assessments above) via the eYST platform, as well as schedule weekly check-ins with the intervention specialist across 12 weeks.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 Known Potential Risks

Aims 1 & 2: There is the risk that confidentiality may be broken. We will take appropriate measures (see Section 14. Data Security for eYST) to minimize this risk.

Aim 2: There are risks of emotional discomfort and distress from talking about suicide and other sensitive topics. Participants will be informed of voluntary participation. At the baseline, youth will be in the psychiatric inpatient unit. If distressed, participants will be directed to speak with clinical staff on the unit. At each follow-up assessment, youth will be provided with crisis emergency information (number to Psychiatric Emergency Services (PES) and Suicide Prevention Lifeline) to be used as needed. This information will also be provided to youth's parent/legal guardians and adult support persons at the onset of the study. A risk management action plan (see below) will be implemented as needed.

2.3.2 Known Potential Benefits

The benefits of YST and follow-up after a hospital visit for suicidal ideation have been well-documented (King et al., 2018; King, Arango, et al., 2019; King et al., 2009) in the research of Dr. King and colleagues. A digital approach will provide this intervention and support systems to individuals who otherwise might go without them.

2.3.3 Assessment of Potential Risks and Benefits

This study presents a minimal risk because the digital platform does not involve any invasive or risky medical procedures and can be considered no greater risk than ordinarily encountered in daily life.

3. OBJECTIVES AND HYPOTHESES

3.1 PRIMARY OBJECTIVES AND HYPOTHESES

This study has two primary aims: 1) develop eYST, a platform to support more efficient implementation of YST; and 2) test the feasibility and acceptability of eYST in a single-group, open-label trial.

SPECIFIC AIM 1: Develop eYST. Development of eYST will be informed by key stakeholder interviews (conducted by Oui Therapeutics) and will include complete quality assurance. The benchmark for success for this aim is to develop a functional app that is consistent with YST.

SPECIFIC AIM 2: Test the feasibility and acceptability of eYST in a single-group, open-label trial (conducted at UM)**.** Participants will be hospitalized youth patients who have acute suicide risk, their respective parents/guardians, and the support adults each youth nominates. The primary objective of this 12 week, single-group clinical trial, is to test the usability and feasibility of eYST. The benchmark for success is for eYST to be rated as usable (i.e. average System Usability Scale (SUS) score = 68 or above). We will also capture frequency of eYST app use for each participant, as well as the duration of app use.

3.2 SECONDARY OBJECTIVES AND HYPOTHESES

The secondary outcome measures will include Feasibility of Intervention Measure (FIM), Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Client Satisfaction Questionnaire (CSQ-I).

We will also collect exploratory clinical outcomes, including suicidal thoughts and behaviors, mental healthcare service utilization, and perception of adult social support, to examine the range and variability of outcomes associated with YST.

4. STUDY DESIGN

4.1 OVERALL DESIGN

AIM 1: To develop eYST, we (i.e., Oui Therapeutics team) will complete the following activities: stakeholder (e.g. youth, parents, mental health providers, clinical administrators, and health plan providers) interviews, wireframe development, software design, software engineering, quality assurance, and training content development.

We will use implementation science frameworks listed below to understand the needs of stakeholders and to examine system-level factors. Concurrently, we will gather product requirements for the wireframes of the entire eYST workflow. This will be completed within 90 days. (See Study Timeline in Appendix A.)

1) *Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE- AIM):* We will use the first components of RE-AIM (Glasgow et al., 1999) to ensure that eYST is designed for ease of implementation and aligns with practice priorities.

2) *Consolidated Framework for Implementation Research (CFIR):* We will use the CFIR (Damschroder et al., 2009) to identify and address barriers and facilitators to eYST uptake across multiple stakeholder levels and within a particular implementation context.
3) *Enhanced Replicating Effective Programs (E-REP):* We will use E-REP (Kilbourne et al., 2019; Kilbourne et al., 2007) to produce an eYST intervention package that facilitates the adoption and widespread dissemination of eYST. The eYST intervention package, which will be accessible to and useable for clinical administrators, will include: 1) a stakeholder guide that describes the implementation context and process; 2) a user-friendly manual; and 3) a fidelity measurement tool.

Complete design, engineering, and quality assurance of the eYST beta version will follow and is expected to take up to 90 days (partially in concordance with and) following stakeholder interviews and wireframe development. The beta version will focus on content of eYST and the User Interface (UI). Content will be developed with existing YST materials. The digital platform will include robust engagement features for youth users, support adult users and YST-Is users to reduce and prevent implementation drift (and thus maintain fidelity).

AIM 2: To test the feasibility and acceptability of eYST in a single-group, open-label trial (conducted at UM), youth participants will be recruited and enrolled while on the child and adolescent psychiatric inpatient unit in the Department of Psychiatry at Michigan Medicine, or following discharge via phone or email. After youth assent and parent/guardian consent, the youth and parents will be directed to the eYST website where eYST will be delivered as described above in Section 2.2.1 Platform Overview. Assessment data from multiple stakeholders (i.e., youth, parents, and support adults) will be collected at baseline, 4 weeks, 8 weeks, and 12 weeks via self-report and semi-structured interviews. Feasibility and acceptability of implementation will be assessed by collecting data on recruitment, retention, usability, and satisfaction. We will review characteristics of youth, parents, support adults, and the program that may contribute to uptake, in addition to the exploratory clinical outcomes noted above in Section 3.2 Secondary Objectives and Hypotheses.

4.2 DEFINITION OF END OF TRIAL

The end of trial is the date of the last visit/telephone follow up of the last participant. A participant is considered to have completed the study if they have completed the baseline assessment, all intervention tasks, and all follow-up assessments.

5. RESEARCH LOCATION

AIM 1: Stakeholder interviews will be conducted by Oui Therapeutics via video calls, telephone, and/or email. Platform development will be facilitated by Github (for code version control), Sentry (for issue reporting and tracking), Firebase App Distribution (for beta/internal releases), and Detox (for automated app testing). To work on the products interface, Oui will use Figma, a web-based design tool that allows for fast wireframing, development of mock-ups and rapid prototyping.

AIM 2: The trial will be conducted at The University of Michigan/Michigan Medicine. Study procedures may occur on site and remotely. Study enrollment will occur in person and virtually at the University of Michigan's child and adolescent inpatient psychiatry unit, or remotely following discharge from the unit. Study follow-up will occur primarily via telephone/video calls, survey tools (such as Qualtrics), and the eYST platform.

A Research Agreement between Oui Therapeutics, Inc. and The University of Michigan will be executed prior to study start.

6. STUDY POPULATION

AIM 1: Participants will be youth, parents, mental health providers, clinical administrators, and representatives from health plan providers that can inform and provide feedback on the development, uptake, implementation, and sustainability of eYST.

YOUTH PARTICIPANT INCLUSION CRITERIA

1) Patients of any gender age 13 to 17 years.
2) Understand written and spoken English.
3) Willing and able to complete study procedures.
4) Patients presenting to the emergency department (ED), observation, or hospitalized for suicide risk OR seeking other mental health services regardless of suicide risk.

YOUTH PARTICIPANT EXCLUSION CRITERIA

1) Patients with active psychosis.
2) Patients experiencing substance withdrawal.
3) Patient unwilling or unable to wear a mask during in person study procedures, if mandated due to current COVID/health safety guidelines.
4) Any other psychiatric or medical condition or custody arrangement that in the investigators' opinion would preclude informed consent or assent or participation in the trial.

Inclusion criteria for parents/guardians includes: 18+ years, understand written and spoken English, parent/guardian of a child participating in Aim 1, and willing and able to complete study procedures.

Inclusion criteria for mental health providers, clinical administrators and representatives from health plan providers includes: 18+ years, understand written and spoken English, and willing and able to complete study procedures.

AIM 2: Participants are hospitalized youth patients who have acute suicide risk, their respective parents/guardians, and the support adults each youth nominates.

YOUTH PARTICIPANT INCLUSION CRITERIA

1) Patients of any gender age 13 to 17 years.
2) Inpatient psychiatric patients who have attempted suicide or have documented SI and a plan to harm themselves at admission.
3) Understand written and spoken English.
4) Own a smartphone or mobile phone.
5) Willing and able to complete enrollment procedures.
6) Parent or guardian and youth able to understand the nature of the study and provide written informed consent and assent for youth
7) Patients who are able to provide at least one verifiable contact for emergency or tracking purposes.

YOUTH PARTICIPANT EXCLUSION CRITERIA

1) Patients with active psychosis.
2) Patients experiencing substance withdrawal.
3) Currently enrolled in other treatment studies for the symptoms and behaviors targeted.
4) Patient unwilling or unable to wear a mask during in person study procedures, if mandated due to current COVID/health safety guidelines.
5) Patients who in the judgment of the investigator would have an unfavorable risk or benefit profile with respect to eYST.
6) Any other psychiatric or medical condition or custody arrangement that in the investigators' opinion would preclude informed consent or assent or participation in the trial.

Inclusion criteria for parents/guardians includes: 18+ years, understand written and spoken English, own a smartphone or mobile phone, parent/guardian of a child participating in Aim 2, and willing and able to complete study procedures.

Inclusion criteria for support adults includes: 18+ years, understand written and spoken English, own a smartphone or mobile phone, nominated by a child participating in Aim 2, and willing and able to complete study procedures.

7. PARTICIPANT RECRUITMENT

AIM 1: Four youth, four parents, four mental health providers and four clinical administrators/health plan representatives will be recruited from clinical sites that our study team is affiliated with in Connecticut and Michigan (e.g., Psychiatric Emergency Services, Michigan Medicine).

At Michigan Medicine, the study team will work with clinical/hospital staff to identify potentially eligible participants. After verifying inclusion criteria, the study team will reach out to potentially eligible participants and provide a brief introduction about the study (verbally in-person/virtual meeting or via email/phone). Those who express interest will be provided with

additional study information (e.g., time duration, compensation, the voluntary nature of their participation etc.).

Providers, hospital staff, or health care representatives will be contacted via email/phone/in person.

If the potential participant does not respond , the staff at Michigan Medicine will send additional reminders (via email or phone), up to three times

Parents and youth will be recruited in person (or during a virtual meeting) while the youth is in care. If research staff cannot connect with parent while they are visiting the unit (virtually or in-person), research staff will reach out to the parent via phone or email (information attained from medical record). If the parent does not respond, up to two additional attempts will be made to reach them.

If a potential participant indicates interest, they will be given information so that they can reach out to the staff at Oui Therapeutics. Additionally, the study team at Michigan will attain contact information from eligible participants (including name, email, phone number) and provide this information to Oui Therapeutics. Oui Therapeutics staff will reach out to potential participants (or potential participants will reach out to Oui Therapeutics). Oui Therapeutics staff will then conduct the remaining procedures of Aim 1 (under WCG IRB approval) including consent/assent procedures and the stakeholder interviews.

AIM 2: Twenty youth, 20 parents/guardians, and up to 80 supporting adults will be enrolled in the trial (up to 120 participants total).

The study team will work with hospital staff in the psychiatric inpatient unit at Michigan Medicine to identify eligible participants. Eligible participants will be invited to participate in the study while they are patients in the psychiatry unit, or following discharge. The detailed recruitment procedures are as follows:

1) Eligible parents (as identified by the research staff) will be invited to meet with a study clinician virtually via telephone/video call or in a private room located in the facility (depending on preference and feasibility). The parent will be provided information about the study's purpose, procedures, risks and benefits. If the parent/guardian is interested in having the youth participate in the study, they will be asked for permission to talk to the patient about the study. The parent may or may not be part of the discussion between the adolescent and study clinician. The study staff will share the study's purpose, procedures, and risks and benefits with the patient.
    a. If research staff cannot connect with parent while they are visiting the unit (virtually or in-person), research staff will reach out to the parent via phone or email (information attained from medical record). If the parent does not respond, up to two additional attempts will be made to reach them. If the parent does respond and expresses interest, a time will be set aside to talk to teen (via video or call) and the "Aim 2 YST recruitment script for youth and parents (verbal in-person or via telephone/video call)" will be used.
2) If the patient is willing to be part of the study, both the parent and patient must provide consent and assent, respectively. The consent forms will include a discussion of confidentiality and that the support adult will receive information on the youth's diagnosis

and treatment plan. A copy of the signed assent and consent forms will be given to the participants and a signed copy will be retained at the study site.

3) Enrolled patients will undergo baseline assessments (see Section 8.1 Assessments) before the intervention begins.
4) The research staff will provide patients and parents with a link to the eYST website and a unique code to create their profiles.
5) Research staff may reach out to parents and youth via telephone/video and complete portions of the recruitment/enrollment process fully virtual (depending on family preference and feasibility).
6) Through the patient profile, the patient will be asked to nominate up to four adults (who will become support adults, if they opt into the study). Youth will be encouraged to choose adults from different spheres of life (e.g. family member, teacher, and religious leader, etc.) who have a good and supportive relationship with the patient.
7) The parent will receive a notification to review and approve the nominated support adults. The notification will have a link to their parent profile where they may click to approve or disapprove of the nominated support adults.. If the parent disapproves of any of the nominees, the parent will be asked to discuss their decision with the patient and the patient may be given the opportunity to identify a suitable substitute.
8) Following parental approval, an automated email and/or text communication will be sent to the nominated adults (up to four attempts), which will contain a link where study information is presented (i.e., required elements of informed consent as part of informed consent waiver requested). After reviewing this information, they will have an option to accept or deny the invitation to participate in the eYST research study. If the nominated adult does not respond to the invitation, the YST intervention specialist (YST-Is) may reach out via phone (up to two attempts) to ensure communication was received and address any questions.
9) Support Adults who accept the invite may have a call with a member of the research team to further discuss the study, responsibilities, benefits and risks. Additionally, at the start of the orientation session, Support Adults will have an opportunity to ask any questions about the eYST research study. If the research team determines that a support adult is not suitable for the role, the YST-Is will report that concern to the Principal Investigator (PI) and Co-Investigators.

Given that our population will include patients who may have arrived at the hospital in crisis and our procedures have the potential to cause emotional distress, participants will not be recruited for the study on the first day of admission.

Waiver of HIPAA Authorization

A waiver of HIPAA Authorization will be requested so that the study team can review medical records of potentially eligible patient participants. Research staff will be trained on specific steps and procedures for collecting data from patient participants' medical record (e.g., search for self-injury and suicide attempt ICD codes) and the patients' care team.

8. STUDY ASSESSMENTS AND PROCEDURES

AIM 1: *The following procedures will be completed by Oui Therapeutics (under WCG IRB approval):* After providing informed consent or assent, parents and youth will complete 45-60 minute interviews separately. Other stakeholders will choose a 45-60 minute individual or group interview with their peers. Interviewers will follow semi-structured interview guides to gather information on factors that influence uptake, implementation, and sustainability of eYST.

Interviews will be conducted via video call or telephone. If feasible and preferred, interviews may be conducted in person. Interviews will be audio/video recorded to aid in data analysis. Participants will complete a standard demographics form after the interview.

AIM 2: Adolescents who are eligible to participate and assent and whose parents provide consent will formally start eYST by completing the support person nomination process while receiving inpatient care. This step can also be completed following discharge, as needed. Study participants will also be asked to complete baseline assessments (described below in Section 8.1 Aim 2 Assessments) while receiving inpatient care.

Once support adults enroll into the study, they are asked to watch a training video to learn about psychosocial health for youth. They will then have a telephone/video call with a member of the research team to learn about the patient's specific psychosocial needs and how to best engage the patient during the intervention. The telephone/video call will be audio/video recorded for fidelity purposes.

eYST implementation. During inpatient hospitalization, the youth and parent are directed to the eYST website by a clinician. eYST will be delivered as described above in Section 2.2.1 Platform Overview. During follow-up, support adults will be able to use the eYST website to communicate with the Intervention Specialist at their leisure throughout the study, in addition to the 12 automatic check-ins. At the 12 eYST automatic check-ins, support adults will be asked to select preferred times for the Intervention Specialist to schedule a telephone/video call with support adults to provide additional support (12 expected video/telephone check-ins during the 12-week intervention). The telephone/video calls will be audio/video recorded for fidelity purposes.

Adolescents, parents, and support adults will complete follow-up assessments at weeks 4, 8, and, 12, as described in Assessment Table 1.

In addition to follow-up assessments, support adults will be asked to complete 12 electronic progress forms (via the eYST platform) regarding their social support of the adolescent during the intervention period.

8.1 AIM 2 ASSESSMENTS

We will collect assessment data from multiple stakeholders (youth, parents, and support adults). In addition to self-report scales, semi-structured interviews will be completed with a clinician and/or study staff via telephone/video call (see Assessments table below; Assessment schedule described in Table 1). Each youth assessment session will begin by confirming via telephone/video whether the youth and guardian are together. If they are not, the YST-Is will schedule another assessment session.

Assessment	Construct	Description
Primary Effectiveness Outcome		
System Usability Scale (SUS)	Usability	We will use the SUS and also conduct a semi-structured user feedback interview to systematically capture usability and acceptability. The SUS is a valid and reliable, 10-item measure that can be used to effectively differentiate between usable and unusable systems by youth and adults. Scores range from 0 to 100. We will calculate the mean score. A mean score of 68 is the minimal indicator of usability.
Frequency and Duration of App Use	Usability	Frequency and duration of app use will be tracked for each participant. We will record the number of logins and duration of logins.
Secondary Outcomes		
Feasibility of Intervention Measure (FIM)	Feasibility	A 5-item scale that measures the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.
Acceptability of Intervention Measure (AIM)	Acceptability	A 5-item scale that measures the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.
Intervention Appropriateness Measure (IAM)	Perceived Intervention Appropriateness	A 5-item scale that measures the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer, and/or perceived fit of the innovation to address a particular issue or problem.
Client Satisfaction Questionnaire (CSQ-I)	Satisfaction	The CSQ-I is a valid and reliable scale for measuring overall satisfaction with health and human services, including digital or internet-based interventions (Boss et al., 2016; Miglietta et al., 2018). This will be adapted for use with youth, parents and support adults.
Exploratory Outcomes		

Assessment	Construct	Description
User feedback questions	Usability	All stakeholders will answer open-ended questions related to the eYST website features to obtain feedback regarding the social support program for future improvements.
Suicide Ideation Questionnaire Jr (SIQ-JR)	Suicide Ideation	The SIQ - JR is a 15-item, validated self-report scale that is part of the PhenX Toolkit (Reynolds, 1987). It assesses suicidal thoughts over the past month. Items are rated on a 0-6 scale that captures the frequency of the thoughts of adolescents.
Patient Health Questionnaire-2 (PHQ-2)	Depression	The PHQ-2 is a self-administered and validated tool to measure depressive symptoms (Kroenke et al., 2003). The PHQ-2 inquires about the frequency of depressed mood and anhedonia over the past two weeks. The PHQ-2 includes the first two items of the PHQ-9 (Kroenke et al., 2001).
Family, School, and Peer Connectedness (FSPC)	Connectedness	We will use the three 2-item scales to assess Family, Peer and School connectedness, which have shown predictive validity for adolescent suicide attempt outcomes (King, Grupp-Phelan, et al., 2019). This brief scale was adapted from the previously validated Parent-Family Connectedness Scale (Resnick et al., 1997), the School Connectedness Scale (Resnick et al., 1997) and the Adolescent Connectedness Scale (Karcher & Sass, 2010).
Social Provisions scale (SPS)	Connectedness	Connectedness will be assessed using the validated SPS (Cutrona & Russell, 1987). This scale is a 24-item scale that consists of six subscales to measure the availability of social support: emotional support or attachment, social integration, reassurance of worth, tangible help, orientation, and opportunity for nurturance.
Sources of Strength Coping Scale	Connectedness	The Sources of Strength Coping Scale (Wyman et al., 2010) assesses the extent to which youth view resources (e.g. family, friends, adult mentors, services, etc.) as helpful to them. We will use this scale to assess adolescents' perceptions of the availability of guidance, attachment, and reassurance of worth from adults in their lives.

Assessment	Construct	Description
Columbia-Suicide Severity Rating Scale (C-SSRS)	Adverse Events related to Suicidal Ideation and/or Behaviors	Adverse event monitoring will be assessed with the Columbia-Suicide Severity Rating Scale (C-SSRS). The C-SSRS is a semi-structured, rater-based interview to assess the severity and intensity of SI and behaviors (Mundt et al., 2013).
	Demographics, Contact, and Information Form	Interviewer will ask participants their age, gender identity, sex, race/ethnicity
	Medical Abstraction Form	Current psychiatric diagnoses will be obtained by reviewing admission reports and electronic medical records.
	Medication use	Youth medication use will be recorded using a combination of medical record review and parent/youth interview. The following information will be recorded for each medication: name, indication, dose, frequency, start, and end date.
Cornell Services Index (CSI)	Treatment Utilization	Treatment utilization will be assessed using the CSI, an interview-based method that assesses engagement in health treatment (e.g., outpatient psychotherapy, inpatient hospitalization).
Chronic Health Conditions Questionnaire (CHCQ)	Chronic Health Conditions	A 31-item questionnaire adapted from the National Survey of Children's Health (2022) to obtain current and past chronic health conditions and their severity among youth participants.
Adolescents' use of 'caring adult' support	Quality/Frequency of support	The Adolescents' use of 'caring adult' support will ask youth about their interactions with their support adults to better understand how they are using eYST for social support.
eYST platform measures	Youth concerns and support progress	Parents will provide information about current concerns for youth. Support persons will complete 12 weekly check-ins via the eYST platform to indicate progress with youth.

8.2. INFORMED CONSENT

IRB-approved study staff will inform potential participants about the voluntary nature of their participation and that their data will remain confidential. We will inform participants that we

have an NIH certificate of confidentiality. We will communicate the limits of confidentiality, which include reports of imminent suicide risk, homicide risk, abuse of vulnerable individuals (e.g., minors, elderly, and individuals with intellectual disability), and compliance with federal, state, or local laws. In these instances, we will report to the appropriate authorities and/or provide participants with referrals for immediate treatment. Participants will also be informed that they have the right to not participate, or to stop participating in the study at any time. Participants will be allowed as much time as needed to consider the information, and the opportunity to question the PI, his/her General Practitioner (GP) or other independent parties to decide whether they will participate in the study.

Written consent will be obtained by means of a dated signature of the participant and a dated signature of the person who presented and obtained the informed consent. The person who obtained the consent must be suitably qualified and experienced and have been authorized to do so by the PI. A copy of the signed Informed Consent/Assent will be given to the participant. A signed copy will be retained at the study site.

AIM 1 (completed by Oui Therapeutics)**:**

Youth participants must assent to the study. Assent may be given in person on hard copies or electronically.

All other participants 18+ years of age (i.e., parents, mental health providers, clinical administrators, and health plan representatives) must provide written consent. Written consent may be given in person on hard copies or electronically.

AIM 2 (completed by UM Team)**:**

Youth participants must assent to the study. Assent may be given in person on hard copies or electronically. Youth participants who turn 18 years old while still enrolled in the study will provide consent after they turn 18, prior to any further study assessments. Written consent may be given electronically.

Parents/guardians of patients must provide written consent. Written consent may be given in person on hard copies or electronically.

Waiver of Written Consent

We are requesting a waiver of written consent for the adult support persons only. Given that we will not be collecting health-related information (only collecting basic demographic information and perspective on the usability and functionality of the eYST platform for support persons) and that this research presents minimal risk, we plan to reach out to support persons (via text/email or call) and provide a link that details study and program information. After reviewing this information, support persons will be provided with an option to opt into the study and the eYST program. Information provided will specify the elements required for informed consent. Participants will be provided with study contact information to use if they wish to discuss questions and concerns. Additionally, an opportunity for questions and to discuss details of the eYST study will be provided at the support person orientation session.

8.3 SCREENING AND ELIGIBILITY ASSESSMENT

AIM 1: At the University of Michigan, the study team will work with clinical/hospital staff to identify potentially eligible participants.

At Oui Therapeutics, researchers will work with their business associates to identify potentially eligible adult participants for the interviews with mental health providers, clinical administrators, and health plan representatives.

AIM 2 (conducted by UM team): The research staff will identify eligible patients by working with clinical staff on the psychiatric inpatient unit and reviewing hospital records daily, and invite the patients' parents to learn about the study.

8.4 PARTICIPANT ENROLLMENT

AIM 1 (conducted by Oui Therapeutics)**:** Eligible participants interested in study participation will schedule their interview with the Oui study team. Oui will share the consent form with participants prior to their interview. Consent may be given prior to the interview or at the beginning of the interview. Participants will be reminded of any audio/video recording at the beginning of the interview.

AIM 2 (conducted by UM team): After providing informed consent/assent, the research team will administer a structured clinical interview focused on medical and suicide attempt history. Participants will also be directed to the eYST website to begin the trial with an eYST introduction and support adult nominations, as described above in Section 2.2.1 Platform Overview.

8.5 CONCOMITANT MEDICATIONS/PSYCHOTHERAPY

All concomitant medications will be recorded at the Baseline Visit. The following information will be recorded for each medication: name, indication, dose, frequency, start date, and end date. Participation in outpatient psychotherapy will also be recorded with the Cornell Services Index (CSI).

8.6 RETENTION METHODS

<u>Patient and parent/guardian:</u>

1) When the adolescent does not show up to scheduled meetings with their support adults, the support adult will be encouraged to reach out to the adolescent to determine the best way to engage the adolescent. The support adult can also consult with YST-Is during the check in calls with the specialist to determine the best way to keep the adolescent engaged.
2) Patients will receive gift cards at the end of each follow-up session as compensation for their participation, as described below in Section 8.7 Participant Remuneration.
3) Parents will also receive a gift card as compensation for their participation in the feasibility testing, as described below in 8.7 Participant Remuneration.

<u>Support Adults:</u>

1) We have intentionally excluded the adolescent's peers in this role. Prior research by Dr. King shows that peers have a higher dropout rate than adults.
2) Support Adults will have 12 scheduled check in meetings with the YST-Is. This communal expectation and coordination are expected to lower the dropout rate.
3) The frequent meetings with the YST-Is will provide abundant support and guidance for the support adults. This too will minimize dropout rate because the YST-Is may quickly assuage any frustration and uncertainty that the support adult may have.
4) Support adults will receive a gift card as compensation for their participation in the feasibility testing, as described below in 8.7 Participant Remuneration.

8.7 PARTICIPANT REMUNERATION

AIM 1:

Participants will be remunerated with a $25 gift card for completing a feedback form following their interview.

AIM 2:

All youth participants will be remunerated with a $25 gift card for completing the baseline assessment, a $25 gift card for completing the 4 week follow-up and $35 for completing the final 12-week assessment. The maximum total payment amount is $85 in gift cards per participant.

Parents will be remunerated with a $25 gift card for completing the 4 week assessment and a $35 gift card after completing the 12 week follow up assessment. The maximum total payment amount is $60 in gift cards per parent. Support persons will receive a $35 gift card for participation in the 12 -week follow. All disbursement will be documented.

9. STUDY DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

9.1 DISCONTINUATION OF STUDY SITE OR STUDY

The Sponsor has the right to terminate the study at any time. Reasons for site discontinuation include:

- Conduct of the study is not in accordance with the GCP guidelines
- Repeated failure to complete documentation (source documents or eCRFs) / quality of data
- Failure to obtain Informed Consent
- Failure to report Serious Adverse Events (SAEs) within 24 hours of knowledge
- Repeated protocol deviations
- Failure to enroll an adequate number of subjects

The Study Sponsor also reserves the right to discontinue the entire study. Reasons the entire study could be discontinued include, but are not limited to:

- SAEs or if special circumstances concerning the eYST intervention or the company itself occur, making further treatment of subjects impossible

In the event of site or study discontinuation, the study investigator(s) will be informed of the reason for study termination. Study materials must be returned, disposed of or retained as directed by the Study Sponsor.

9.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants (patients, parents, or support adults) may voluntarily withdraw from the study at any time. Patients may notify the study clinician by calling the phone number(s) listed on the informed consent document. Support adults may do the same or contact the YST-Is. An exit interview to gather information about their experience with study may be conducted. Participants may be withdrawn from the study by the PI if they are unable to be contacted (lost to follow-up), become incarcerated or incapacitated, or are determined to be adversely affected by the program.

10. SAFETY

10.1 SAFETY HYPOTHESIS

eYST is safe for use by individuals with a previous history of suicidal ideation and attempts and their support network (i.e., parents and nominated adults).

10.2 ADVERSE EVENTS

Adverse Events (AEs) will be monitored and documented at each study visit. Reporting of AEs will follow Michigan Medicine Institutional Review Board Policy and NIMH policy. Given that all enrolled participants will have a history of suicidal ideation with plan, AEs related to suicidal thoughts/behaviors will be categorized as “expected”.

10.3 RATIONALE FOR IDENTIFICATION OF ADVERSE CLINICAL EVENTS

The proposed study protocol is based on previous trials of YST. Anticipated adverse clinical events are therefore derived from these previous trials. The YST developers have observed the following adverse events in their studies:

- suicidality
- suicidality-related hospitalization

10.4 EXPECTED ADVERSE EVENTS IN PARTICIPANTS

Given that all enrolled patient participants will have a history of suicidal ideation with plan, AEs related to suicidal thoughts/behaviors will be categorized as “expected”.

Therefore, primary anticipated events include:

- increased suicidal ideation and behavior
- suicide-related hospitalization

Any study participation related adverse events are to be followed until there is evidence of resolution or permanent change.

The determination of whether an adverse event is classified as a SAE is based on the definitions below, taking into account the clinical judgment of the investigator.

10.5 SERIOUS ADVERSE EVENTS

AEs meeting any of the following criteria will be categorized as “Serious”:

- results in death
- is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in a persistent or significant disability/incapacity
- results in a congenital anomaly/birth defect
- an important medical event, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition, or
- results in a severely debilitating situation for the subject, such as psychological distress, financial hardship or damaging impact on social standing or employability

Suicidal behavior is an expected outcome of preexisting psychiatric illness. Suicidal behaviors that occur as a result of preexisting psychiatric illness will not be classified as an SAE unless they are associated with the use of the eYST website and also meet the SAE criteria listed above.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participants’ ability to participate and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a SAE.

A SAE may or may not be considered related to study participation.

10.6 REPORTING OF ADVERSE EVENTS

AEs which are unexpected, related, and serious will be reported to the Michigan Medicine IRB within 7 calendar days and to the NIMH PO within 10 business days. Death related to the study will be reported to the NIMH PO within 5 business days. All other AEs will be documented and reported to Michigan Medicine IRB and NIMH PO at the time of the respective annual progress reports.

10.7 REPORTING PERIOD

In this study, all adverse events are collected starting at the time informed consent has been signed. AEs are collected until the last study visit and exit from the study.

10.8 SAFETY MONITORING AND REPORTING

Suicidal ideation/behaviors and other clinical outcomes will be assessed at the Week 0 and Week 12 follow-up assessments. Week 0 is the study baseline assessment, which occurs while the participant is housed in an inpatient treatment facility. For purposes of risk management, results of the study assessment at Week 0 will be shared with the inpatient treatment team in order to provide information relevant to their treatment/discharge planning. The 12 week follow up assessment is conducted by phone. In order to facilitate risk management during study interview calls, we will do the following:

1) Only enroll participants who are able to provide at least one verifiable contact for emergency or tracking purposes;
2) Obtain location information at the start of each phone assessment; and
3) Schedule assessments at a time when the parent/guardian is present at the same location as the participant.

Each youth assessment session will begin by confirming via telephone/video whether the youth and guardian are together. Increases in suicide risk will be communicated to the parent/guardian and outpatient provider (see Appendix B). . In addition, interviewers will engage in risk management interventions as clinically indicated following the guidelines outlined in the Risk Management Plan (see Appendix B). Participants will be informed that information they input to the digital platform is not monitored for purposes of risk assessment.

11. CLINICIAN TRAINING AND SUPERVISION

The original YST manual and measure will be updated to fit the eYST procedures. The eYST platform will provide explicit guidelines (including model scripts) to clinicians regarding intervention components (e.g., facilitating youth nominations, conducting the support adult psychoeducation sessions and check-ins). YST-Is will be licensed mental health professionals with training and experience in adolescent mental health and suicide risk assessment. YST-Is will complete YST-specific training and must successfully complete a certification exam that assesses knowledge of YST components and intervention competencies (via roleplays of psychoeducation session units and telephone check-ins). Additionally, weekly supervision will be provided (individually or in small groups) to YST-Is by a clinical psychologist.

All psychoeducation and weekly check-in sessions will be taped with 25% of sessions reviewed by Dr. Arango and/or Dr. King for clinical supervision and for coding of the successful completion of key components. In addition, YST-Is will complete session checklists following each psychoeducation session as a self-check for coverage of key components.

12. STATISTICAL CONSIDERATIONS

12.1 STATISTICAL PROCEDURES AND DATA ANALYSIS

12.1.1 Primary Effectiveness: Definition of Success (or Failure) of the Endpoint

AIM 1: We will use content analysis to identify themes from qualitative data(Hsieh & Shannon, 2005). Using two raters, transcribed responses will be grouped into themes and a summary of lessons learned. Our team will identify required adaptations for implementing and adopting eYST and use these findings to advise on all subsequent eYST development. We will

use the Consolidated Criteria for Reporting Qualitative Research Checklist (COREQ) (Tong et al., 2007) to provide a detailed report of all qualitative research methods used in our project.

AIM 2: For quantitative data, descriptive statistics will be calculated to examine feasibility and acceptability, including rates of recruitment and eligibility, completion of eYST tasks (for each user type) and completion of assessment appointments. The benchmark for success is for eYST to be rated as usable (i.e. average System Usability Scale (SUS) score = 68 or above). Also, eYST's feasibility measures, such as percentage of nominated adults agreeing to participate in the study and percentage of youth having 3 or more adults participating in the psychoeducation session, must be comparable to metrics from prior YST studies.

12.1.2 Rationale

A single arm design (vs. a controlled design) is appropriate as the workflow for eYST has not been implemented elsewhere. At the end of this study, we will know how to support implementation fidelity, which is key for a future RCT.

Missing data: For missing post-tests, we will use a last observation carried forward imputation, as more sophisticated missing data methods are not appropriate for our sample size.

12.1.3 Justification of sample size-suicide attempts

No power calculation was used to determine sample size because this is an exploratory feasibility study (Jones et al., 2003). Research shows that 5 participants are sufficient to detect 80% of usability issues (Bailey, 2005; Nielsen & Faber, 1996) and 15 are sufficient to detect serious usability issues (Spool & Schroeder, 2001). Therefore, we plan to recruit 20 youth participants, accounting for dropouts.

We will not make conclusive statements about intervention effects due to the small sample size, the single arm design and the fact that clinical improvement may be expected with the passage of time (i.e., without eYST), especially post inpatient admission.

12.1.5 Secondary Endpoints

Analysis of our exploratory outcomes associated with YST including suicidal thoughts and behaviors, healthcare service utilization, and perception of social support will be conducted only to document the extent and variation of change across subjects. The results of these analyses will be interpreted with great caution given the small sample size and single arm design. Clinically Significant Change (CSC) is a metric that can be applied to assess within patient change at the individual level. We will document the percentage of participants who experience CSC from baseline to 12 weeks on the outcomes of interest using procedures described by Morley and Dowzer (Morley & Dowzer, 2014). We will compare patterns of change from baseline to follow-up periods to parallel data from a former RCT of YST (King et al., 2009).

12.2 ADDITIONAL CONSIDERATIONS

Staff training at study initiation

1. Trained/Designated Staff: There will be designated research staff who will be trained to collect study outcomes.

2. Clear Definitions and Electronic Data Capture: We will use a structured method for obtaining all study outcomes. For variables assessed, there will be clear definitions. Staff will receive training in how to apply those definitions and record them in the study electronic data capture (EDC) system.

During study monitoring and support

1. Study Monitoring and Data Fidelity Checks: The sponsor or its representative may visit the study facilities at any time (remotely and /or in person) in order to maintain current and personal knowledge of the study through review of the records, comparison with source documents, observation and discussion of the conduct and progress of the study. The clinical site will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.
2. Fidelity Checks: As part of study monitoring, we will conduct ongoing fidelity checks for the primary outcomes (and other variables of interest). During fidelity checks, records will be pulled randomly. If errors in coding the variables are observed, the nature of the error will be evaluated to determine whether study procedures need to be updated to improve clarity (though unlikely as we are using methodologies established in prior work) and/or staff require additional training in how to capture the study variables.

Procedures for participants who drop out or are lost to follow-up

If subjects drop out or are lost to follow-up, there will be agreements with the subject per the Informed Consent that the research staff can access different sources of information other than medical records. Additional sources of information will be the persons listed as individuals the research staff may reach out to if the research staff cannot contact the participants. The study team may also attempt to obtain final study assessments if possible before withdrawal of consent, as previously mentioned in Section 9.2 Participant Discontinuation/Withdrawal From The Study.

13. APPROACH TO ENSURE INTEGRITY OF DATA TO SUPPORT PRIMARY ENDPOINTS

13.1 REDUCE LIKELIHOOD OF INACCURATE OR BIASED PATIENT REPORTS DURING ASSESSMENTS

- Participants will be instructed to schedule their phone call during a time when they are free from distractions and can provide reliable and accurate responses.
- Data will be collected by research staff or via the eYST platform. The Clinicians (PIs) may be responsible for patient care during study participation, so having independent research staff helps mitigate the risk of potential bias.

13.2 REDUCE LIKELIHOOD OF STAFF DEVIATING FROM THE DATA COLLECTION PROTOCOL

- The data collectors will be trained on conducting the interviews and recording data. The training may include role-playing and simulations. Training will cover how to respond to adverse events.

- The data safety and monitoring plan will be shared with the clinicians. For example, they will be trained on how to differentiate an active suicide crisis from a person who has suicide intent.
- Data collectors will receive ongoing supervision.
- The study team will make appointments for assessments when there will not be distractions for the participants.
- The EDC system will be programmed to validate data where feasible to ensure accurate reporting and to reduce data entry errors and incomplete data

14. DATA SECURITY FOR EYST

14.1 CYBERSECURITY AND DATA COLLECTION

Participant data (including electronic consent forms) will be stored on Michigan Medicine's HIPAA compliant servers. Participants will be given an identification number, which will be matched to participant names in a password-protected electronic document, which will only be accessible to IRB-approved study staff. Only coded, de-identified data will be shared with our company through secure data transfer.

The team at Oui has developed and implemented certain measures to ensure cybersecurity and data protection on previous digital platforms. eYST is built on the fundamental principle of anonymity with security and privacy engineered into the core design. This includes (1) applying a security framework, and (2) ensuring data segregation of Protected Health Information (PHI). The data will not retain participant names when entered into our system and will only be accessible by authorized users. Our measures to ensure cybersecurity and data protection include:

1) Unique password-protected user accounts.
2) Detailed user account enrollment. When users begin the enrollment process and have provided their access code, they will be prompted to fill in their identity information, including their name, date of birth, email address, etc., and a personal password to protect their account. The combination of both their enrolled phone number and personal password will authorize them access to the application on a supported mobile device.
3) Strong password requirements. User passwords will be required to be 8 or more characters in length.
4) Security and penetration testing.

14.2 SECURITY CULTURE

The technology group's primary tool to ensure security for the users will be by starting with a security culture. All server-side processes will be run in docker containers with minimal privileges. Access to non-development environments will be restricted to a few employees and our policy will require it to be used only in emergency measures and with oversight.

14.3 COMMUNICATION

Connectivity to and within eYST will be severely restricted, and all communication will be encrypted.

14.4 ROLE-BASED PRODUCTION ACCESS

Access across all deployment tiers (development, beta, production) leverages a role-based entitlement system that associates privileges with a certain role, which will be then associated with appropriate users to ensure comprehensive access management.

14.5 DATA ENCRYPTION

All personally-identifiable information will be decrypted only in-memory and encryption keys provide a second check on access controls.

eYST data is stored using Google Cloud Platform which ensures that all our data is encrypted in transit and at rest.

14.6 AUDITING

All activity within, access of, and attempted access of eYST will be monitored, logged, and stored for anomaly detection and auditing.

14.7 TESTING

eYST will be declaratively provisioned and will have an extensive testing process run with automated scripts.

15. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Direct access will be granted to authorized representatives from the sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

16. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures. Regular monitoring will be performed according to ICH GCP. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted, and the data generated, documented and reported in compliance with the protocol, GCP and applicable regulatory requirements.

17. KEY STUDY PERSONNEL

OUI THERAPEUTICS, INC.:

Patricia Simon, PhD (Principal Investigator)

Dr. Simon will be responsible for the overall supervision and administration of the project. She will support this project by coordinating the clinical trial protocol and communicating with Co-Investigators. As the Principal Investigator, Dr. Simon will assume primary responsibility for all aspects of the research project and will assure that milestones are met in a timely manner.

Brian Keenaghan, MS (Operations Lead)

Mr. Keenaghan will be responsible for coordinating project activities and managing different stakeholders. He will also coordinate meetings with research partners at the University

Michigan, facilitate team meetings, track progress and report on key milestones. Mr. Keenaghan will also assist Drs. Feuerstein and Simon with writing research reports, patent filings and papers that will result from this project.

UNIVERSITY OF MICHIGAN/MICHIGAN MEDICINE:

Alejandra Arango, Ph.D. UM Principal Investigator/Clinical Psychologist/Study Manager
Dr. Arango is an Assistant Professor in the Department of Psychiatry at Michigan Medicine and a clinical child and adolescent psychologist. She has advanced training in intervention science and is a former doctoral student and ongoing scientific collaborator with Dr. King. Dr. Arango has multiple years of clinical experience working with youth at risk for suicide and is a trained YST intervention specialist. Dr. Arango will oversee the integrity of pilot study implementation with adolescents at the University of Michigan, train the YST-Is, and provide leadership for financial, personnel, and regulatory management of study activities at the University of Michigan. Dr. Arango will also have the following responsibilities: 1) provide day-to-day project management for the pilot study, assisting with the preparation of study operational guidelines, IRB applications, study protocol and assessment surveys, and risk management; 2) provide direct supervision to the clinical social worker, providing backup as needed; 3) supervise the research assistant in the completion of study follow-up assessments, assisting Dr. King with implementation of the risk management protocol; and 4) contribute to the interpretation of data and the preparation of the pilot study report.

Cheryl King, PhD, Co-Investigator
Dr. Cheryl King is a Professor and Director of the Youth and Young Adult Depression and Suicide Prevention Research Program in the Department of Psychiatry at Michigan Medicine. Her research focuses on the development of evidence-based practices for suicide risk screening, assessment, and intervention. She is currently the Principal Investigator of the NIMH-funded project 24-Hour Risk for Suicide Attempts in a National Cohort of Adolescents. A clinical educator and research mentor, Dr. King has served as Director of Psychology Training and Chief Psychologist in the Department of Psychiatry. She is the lead author of Teen Suicide Risk: A Practitioner Guide to Screening, Assessment, and Management; has provided testimony in the U.S. Senate on youth suicide prevention; and is a Past President of the American Association of Suicidology, the Association of Psychologists in Academic Health Centers, and the Society for Clinical Child and Adolescent Psychology. Dr. King will provide ongoing input and expertise regarding the YST intervention and the implementation of the pilot and work with Dr. Simon to develop study operational guidelines, consider study protocol changes, interpret study findings, and prepare study reports.

Social Worker/YST Intervention Specialist
The Intervention Specialist will work under the direct supervision of Dr. Arango, an experienced YST intervention specialist, to implement YST with the 20 pilot study participants. Responsibilities include: 1) participation in YST intervention training and weekly supervision; 2) conduct support person nomination sessions with study participants; 3) conduct psychoeducation sessions with nominated adult support persons; 4) maintain weekly contact with nominated adults support persons; 5) implement risk management protocol.

Research Assistant
The Research Assistant will work under the direct supervision of Drs. King and Arango and have primary responsibility for the following activities: 1) assist in preparation of IRB applications and required progress reports; 2) schedule and implement follow-up assessments for 20 pilot study participants; 3) assist in the preparation of preliminary data reports, poster and oral presentations, and manuscripts; and 4) assist with literature reviews and preparation of other study materials.

18. ETHICS

18.1 DECLARATION OF HELSINKI

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

18.2 ICH GUIDELINES FOR GOOD CLINICAL PRACTICE

The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996.

18.3 APPROVALS

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Institutional Review Board (IRB), regulatory authorities, and host institution(s) for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

18.4 PARTICIPANT CONFIDENTIALITY

The trial staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant's ID number on the eCRF and in any electronic database. All documents will be stored securely and only accessible by trial staff and authorized personnel. The study will comply with the Data Protection Act 1998 which requires data to be anonymized as soon as it is practical to do so.

18.5 OTHER ETHICAL CONSIDERATIONS

Digital therapy: Concerns raised regarding the digital delivery of psychotherapy include confidentiality (Borcsa & Pomini, 2017; Martinez-Martin & Kreitmair, 2018; VA/DOD, 2019) and the absence of a mental health professional (Martinez-Martin & Kreitmair, 2018; Spence et al., 2011). Therefore, the benefits (e.g., convenience, accessibility, and effectiveness) of digital psychotherapy must be assessed in contrast to associated risk of potential disadvantages and harms (Lawlor-Savage & Prentice, 2014).

Research with vulnerable populations: In alignment with 45 CFR 46 subpart D, we include the additional safeguards below to protect the rights and welfare of children during this study.

- Assent and Consent: Youth between the ages of 13 years and 17 years must give assent and at least one of their parents/guardians must consent to the study before

they are enrolled. Patients who turn 18 years old while still enrolled in the study will provide consent when they turn 18 years of age. Both assent and consent forms will be documented following the guidelines of the Institutional Review Board at the University of Michigan's Child and Adolescent Psychiatry.

- Additional risk: This study presents risks no greater than those of treatment as usual (TAU). This is because eYST digitalizes the coordination and training materials of the YST program. The YST program supports suicidal youth by 1) improving their treatment adherence and 2) addressing their negative perception of family and social support. These activities can be part of patients' treatment as usual.

19. DATA HANDLING AND RECORD KEEPING

All study data will be entered on a HIPAA compliant software. ICH GCP requires that electronic data entry systems are validated, and that Standard Operating Procedures are maintained. The participants will be identified by a study specific participants number and/or code in any database. The name and any other identifying detail will NOT be included in any analytical data electronic file.

20. FINANCING AND INSURANCE

The funding for this study comes from the National Institute for Mental Health (NIMH). The sponsor has insurance arrangements and product liability in place.

21. PUBLICATION POLICY

Publication of study results is governed by the Research Agreement with The University of Michigan.

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APPENDIX A

Title: Study Timeline

Project Activities	**MONTHS**																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Specific Aim 1: Develop a Beta Version of eYST																		
Stakeholder Interviews + Collate Product Feedback																		
Assemble Resources + Develop Wireframes																		
Complete Designs + Finalize Content																		
Deploy Beta + Stakeholder Meetings + Study Start-Up																		
Specific Aim 2: Conduct Feasibility and Usability Testing of the eYST Beta Version																		
Enrollment Period (rate of 4 patients/month)																		
3-month Intervention																		
Data Analysis																		

Legend

	On-Going Study Activities

	No On-Going Study Activities

APPENDIX B

Title: Risk Management Plan

GUIDELINES FOR ALL PARTICIPANTS

1. Attentive Listening, Empathic Listening, and Calmness during Assessments and Interactions

It is important to listen carefully and try to understand the participant. The goals are to pay close attention, try to understand the adolescent's distress, and take concerns and suicidal thoughts seriously. Attentive listening shows that the staff member cares. Empathic listening ("It sounds like you are feeling really down about what happened.") will help the patient feel validated. This can decrease stigma and the sense that it is shameful to talk about personal concerns or suicidal thoughts. It is most important that staff never ignore or minimize concerns. We do not want an escalation of their risk behaviors in an effort to communicate the severity of their distress or psychological pain. When appropriate, it is also important to provide a statement of positive affirmation of the participant being willing to share this information with the staff member, both to validate and acknowledge the disclosure and to reinforce future sharing of this type of information.

2. Suicide Risk Assessment

The research staff member will review all available assessment information before terminating the interview to determine if the participant meets high risk criteria. Any indication of increased suicide risk will be followed up on as soon as possible. If the participant meets high risk criteria (described below and in the Action Plan), the research staff member will follow steps described in the Acton Plan, including contacting the supervising clinician on call in order to make a decision about next steps to be taken to evaluate the participant's risk status.

For non-adult participants, a parent/guardian will always be contacted prior to the interview to ensure they are reachable if they need to be contacted for safety concerns or recommendations. If a minor meets High Risk criteria, we will discuss the details of our concerns with both adolescents and parents.

3. Good Documentation

Careful monitoring of risk status over time and solid clinical decision-making require up-to-date documentation of each adolescent's risk status. These will be kept in secured files where they will be available to the Principal Investigator and research staff. In addition to follow-up if participant meets high risk criteria, a risk status review will be conducted by the study Principal Investigator and/or Co-Investigator (Dr. Cheryl King & Dr. Alejandra Arango) on a regular basis to ensure that each participant's risk status was correctly identified and recorded. These review documents will be kept securely.

DETERMINATION OF RISK STATUS AND DEFINITION OF HIGH RISK

If the adolescent expresses suicidal ideation or behaviors consistent with one or more of the high-risk criteria outlined below at the time of the baseline assessment or 3-month follow-up assessment, research staff will notify the attending/treatment team of information learned (if

during psychiatric inpatient stay) or the senior on-call clinician (if assessment occurs outside of inpatient unit) immediately. Follow-up assessments will be completed by phone by a trained study team member who will contact supervising clinician (PhD level, licensed clinical psychologist) immediately if a youth meets high-risk criteria.

Definition of High Risk
(1) Suicidal ideation in the past week with thoughts of a method, plan, or intent (C-SSRS items 3-5)
(2) A suicide attempt since baseline assessment (per C-SSRS) and no psychiatric evaluation was conducted following this attempt (no ED visit or psychiatric hospitalization).
(3) A verbal statement of clear suicidal intent or a plan to attempt suicide.

MANAGEMENT OF HIGH RISK STATUS

1. Procedures

If a participant meets one or more of the above criteria, the project staff member may ask one or more of the following additional questions to help in determining next steps. Responses are recorded in the Action Plan form.

In the last week...
- Has the participant experienced suicidal ideation?
- Has the participant thought of a plan for how to kill self?
- Has there been alcohol or drug use?
- Have there been any psychotic signs or symptoms?

And…
- Has the participant talked about their past week suicidal ideation or behaviors with a provider or with a guardian?
- Does the participant have access to a firearm?
- Is the participant currently in treatment with a psychiatrist, psychologist or social worker? If yes, when was the most recent appointment and when is the next appointment?

2. Action Plan

The staff member will contact the Principal Investigator or on-call Senior Clinician by pager or telephone. Based on the information available, this individual will decide if sufficient information is available to make a determination of risk status, and if so, the degree of risk for suicide. It is possible that the Project Director or on-call Senior Clinician will recommend that the participant and/or parent/guardian go to an emergency room or schedule an appointment (with Access or current mental health professional) in the near future. For any adolescent with *High Risk* status, this information will be shared with the adolescent's parent/guardian. The On-call Senior Clinician may recommend that the participant and/or parent/guardian call 988 or the PES crisis phone service (24-hour line: 734-936-5900) if they are High Risk.

DETERMINATION AND MANAGEMENT OF MILD OR MODERATE RISK STATUS

Definition of Mild or Moderate Risk

(1) Suicidal ideation in the past week (C-SSRS item 2)
(2) Verbal statement of suicidal ideation

Management of Mild or Moderate Risk
If a participant meets one or more of the above criteria, the project staff member will share the information with the youth and parent, provide emergency contact information (e.g., 988, PES crisis phone service [24-hour line: 734-936-5900]), encouraging continued adherence to treatment plan, and encourage the use of the youth's safety plan (i.e., bring up and reinforce efforts and strategies aim at maintaining safety).