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Network Health Intervention for Adolescents Leaving Acute Psychiatric Care

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Network health intervention for adolescents leaving acute psychiatric care
Study Protocol for KL2TR001999

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1. PURPOSE OF STUDY

Our research group developed a new youth-centered module (YM) for the previously validated Youth-nominated Support Teams (YST) intervention, a broader program to prevent re-attempts among adolescent suicide attempters. As part of the principal investigator's KL2 award, we propose a one-armed pilot trial to optimize and evaluate the feasibility, acceptability, and target engagement achieved by adding this module (YST+YM) to the existing intervention. This pilot trial ("study") will proceed in two phases. Phase one (content refinement): we will optimize the YST+YM intervention for feasibility and acceptability (n = 5-10); phase two (pilot): we will conduct a within-subjects pilot trial to test target engagement (social support) with this population (n = 60-70).

2. BACKGROUND AND RATIONALE

Adolescent suicide rates have increased 44% since 2000, and suicide is now the 2nd leading cause of death for youth ages 14-25.[1] Adolescents hospitalized for suicide attempts (ASAs) are a uniquely high risk subgroup: 30% reattempt suicide within a year of discharge.[2,3] Current interventions for ASAs are predominantly individual treatments, which meta-analysis shows reduce adolescent suicide attempts by less than 9%.[4] In contrast to these individual-centered approaches, numerous studies demonstrate that key suicide risk factors (e.g., depression,[5] emotion dysregulation,[6] outpatient treatment adherence [7]) are influenced by social networks - including the peer and adult relationships in which adolescents are already embedded.[8–12]

Overview of traditional YST. The Youth-nominated Support Team (YST)[13,14] is an established intervention for ASAs leaving acute treatment. YST is a supplemental intervention, designed to be added onto normal post-discharge treatment as usual (e.g., outpatient psychotherapy). Patients randomized to YST show a roughly 50% reduction in mortality (all-causes, not just suicide) over 10 years after the intervention, compared to patients discharged to outpatient therapy alone.[15] YST begins roughly one week before discharge from psychiatric hospitalization. At this time, the ASA subject nominates 3-4 trusted adults they already know who will provide social support to the patient for the 12 weeks following discharge. Those adults then receive psychoeducation on the ASA's mental health concerns, as well as weekly check-ins from a trained mental health provider to help those adults troubleshoot any issues with their support role for the ASA. Note, these adults are explicitly told to provide only social support. They do not provide clinical treatment or crisis management as part of YST. Those roles are already fulfilled by each youth's outpatient psychotherapist. Being enrolled in outpatient therapy is a precondition for participating in YST.

Limitations of traditional YST. Despite its established reductions in mortality, YST is limited in that it contains no direct content for the patient at the center of the intervention. In traditional YST, once the patient has nominated their trusted adults, no additional intervention is conducted with the patient - the intervention subsequently targets the behavior of the supportive adults only. These adults are the only ones who receive any contact, psychoeducation, or check-ins with study staff. This leaves multiple social needs of the adolescent unaddressed, such as the need to develop proactive help-seeking skills and the effective utilization of the social support that is now available to them.

Overview of the study and the proposed YST+YM intervention. This investigation proposes a two-phased, one-armed pilot trial to optimize and evaluate the addition of a new youth-centered module (YM) to the traditional YST intervention (i.e., a pilot trial of YST+YM). This module was produced in consultation with YST's creator, Dr. Cheryl King[13–15] and revised with feedback from the Department of Psychiatry Advisory Council of Consumers (DPACC), as well as with feedback from patients from the Child and Adolescent Partial Hospital Service (CAPHS) at the University of Rochester Medical Center.

YST+YM will include **everything in traditional YST**, **plus three one-hour patient-involved sessions** designed to help the ASA set goals for the 12-week post-discharge period and to strategize how they want to utilize the support from their adult team. The first of these sessions will occur prior to discharge and will be either in-person or administered remotely, depending on current URMC policy. The rest of the intervention - mirroring traditional YST - will be entirely remote and conducted either via phone or Zoom. Based on feedback from adolescents in the CAPHS program, patients participating in YST+YM will also receive **weekly automated text messages** asking basic questions about their progress and providing them with encouragement to continue regular contact with their adult support team members. About two thirds of these text messages will be **group text messages** that include both the youth and at least one member of their support team. These multi-person text messages will be designed to prompt co-reflection on healthy relationships and behaviors, consistent with the interventions themes.

Specific Aims & Hypotheses:
Aim 1 - *To optimize YST+YM for feasibility and acceptability.* Outcome**:** Semi-structured interviews and rating scales will identify the most and least preferred elements of the YM module. Response rates to automated text-messages will also be used to evaluate message appeal.

Aim 2 - *To test target engagement: does YST+YM increase utilization of interpersonal emotion-regulation strategies and social support among adolescents with recent suicidal ideation or attempts?* Hypothesis**:** over 12 weeks of YST+YM, subjects will demonstrate increases in: (a) the number of weekly contacts initiated to supportive adults in their lives, (c) the utilization of interpersonal emotion regulation strategies, and (c) their perceived sense of social support. These gains will be maintained at 3-month post-intervention follow-up.

Aim 3: *Estimate prevalence of clinical outcomes for planning of subsequent trials - what is the average rate of clinical over the course of intervention and through 3-month follow-up?* Outcome**:** Estimates of changes in distal targets, including anxiety, depression, and suicidal ideation and attempts for the planning of larger subsequent trials.

3. ADMINISTRATIVE ORGANIZATION

This study will be conducted in the URMC Department of Psychiatry's Child and Adolescent Partial Hospital Service (CAPHS). The director of CAPHS is Charlene Weeks (LCSW-R). Ms. Weeks has been implementing traditional YST for a subset of patients for the last year and reports it has been both feasible and acceptable to patients, caregivers, and clinic staff in CAPHS. Administration of YST+YM will be conducted either remotely via telephone and Zoom, or a mixture of in-person (at CAPHS) and remote administration as the surrounding pandemic context and current CAPHS policy allows. *Information regarding research safety during the **COVID-19** pandemic:* To ensure appropriate safety precautions when conducting in-person study procedures, the process for conducting in-person visits outlined in the Guidance for Human Subject Research (https://www.urmc.rochester.edu/coronavirus/coronavirus-research/guidance-for-researchers/human-subjects-research.aspx) will be followed. The study team will continue to monitor the guidance provided by UR/URMC for updates and revisions to

ensure all study activities are conducted according to current safety guidelines. This protocol was constructed under consultation with Ms. Weeks, who provided guidance on the feasibility and acceptability of the research activities in her clinic.

4. STUDY DESIGN

This study is a two-phased, one-armed pilot trial to evaluate feasibility, acceptability, and target engagement of YST+YM. It will also facilitate estimation of clinical outcome prevalence, including suicidal ideation and attempts over the intervention period and through post-intervention follow-up.

In phase one (content refinement; n = 5-10), feasibility and acceptability will be optimized via measures of subject engagement with the intervention (i.e., text-message response rates) and with subject feedback during semi-structured interviews. We will also assess feasibility of the assessments used to measure emotion regulation, perceived social support and connectedness, and clinical outcomes (i.e., anxiety, depression, and suicidal ideation and attempts).

In phase two (pilot; n = 60-70), target engagement and prevalence of clinical outcomes will be addressed, as well as continued assessment of feasibility and acceptability of YST+YM. Consistent with specific aims above, intervention targets include engagement with treatment (i.e., initiating contact with support team members), changes in emotion regulation skills, and perceived social support and connectedness. Distal targets, including anxiety, depression, and suicidal ideation and attempts will also be assessed to establish point estimates for power analysis and sample size planning in future trials. Subject engagement with the intervention and feedback during semi-structured interviews will be used to assess feasibility and acceptability of YST+YM (following initial modification in response to phase one subject feedback).

Because the intervention lasts approximately three months per subject, the phases will be staggered, such that some subjects will be enrolled in phase two before all phase one subjects have completed their entire intervention course. For example, we anticipate that n = 5-10 phase one subjects may complete the first remote session of YST+YM within 6 weeks of the study start date. Because we collect feedback immediately following each session, this means we will have received all the information required to finalize that session's outline and content for the launch of phase two – even though these phase one subjects will have several weeks left of YST+YM overall.

This study, encompassing both phases one and two, utilizes a one-armed, within-subjects design and will run for roughly 24 total months. Youth subjects will receive the intervention (YST+YM) and will each be assessed at 4 timepoints: prior to initiating intervention (baseline, week 1), the intervention midpoint (week 6-7), the conclusion of the intervention (post-test, week 12), and then 3 months after the intervention concludes (follow-up, 24 weeks). Adult support team members will be assessed only at post-test (week 12).

5. SUBJECT POPULATION

Number of Subjects: This study includes three sets of subjects, including (1) youth patients, (2) parents, and (3) their respective adult support team members. The subject population is the same for both phases one and two.

- Youth patients: We will enroll approximately n = 60-70 total adolescent patients in the Child and Adolescent Partial Hospitalization Service (CAPHS). The first n = 5-10 of these will be used to refine and optimize the feasibility and acceptability of YST+YM. All

subjects will be used to evaluate target engagement. Based on consultation with CAPHS clinical director, Charlene Weeks (LMSW-R), greater than 80% of patients are expected to be eligible for participation. Of eligible patients, roughly 50% are estimated to enroll in the study. Again based on consultation with Ms. Weeks, 75% of the initially enrolled patients are expected to complete the study. Thus, we will screen approximately 165 patients to identify 130 eligible subjects, of which 65 are expected to enroll. Given low attrition for comparable clinical programs in CAPHS (i.e., a year of pilot implementation of traditional YST in that clinic), we conservatively estimate a 25% attrition rate. Attrition will be handled with an intent-to-treat design. Given these considerations, we anticipate n = 50 subjects will provide follow-up data, providing a sufficient sample size to detect a signal for intervention target engagement.

- Parents / legal guardians: We will invite one parent / legal guardian per enrolled youth to provide feedback on the intervention, proxy-ratings of the youth's emotional well-being, as well as self-report of their own well-being. Based on consultation with clinic staff who regularly interact with this population, recruitment and retention rates for parents are expected to be roughly 80% per youth who completes the study. Thus, for the roughly n = 50 youth subjects who provide full follow-up data, we expect roughly n = 40 parents / guardians to complete all measures. This is a sample size sufficient to refine the intervention with informal feedback and to further evaluate target engagement as assessed by proxy-report.
- Adult support team members: Each adolescent patient will be encouraged to nominate n = 3-4 adults they already know and would like to serve on their support team. Because n = 65 adolescent patients are expected to enroll, this means we will screen n = 195 - 260 adults. Prior consultation with CAPHS clinic director Charlene Weeks suggests for every 3-4 adults who are nominated, roughly 2-3 can be expected to enroll. Once enrolled, Ms. Weeks indicated retention of these adults is typically greater than 90%. With these benchmarks, we thus expect n = 130 - 195 supportive adults to enroll in the study and roughly n = 115 - 175 to complete the study in its entirety.

Age of Subjects. Adolescent patient subjects must be between the ages of 12 and 18 at the time of enrollment. Adult subjects will all be over the age of 21.

Gender, Age, Racial, and Ethnic Origin of Subjects: Youth subjects will all be recruited from the Child and Adolescent Partial Hospitalization Service (CAPHS). Their demographic characteristics are thus expected to reflect the demographics of Monroe County, NY, from which CAPHS draws its patients. Adult subjects are most often members of the families and communities in which the youth subjects reside. For this reason, we expect adults to have similar demographic characteristics to the youth subjects from Monroe County, NY. Regarding race, based on US Census data from 2010-2019, the distribution of race in Monroe, NY is as follows: 76.8% White, 16.2% Black, 0.4% American Indian, 3.7% Asian, 0.1% Hawaiian, Two or More Races, 2.7% Mixed. Regarding ethnicity, 9.2% of this population is Hispanic or Latino. We will seek a similar racial and ethnic distribution in this study. The proposed study will be inclusive of all genders and we will seek to recruit an equal number of male and female subjects.

Vulnerable Subjects: The proposed study involves minors with recent suicide-related concerns. Additional protections against risks and coercion are documented below since minors are more "likely to be vulnerable to coercion or undue influence". (45 CFR 46.111(b)) Due to the vulnerable nature of the population we have strictly adhered to guidance provided in the Code of Federal Regulations (45 CFR 46 Subpart D) and specific IRB requirements for subject safety, permission and assent. These additional protections are described in the Risk/Benefit section of the protocol.

6. INCLUSION AND EXCLUSION CRITERIA

Youth subjects:

Subjects will be **included** if:

- Youth subject is being discharged from the Child and Adolescent Partial Hospital Service (CAPHS) in the URMC Department of Psychiatry.
- Youth subject endorses past year suicide attempt OR past year suicidal ideation at time of partial hospitalization, as assessed on standardized intake questionnaire used by CAPHS.
- Youth subject has a cellular phone, with an active service plan, that is capable of sending and receiving standard SMS text messages.
- Youth subject is aged 12 - 18 at time of enrollment.

Subjects will be **excluded** if:

- Youth subject has medical or psychiatric comorbidities that impair ability to assent (e.g., active psychotic or manic episode, cognitive impairment).
- Youth subject patient or guardian does not speak fluent English, as meeting translation costs is not possible in this study.
- Youth subject is unable to name at least 2 trusted adults (at least 1 of which is not a parent or caregiver) they would like to serve on their support team.
- Youth is unable or unwilling to share their suicide-related safety plan

Parent / legal guardian subjects:

Subjects will be **included** if:

- Adult subject is at least 21 years of age.

Adult support team subjects:

Subjects will be **included** if:

- Adult subject is nominated by a youth subject to serve on their adult support team
- Adult subject is approved by youth subject's parent or legal guardian
- Adult subject has a cellular phone, with an active service plan, that is capable of sending and receiving standard SMS text messages.
- Adult subject is at least 21 years of age.

Subjects will be **excluded** if:

- Adult subject has medical or psychiatric comorbidities that impair ability to consent (e.g., active psychotic or manic episode, cognitive impairment).
- Adult subject does not speak fluent English, as meeting translation costs is not possible in this study.
- Adult reports being unable to be in contact with youth at least once per week, for the 12 weeks of the intervention

7. RECRUITMENT METHODS

Over the past year, the Department of Psychiatry's Child and Adolescent Partial Hospitalization Service (CAPHS) already piloted traditional YST to evaluate the feasibility and acceptability of incorporating it into regular clinical care. Consultation with Charlene Weeks (LCSW-R, Director of CAPHS) revealed their existing recruitment procedure for traditional YST was both efficient and acceptable for clinic staff, patients, and their caregivers. The current recruitment procedure is designed to be consistent with CAPHS' previously successful approach. Phases one and two will utilize the same recruitment procedure.

Youth patient identification: All CAPHS therapists will receive a verbal overview of the study,

prior to its implementation. When the study is active, CAPHS therapists will ask their patients with recent suicide concerns (see inclusion criteria) whether they are interested in participating in a post-discharge study. This introduction will occur during normal clinical interaction. Therapists will attempt to time the introduction to be within approximately one week of the patient's expected discharge from CAPHS. If the patient expresses interest during this initial introduction, and confirms to the therapist that they can name two trusted adults they believe would be interested in serving on their support team, the therapist will notify study staff of the patient's interest.

Youth screening: When a CAPHS therapist notifies study staff of an interested patient, study staff will confirm with the therapist that the patient meets study inclusion and exclusion criteria. Consultation with CAPHS therapists confirms they reliably have the information needed to confirm inclusion or exclusion, as this information consistently arises as part of their normal assessment and treatment process with patients.

Importantly, although we will collect clinical information from these therapists for purposes of subject screening, the therapists themselves are not engaged in formal research. Any information we receive from the therapists will be used for screening purposes only and will not be analyzed as part of the study.

Initiation of youth assent process: After confirming with the therapist that the patient is eligible for the study, study staff will schedule a screening and youth assent / parental consent session (see CONSENT PROCESS, below) involving a study interventionist, the patient's current therapist, the patient, and the patient's caregiver. The CAPHS therapists will be included in these sessions, given consultation with Charlene Weeks that patients appear more comfortable during the assent / consent process when the therapist is present. This session will occur before discharge and happen either in-person or remotely (via Zoom), depending on current CAPHS policy.

Parent / legal guardian identification: The parent / legal guardian providing parental permission for each youth subject will also be invited to participate in the study.

Parent / legal guardian consent / permission process: Parents / legal guardians will be asked to consent to their own study participation at the same time they provide youth subject permission.

Adult support subjects identification: Youth subjects who assent (and whose parents / legal guardians also give permission) will be asked to nominate 3-4 adults they already know and who they would like to serve on their support team. Parents and legal guardians will be asked to provide input on the nominations and must provide final approval for all support team members before study staff will attempt contact. Once the youth subject and parent agree on the final list of support team members, study staff will ask for contact information for those adults.

Initiation of adult support subjects consent process: Study staff will attempt to contact adult support team nominees for consent, using the contact information provided by youth subjects and their parents.

8. CONSENT PROCESS

Electronic documentation of consent (eConsent / eAssent): The assent / consent process informs a youth subject, their parent/legal guardian, and adult support team members about the study, indicates the participation is voluntary and he/she has the right to stop at any time. Risks are enumerated in the informed consent form and described orally during the consent process.

The assent / consent documents are a REDCap-based electronic consent forms. The IRB-approved form is developed in REDCap, a secure, web-based, HIPAA- compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g., read only, de-identified-only data views) for other users. Potential subjects participate in the assent / consent process by eConsent obtained in-person or remotely. eConsent is obtained in a private setting, prior to baseline data collection. When obtained in-person, eConsent is accessed on REDCap via the University-issued computer, tablet, or another portable electronic device. University-issued tablets are already available on the study unit and regularly available to patients. Once the eConsent form is signed and submitted, subjects will be able to receive a print out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form. Of note, youth subjects ages 12-17 will complete an eAssent form, while youth subjects who are 18 years old will complete a subject eConsent form.

When obtained remotely, subjects speak on the phone or HIPAA-compliant video conference with URMC staff throughout the consent process. URMC staff request verbal permission to send the eConsent via email or text. The request will state: “Because URMC can’t control the security of email or text messages once we send them, we need your permission to text or email you. Do you want to receive the link to the eConsent via text or email?” The permission will be documented. The email/text will not include PHI. eConsent is accessed on the subject’s personal electronic device (e.g., computers, portable tablets, smart telephones). URMC staff ensure real-time identity verification prior to consent by requesting verification of an established passcode. An agreed passcode is communicated between subjects and the study team. This passcode is saved as part of the subject’s record on REDCap for verification use later. Patients must then enter the passcode which is compared with the stored version entered by URMC staff. Matching responses to the passcode grants entry and non-matching responses block the individual based on specified settings.

All eConsent includes a detailed description of the study procedures, along with statements regarding subjects’ rights to withdraw from the procedure at any time without consequences. It is explained to subjects in easy-to-understand language. eConsent is documented by the signature of the subject on the eConsent, accompanied by the signature of a member of the research team. All signatures are captured using a stylus, finger, or mouse on the tablet/computer and are stored in REDCap.

During assent / consent and throughout the study, it is emphasized that participation or non-participation in the study does not affect the youth patient’s treatment at the hospital, nor will it affect any current or future care of the adult support team members. Likewise, both youth and adult subjects are advised that they can withdraw their participation in the study at any time. The limits of confidentiality are also explained, including the potential to break confidentiality in the event of acute risk of suicidal behavior or violence, or disclosures of unreported physical or sexual abuse of a child.

Youth assent process timeline: As noted in RECRUITMENT METHODS, therapists will notify study staff of any patients who express interest in the study. After confirming with those therapists that the candidate patient meets inclusion criteria, study staff will assign a YST+YM study interventionist to begin the assent / parental consent process. Specifically, the interventionist will schedule an individual consent session involving the patient, patient’s primary caregiver, and current CAPHS therapist. The session will occur either physically in the CAPHS unit or on Zoom, depending on current clinic policy and public health guidance.

Note, because the intervention in this study is focused on the immediate post-discharge period, both parent / legal guardian consent and child assent must be given prior to discharge from the

Child and Adolescent Partial Hospital Program (CAPHS). Parents / legal guardians and children who do not consent (or assent) will not be eligible to participate in this study.

During the youth assent / consent process, the YST+YM intervention and data collection procedures will be explained in more detail to the patient and caregiver. Patient's current therapist will also be present to answer any questions that patient or caregiver may have about the study's consistency with the patient's clinical goal. Therapists will also be instructed to remind both patient and caregiver they should not feel pressure to participate in the study and that patient's care will not be negatively affected if they decline.

The informed assent / consent process will be conducted in a manner to facilitate questions from potential study subjects. If a study team member is unable to answer a question, an investigator will be contacted. All questions from potential subjects should be answered prior to signature. No subjects will be involved in research activities unless an investigator or a designated study staff has obtained documentation of legally effective informed assent / consent of the subject and at least one parent/legal guardian. The collection of protected health information (PHI) and questionnaires are considered to be research activities requiring prior documentation of informed assent / consent. Subjects will be offered a copy of signed forms.

Assent / consent will only be sought under circumstances that provide the prospective subject and their parent/legal guardian sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject and their parents/legal guardians. Potential study subjects and parents/legal guardians will be given ample time to read and consider the assent / consent forms. All subjects and parents/legal guardians will be reminded of the voluntary nature of study participation. Using the assent / consent forms to structure discussion, research personnel will explain the study, its potential benefits and risks, and alternatives, and document the assent / consent process by signature of the subject and the person obtaining consent.

During informed assent / consent procedures, individuals will be told about possible risks and benefits of participation. This will include information that questions asked may cause them to feel uncomfortable or upset. They will be informed that: they may withdraw from an assessment at any time for any reason and receive full reimbursement for that assessment; and, they may withdraw from the research study at any time without negative consequences. Subjects are further informed that we will perform an immediate evaluation of their dangerousness towards self or others should safety concerns arise during assessments or treatment sessions, and that certain types of responses to intervention text messages will trigger immediate review for safety concerns as well. Additionally, they will be informed that we may contact their parents or emergency contacts, should concerns arise about medical or psychological risk. The staff will assess the subject's understanding of the study with a series of questions about the study. If a subject or their parent/legal guardian fails to answer all questions correctly, the staff will re-explain the study and then test the subject again. The assent / consent will be an ongoing process during the study. Explanations of the study and verbal assent will be conducted at each data collection. Subjects will be reminded that their participation is voluntary and that they can withdraw at any time for any reasons.

Youth subjects and their parents / legal guardians will also be asked to share the youth's current suicide safety plan, which all adolescents in the CAPHS clinic are required to have before discharge as part of standard clinic policy. This safety plan will then be stored on a secure REDCap server and will be shared with their adult support team members as part of the YST+YM intervention.

Parent / legal guardian consent timeline: The parent granting permission for each youth

subject will also be invited to participate in the study at the time of permission. To simplify this process for parent / guardian subjects, we have created a combined parental permission and consent form. Parental permission and consent will be acquired during at the same time as youth assent. Of note, the parent/guardian of youth subjects who are 18 years old will be informed that they do not have to provide permission for their youth to participate, as their youth is a legal adult. Parental permission is required for youth subjects ages 12-17.

Adult support subjects consent timeline: As explained in RECRUITMENT METHODS, youth subjects and their parents / legal guardians are asked to nominate supportive adults for the intervention immediately after the consent process is completed. At this time they also provide contact information for these potential adult support team subjects, who will be contacted by study staff as soon as possible after the youth consent process is complete. During contact with these potential adults, study staff will describe the intervention and confirm the adults are willing and able to serve in the support team role and are interested in participating in the study. Adults that express initial ability to serve in the support team role and interest in participating in the study will then set up a meeting with study staff via HIPAA-secure video conference to complete the eConsent process above.

A **Certificate of Confidentiality (CoC)** is automatically granted to the research team from the National Institutes of Health (NIH) in order to further protect the privacy of the subjects involved in this research. The CoC will allow the research team to refuse to disclose subjects' identifying information (including sensitive health information assessed in this study such as their psychiatric diagnoses or self-injurious thoughts and behaviors) in the unlikely event of any civil, criminal, administrative, legislative, or other proceedings. Language describing the Certificate of Confidentiality will be included in the assent / consent forms.

9. STUDY PROCEDURES

Phases one and two will utilize the same study procedures. Screening will occur via consultation with youth subjects' current therapists, who have all the necessary information to confirm youth eligibility as part of their normal clinical practice. Demographic information on youths who are screened, but determined to be ineligible, will be documented; however, no identifying information will be retained on these ineligible subjects.

After screening and signing assent / consent forms, study staff collect background information from subjects, such as demographics and nomination of 3-4 trusted adults to serve as their support team, via REDCap. Parents and guardians will be involved in the nomination process and must verbally approve all of the subject's adult nominees. Then, the baseline session is scheduled. This baseline session includes both the baseline assessment and initial session of the Youth-centered Module (YM) of the YST+YM intervention. Subjects have the option of completing this visit in-person or remotely, depending on current URMC and clinic policy. Those who complete it remotely do the baseline assessment and intervention via HIPAA-compliant video conference. After the baseline session has been scheduled with the subject, study staff will contact the subject's adult support team nominees, explain the intervention to them, and then confirm they are willing and able to serve as a support team member for the subject. Per subject need/request, URMC study staff will read aloud instructions and questions to aid their responding via tablet, phone, or computer. In the case that the REDCap site is down or malfunctioning, screening, assent / consent and questionnaires are completed on paper and later entered into REDCap.

Select questionnaires from the battery are re-administered at 6 weeks (mid-intervention), 12 weeks (immediately post-intervention), and 24 weeks (follow up). All of these assessments will be completed live (via HIPAA-compliant video conference) with study staff, who will review

subject responses for safety concerns immediately after the assessment is completed. Table 1 depicts the assessment timeline for all subjects in the study. Table 2 provides the content of all the measures included in each assessment.

Table 1. Assessment timeline by subject type

	Pre-discharge	Post- discharge week				
		1-3	4 – 6	7-10	10-12	22-24
Teen	• **Child pre-screening (with therapist)** • **Consent & contact information** • **Adult team pre-screening & nominations** • **Social & emotional survey** • **Interactive Session 1 (only teen)**	• **Weekly texts** • **Weekly contact with support team**	• **Weekly texts** • **Weekly contact with support team** • **Social & emotional survey** • **Interactive session 2 (can bring adult team members)**	• **Weekly texts** • **Weekly contact with support team**	• **Weekly texts** • **Weekly contact with support team** • **Social & emotional survey** • **Interactive session 3 (can bring adult team members)** • **Feedback survey & semi-structured interview**	• **Social & emotional survey** • **Feedback survey & semi-structured interview**
Parent / Guardian	• **Consent & contact information** • **Adult team pre-screening & nominations**	• **Adult experience and feedback survey**			• **Adult experience and feedback survey**	
Supportive Adults	• **Consent & contact information**	• **Adult experience and feedback survey** • **Education session** • **Weekly contact with teen** • **Weekly phone check-ins with study staff**	• **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	• **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	• **Adult experience and feedback survey & semi-structured interview** • **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive*	

					weekly texts with teen	

Table 2. Study measures and their contents

Measure Group	Contents
Child pre-screening *Format: staff-administered* *Recipients: referring therapist* *Administered (1x): Prior to assent / consent* *Approx. duration: 5 mins*	• **Inclusion / Exclusion:** Custom questions designed to evaluate whether youth meet criteria to participate in the study (see criteria above).
Adult support team member pre-screening *Format: staff-administered* *Recipients: youth and consenting parent/guardian* *Administered (1x): Prior to consent* *Approx. duration: 5 mins*	• **Inclusion / Exclusion:** Custom questions designed to evaluate whether youth-nominated adults are appropriate for joining the youth's support team.
Contact information *Format: staff-administered* *Recipients: All* *Administered (1x): After consent* *Approx. duration: 5-10 mins*	• **Personal contact information** (e.g., phone, email) • **Youth only**: emergency information and pre-existing suicide safety plan for youth subjects (acquired from youth's current therapist)
Adult experiences and feedback survey *Format: Self-report*	• **Identity confirmation**: Name and date of birth for longitudinal linking survey linking in database • **Demographics** (e.g., age, race, gender) • **Acceptability ratings and feedback**: Custom rating scales and open-ended questions about intervention

Recipients: Parents, adult supports *Administered (2x): After first session, Weeks 10-12* *Approx. duration: 15-20 mins*	acceptability, time taken, and perceived benefits for child • **Child depression symptoms**: PROMIS Parent Proxy Short Form v2.0 - Depressive Symptoms 6a • **Child life satisfaction**: PROMIS Parent Proxy Short Form v1.0 - Life Satisfaction 4a • **Adult depression symptoms**: PROMIS Short Form v1.0 - Depression 4a • **Adult general stress**: NIH Toolbox Perceived Stress Fixed Form Age 18+ v2.0
Youth social and emotional survey *Format: Self-report* *Recipients: Youth only* *Administered (4x): During the three intervention sessions, follow-up (week 22-24)* *Approx. duration: 30-60 mins*	• **Identity confirmation**: Name and date of birth for longitudinal linking survey linking in database • **Demographics** (e.g., age, race, gender) • **Acceptability ratings and feedback**: Custom rating scales and open-ended questions about intervention acceptability and perceived benefits. • **Depressive symptoms**: PROMIS Pediatric Short Form v2.0 - Depressive Symptoms 8a • **Suicidal thoughts and behaviors**: Short Mood and Feelings Questionnaire – Suicidal Ideation subscale, custom questions about recent and historic suicide attempts • **Social Connectedness**: Interpersonal Needs Questionnaire – Belongingness subscale • **Feelings of meaning and purpose**: Claremont Purpose Scale – Goal-directedness and Personal Meaning subscales • **Emotion Regulation**: Interpersonal Emotion Regulation Questionnaire - Social Modeling Subscale, Difficulties in Emotion Regulation Scale – Regulation Strategies Subscale • **Engagement with healthy activities**: Behavioral Activation for Depression – Short form – Activation Subscale • **Adult support team activities**: Custom questions about frequency of contact with parents and team adults on intervention support team. Questions include content about different activities (e.g., help with homework, social support) and forms of interaction (e.g., in person, over the phone).
Semi-structured feedback interview *Format: Staff-administered* *Recipients: Youth only* *Administered (4x): During the three intervention sessions, follow-up (week*	• **Open-ended feedback:** Three questions designed to invite feedback from the subject, including intervention content subjects want to change in the future, what they would want to retain, and their overall impressions of the program.

22-24) *Approx. duration: 15-20 mins*	
Columbia Suicide Severity Rating Scale (C-SSRS) *Format: Staff-administered* *Recipients: Youth only* *Administered (4x): Immediately following each Youth Social and Emotional Survey (i.e., after the three intervention sessions, and once at follow-up – week 22-24)* *Approx. duration: 5 mins*	• **Suicide risk assessment:** Administered to all youth following all social and emotional surveys, the C-SSRS asks a series of questions about recent suicidal thoughts and behavior in plain language. • **Only administered to youth who screen positive on *Social and Emotional Survey* for current suicidal planning**

The study intervention consists of two components: the already established Youth Support Team (YST) intervention that provides education and check-ins for the adults on the support team and a Youth-centered Module (YM) that includes 3 remote sessions involving the youth and weekly text messages. The timeline for each component is described below.

Youth Support Team (YST): As soon as a given supportive adult agrees to serve on a subject's support team, study staff will schedule a psychoeducation session (45-90 minutes). This session will be conducted remotely via HIPAA-compliant video conference and includes information about how to provide social support to youth with psychiatric symptoms. Adults are reminded their only role is to provide social support (not clinical assessment or care), but they are still provided with information on how to handle any safety concerns with the adolescent that may arise. Each adult on the support team is instructed to remain in active contact with the youth at least once a week. Adults also receive weekly 3-15 minute check-in calls from study staff for 12 weeks to help them optimize the social support they provide.

Youth-focused Module (YM): The YM consists of three remote sessions involving the youth and 12 weekly text message prompts encouraging the subject to reflect on their usage of content from the YM. The first session occurs before discharge and will be either in-person or remote, depending on current clinic policy and patient/interventionist availability. The first session includes only the patient and the interventionist. The second (post-discharge weeks 4-6) and third (post-discharge weeks 10-12) sessions happen after discharge and will all be remote. For these post-discharge sessions, youth subjects will also be encouraged, but not required, to invite one or more members of their support team. The YM content is strengths-based and centers on seeking social connection, emotional balance, and purpose/meaningful activities. Dr. Cero will supervise the treatment through regular review of audiotapes (random sample of 20% of sessions) to ensure fidelity.

- **Text Messages:** Subject identifying information, clinical symptoms (including suicide risk) and **PHI is not exchanged in the text messages** themselves. Detailed information about text messaging is included under the “Privacy and Confidentiality of Subjects and Research Data" section. Privacy and security risks associated with text messaging are described in detail to all subjects during assent / consent, including the inherent unprotectability of text-message data and the option to automatically withdraw from texts at any time with the phrase “unsubscribe”.

Refinement phase versus pilot phase: *All subjects in all phases will complete the same procedures and will receive a brief semi-structured interviews to assess acceptability and appeal of the intervention.* In phase 1 (content refinement), feedback from the first N = 5-10 youth subjects and their supportive adults (estimated N = 15-20) will be used to refine YM content. Note, the YM text messages will also be refined using any available input from a related text message pilot study (STUDY00006613). In phase 2 (pilot), all remaining subjects will receive the refined content that was updated with feedback from phase 1 subjects. Note, the broader and previously validated YST intervention will not be modified; only the novel YM being added to it in this study will be modified after patient feedback. Post-feedback refinements will be limited to streamlining improvements (e.g., better phrasing of text messaging, more intuitive examples for one-on-one sessions). The overarching themes and structure of the YM will not be edited without submission and approval of a written revision to this protocol (e.g., content will stay focused on connection, emotional balance, finding goals and purpose - promoted by three sessions across 12 post-discharge weeks).

COVID-19 Re-boot Guidance Information

Study staff will follow all COVID-19 reboot guidelines for safe conduct of research, per the URMC Guidance for Human Subject Research website. The PI and staff will remain vigilant about any further changes that need to be made to study procedures if there are changes to the research reboot guidance. URMC guidelines:

> https://www.urmc.rochester.edu/coronavirus/coronavirus-research/guidance-for-researchers/human-subjects-research.aspx

Research results will not be provided back to the subject.

10. AUDIO/VIDEO RECORDINGS

YST+YM interactive sessions and semi-structured feedback interviews will include audio-video recordings, collected via URMC supported video conference software (e.g., Zoom). These recordings will be labeled only with a code number, which will be kept in a URMC supported HIPAA-compliant data storage platform (Box.com). These recordings will be used to evaluate intervention fidelity and patient engagement with the intervention, as well as for further refinement of the intervention content.

11. RISKS TO SUBJECTS

Research assessments: During self-report questionnaires and semi-structured interviews, the primary risk is invasion of privacy (including because study staff may utilize phone and email reminders of assessment visits), breach of confidentiality (if safety issues are detected), or mild reactions of distress or fatigue. Given that assessments and intervention may be conducted in the subjects’ homes (i.e., during remote administration via phone or Zoom), others could be present and there is a risk of revealing the subject's participation in the study to members of the household who were not otherwise aware. Subjects will have full discretion in having others

present. All assessment measures and procedures have been safely used in previous research with psychiatric populations and have been reviewed by experts in the treatment of acutely suicidal adolescents at URMC. No sustained negative effects from assessments are expected, but negative outcomes cannot be ruled out.

Intervention: The primary risk of participation in YST+YM is emotional distress or fatigue. Although YST+YM is an adjunctive, strengths-based intervention with a positive emphasis, youth and adult support subjects may still think about stressors and negative life events. They will receive support from the YST+YM interventionist for such experiences. No sustained negative effects are expected, but negative outcomes from behavioral interventions cannot be ruled out. The study PI (Dr. Cero) has an active limited permit to practice psychotherapy under a Co-I (Dr. Wyman) and the PI will be a fully licensed clinical psychologist by October 2021. The PI will provide weekly (and as needed) clinical supervision YST+YM interventionists. Dr. Cero has experience working with psychiatrically distressed adolescents and adults, including those with active suicide risk and will be on-call at all active study times (i.e., URMC business hours, when the intervention is being administered) to support interventionists and subjects as needed.

Recordings: Audio recordings of semi-structured interviews will be transcribed and then destroyed to protect the security and confidentiality of identifiable information. In order to protect subjects' **privacy**, audio-visual recordings will only be made with subjects' written assent / consent; subjects will be free to refuse to answer any questions they would prefer to not answer; interviews will be conducted in private settings. The data on the recording will be identified only by an ID number. Recordings for sessions will be uploaded onto UR Box.

Coercion / Vulnerable Subjects: Some subjects in the study will be minors who were recently placed in partial psychiatric hospitalization for suicide-related concerns. Their age and their expected level of mental health distress make them vulnerable to coercion (e.g., coercion to participate in the study). We take several precautions to minimize this risk, including utilization of study personnel with prior mental health training, the presence of the subject's current mental health therapist who is reminded to instruct the patient their participation will not affect their non-study care (which consultation with clinic staff has revealed is typically soothing to the patient), and the additional requirement that the subject's parent or legal guardian consent to their participation.

Minimization of Risk:

- Informed Assent / Consent: All study team members must read and understand the study protocol, the informed assent / consent forms, and the case report forms prior to being involved in the informed consent process. The PI will practice the consent process with the consent designee(s) prior to the enrollment of the first subject. The PI will train the study staff to conduct consent by explaining, demonstrating, and observing the consent process until they master the consent process. The PI will randomly check the consent process quarterly and re-train staff as needed. Before the written consent, a verbal consent will be obtained in the stage of phone screening.
- The Certificate of Confidentiality (CoC) automatically granted to the research team from the National Institutes of Health (NIH) in order to further protect the privacy of the subjects involved in this research. The CoC will allow the research team to refuse to disclose subjects' identifying information (including sensitive health information assessed in this study such as their psychiatric diagnoses or self-injurious thoughts and behaviors) in the unlikely event of any civil, criminal, administrative, legislative, or other proceedings.
- Risks associated with **emotional distress or fatigue** will be minimized by employment of research personnel with appropriate backgrounds and experience and work with psychological factors. All assessments will last approximately 30 - 60 minutes. Subjects

will be reminded that if they become fatigued, they may terminate the assessment at any time.

- During the course of assessment interviews, study staff will monitor subjects' reactions for signs of distress or fatigue. If necessary, subjects may take breaks from the assessment before completing it.
- If a subject's safety becomes a concern, the researcher will evaluate the subject's emotional state and safety. If the subject appears distressed, study staff will briefly attempt to de-escalate the patient's distress. If these measures do not effectively reduce the patient's distress within 10-15 minutes and depending on the severity of the patient's distress, study staff will call Dr. Cero (or the person covering for him), who will maintain a cell phone for this purpose. In case of an emergency, study staff will call 9-1-1.
- Given that **we will be assessing suicidal ideation and attempts for youth subjects** and that youth subjects may report these outcomes, study staff will be trained in the study's safety protocol for mental distress and suicide risk, which involves items from the Columbia Suicide Severity Rating Scale and clinical interview. Note, **adult support team subjects will never be asked questions about any mental or physical health outcomes**, only about the feasibility and acceptability of the intervention. Youth subjects will be informed that study staff will perform an immediate evaluation of their dangerousness towards self or others should safety concerns arise during assessments or treatment sessions. Subjects will also be informed that their confidentiality may be breached should concerns arise about their dangerousness to self or others. Any endorsements of suicidal planning or recent suicide attempt will involve notifying Dr. Cero for review of risk and protective factors and consideration of appropriate steps, including (but not limited to) safety planning, contacting therapist or primary care provider, contacting mobile crisis team, emergency psychiatric services, or hospitalization within 24 hours. Subject providers will be notified of elevated risk. Dr. Cero has expertise in suicide among high-risk populations. While it is expected that most subjects for the current study (given inclusion criteria of passive or active ideation in the past month) will report significant distress and suicide ideation, staff will be trained in the study's safety protocol and data from each assessment will be reviewed with Dr. Cero weekly, or more often if needed. Finally, subjects will be informed that suspected child abuse will be reported, as mandated by law. Situations involving potential imminent dangerousness may involve the use of emergency services and law enforcement authorities. This safety protocol has been modelled after previously successful protocols utilized by a co-investigator (Dr. Pisani).

Alternatives to participation: if the youth subject elects not to participate in the study, they will simply proceed to treatment as usual (as recommended and implemented by CAPHS staff). There are no alternatives to participation for parents / legal guardians or adult support team subjects.

12. POTENTIAL BENEFITS TO SUBJECTS

In a similar study population of acutely suicidal adolescents, traditional YST reduced all-cause mortality by 50% over the subsequent 10 years.[15] Because our study intervention (YST+YM) includes a full administration of traditional YST, it is likely some youth subjects may experience reduced risk of suicide attempt or longer term risk of all-cause mortality as a result of participation in the study. Because the study intervention further targets social support surrounding youth, which is known to have anti-depressive and anti-anxiety effects, youth subjects may also experience improved mood and emotional state over the course of the study.[2-5] There are no direct benefits of the intervention for parents / legal guardians or adult support team subjects. For all subjects, it is possible the assessment portion of this study may

provide benefit by facilitating subjects' learning about themselves.

13. COSTS FOR PARTICIPATION

All subjects will be responsible for all fees charged by their carrier's service plan for text messaging. This research study will not reimburse subjects for any increased charges, data usage against plan limits or changes to data fees from the research texts. However, because the entire study involves under 50 total text message prompts per subject, it is unlikely subjects will incur meaningful costs beyond what they were already paying for cell-phone service.

14. PAYMENT FOR PARTICIPATION

Youth subjects will receive $100 in Amazon.com e-gift cards for completing the entire study. These will be administered in $25 increments after each of the four assessment points in the study. Because each assessment lasts approximately 1 hour total, this compensation rate roughly translates to $25 an hour for each subject's time.

Compensation will be prorated according to the assessment points completed. For example, a subject dropping out after completing the first three assessment points (baseline, treatment midpoint, post-test) would receive the first three $25 payments at the time of those assessments. However, they would not receive the final payment for the assessment they did not complete.

Participation as a parent / legal guardian or an adult support team subject is voluntary and will not be monetarily compensated.

Compensation for participation is the same for subjects in both phases.

15. SUBJECT WITHDRAWALS

Youth psychiatric re-hospitalization: Subjects will be withdrawn from the study and from treatment if they are hospitalized for psychiatric concerns (e.g., suicide attempt, manic episode). Under these conditions subjects (a) will likely be in sufficient distress that they can no longer maintain assent for participation and (b) require more immediate and intensive care than is appropriate for subjects in YST+YM. Non-psychiatric hospitalization (e.g., broken bone, chronic medical condition) will not trigger withdrawal from the study.

Youth failure to complete treatment: Youth subjects will have 14 weeks from the time of discharge to complete the 3 sessions of the YM module in the YST+YM treatment. Patients that have not completed these three sessions after 14 weeks will have their treatment terminated, but will still be allowed to complete any remaining assessments in the study.

Parent / legal guardian withdrawal: Any parents / guardians who wish to withdraw from the study will be allowed to do so at no penalty to themselves or their children. If a parent / guardian wished to withdraw but still allow their child to participate, that youth will still be allowed to continue independently.

Adult failure to complete treatment: Adult support team subjects will have 14 weeks from the time of discharge to complete the 12 YST-based phone check-in sessions with study staff. Subjects that have not completed these sessions after 14 weeks will have their support team role terminated, but will still be allowed to complete any remaining assessments in the study.

Failure to establish adult support team: The YST+YM intervention requires community adults

to commit to providing 12 weeks of social support to a teen in psychiatric distress. Even when the youth subject makes several nominations, it is possible none of the adults they nominated will be able to join the intervention. If study staff are unable to confirm at least one supportive adult is willing to serve on a subject's support team by 2 weeks after the patient's discharge date, that subject will be withdrawn from the study.

Partial withdrawal: Subjects who wish to withdraw from the intervention, but continue assessments will be allowed to do so. They will be compensated at the same rate for all remaining assessments. Subjects who wish to withdraw from the assessments, but remain in the intervention will be allowed to do so. However, they will only be compensated for assessments they have already completed. Attempts will be made to add a replacement subject to the study in all of these cases, as long as there is sufficient funding and study time remaining to do so.

Data use after withdrawal: Unless otherwise requested by the subject at the time of withdrawal, all available data will be retained and integrated into subsequent analysis.

Sample size maintenance: Study staff will attempt to replace any withdrawn youth subjects with the next available patient - as long as there is sufficient time remaining in the study (i.e., at least 6 months) for new subjects to complete the intervention and all assessments. No replacement attempts will be made for adult support team members who withdraw.

16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

Data Storage & Confidentiality: In order to protect the **confidentiality of subject information**, we will take a number of precautions. These include training research interviewers in confidentiality procedures; entry and storage of data using coded identification labels; maintenance of project computers in secure locations with restricted access by enforced password protection; use of HIPAA compliant data management software (REDCAP). Back-ups of all study files will be made daily to allow for recovery of data due to disk failure. All data, including assessment measures, will be obtained with the documented eConsent of the patient. Information pertaining to individual subjects will be released with the patient's informed and written assent and parental consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the subject or others. All data will be identified by a uniquely coded study number assigned to each subject. Access to the master list of study numbers will be restricted to Dr. Cero and study staff. Confidentiality will be further maintained by the storage of "hard copy" data in locked files in a locked office. Access to computerized data is restricted and subject to review by Dr. Cero. Publications or presentations will report only cumulative data or descriptions expected to maintain subjects' anonymity.

All **clinical data** collection involving human subjects will be HIPAA compliant. All clinical data involving human subjects will be stripped of any identifiers; the data will be stored in a secure HIPAA compliant program called REDCAP, which manages protected health information in a HIPAA compliant manner.

Text message communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is an inherent risk that the content of the communication, including subjects personal information, could be shared beyond the subject and the study team. To mitigate this risk to confidentiality:

- Subject information will not be entered into text messaging software (Twilio), unless they have provided explicit eConsent to receive text messages as part of the study.

- Subjects will be specifically notified of this risk during the assent / consent process and on the assent / consent form and reminded that this form of communication is not secure.
- We will never solicit any PHI from subjects via text message and will instruct them not to include PHI in their responses to text messages.
- All subjects will also have the opportunity to withdraw from the text message portion of the study at any time by replying to a study text with the phrase “unsubscribe” and this is made explicit in the assent / consent documentation. This withdrawal option will also be explained verbally to subjects during the assent / consent process and repeated during remote intervention sessions.
- At the conclusion of the study, all subject text message information will be downloaded and stored on a HIPAA-compliant storage platform supported by URMC (Box.com). Only the PI (Dr. Cero) will have access to this data. After text message data has been downloaded and stored on Box, it will be deleted from Twilio, which provides explicit options to permanently delete any subject’s information.

Audio recordings of semi-structured interviews will be transcribed and then destroyed to protect the security and confidentiality of identifiable information. In order to protect subjects’ **privacy**, audio-visual recordings will only be made with subjects’ written assent / consent. Sessions will be audio recorded for supervision of study interventionists, to evaluate fidelity, and to further refine the intervention. The data on the recording will be identified only by an ID number. Recordings for the sessions will be uploaded onto UR Box.

In order to protect subjects’ **privacy**, subjects will be free to refuse to answer any questions they would prefer to not answer and intervention sessions will be attempted in private settings, when possible. Subjects may be re-contacted in the future to update basic information, but will not be penalized for refusing such contact.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

We are willing to share data with other researchers and have chosen measures that are useful for future analyses; however, the data sharing agreement involves sharing only de-identified data with other investigators and the use of data-sharing agreements that provide for: (1) a commitment to use the data only for research purposes and not to identify any individual subject; (2) a commitment to secure the data using appropriate computer technology; and (3) a commitment to destroy or return the data after analyses are completed.

16. DATA AND SAFETY MONITORING PLAN

Please refer to attached Data and Safety Monitoring Plan. Note, only youth subjects will be asked about safety-related issues. Adult support team members are only asked about feasibility and acceptability of the intervention.

Note, the intervention itself also involves acquiring a pre-existing safety plan from each youth and their therapist – all youths have these as a requirement of discharge from the CAPHS clinic. This safety plan will be stored on the HIPAA-compliant REDCap server. It will also be shared with parents and support team members.

17. DATA ANALYSIS PLAN

For Aim 1, we will use descriptive statistics to gauge achievement of feasibility and acceptability thresholds for patients. Means above 3.5 (on a 5 point scale) will be regarded as adequate feasibility and acceptability.

For Aim 2, a linear mixed effects model will be used to evaluate (a) overall frequency of responding to text messages and (b) trends in text response rates over time. Aim 2 will also utilize generalized linear mixed effects models (fixed effect for time, with a random effect for individual) to evaluate changes in intervention target scores over time. Each of the intervention targets will serve as the outcome variable in its own separate model.

For Aim 3, means and proportions will be estimated and retained for future study planning.

A power analysis evaluating these models was conducted via simulation. For the linear mixed effects models (Aims 2), assuming a moderate effect size (d = .50) and moderate within-subject shared variance attributable (ICC = .05), simulations show this model will have adequate power (.82) to detect target engagement over the course of the intervention. Because Aims 1 and 3 utilize only descriptive statistics and require no statistical inference, no power analysis was conducted.

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Consent forms

PARENT / GUARDIAN CONSENT & PERMISSION FORM

Network health intervention for adolescents leaving acute psychiatric care

Principal Investigator: Ian Cero, PhD
Co-Investigators: Peter Wyman, PhD, Anthony Pisani, PhD
Sub-Investigator: Annamarie Defayette, MA

This consent form describes a research study, what you may expect if you decide to take part, if you decide to let your child take part, and important information to help make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions at any time and about anything that is not clear before you agree to participate or to let your child participate. You may take this consent form home to think about and discuss with family or friends. However, you must decide whether to allow your child to participate BEFORE they are discharged from the Child and Adolescent Partial Hospital Program (CAPHS).

- Your being in this study is voluntary – it is your choice and your child's choice.
- If your child joins this study, your child can change their mind and stop it at any time.
- If you join the study, you can change your mind and stop at any time.
- If you or your child choose not to take part, your eligibility for and access to care through the Strong health system will not be changed in any way.
- There are risks from participating and you should understand what these mean to you and your child.

Introduction

You and your child being asked to take part in this study because your child is about to complete acute psychiatric treatment and is between the ages of 12 and 18. You are also being asked because your child reported thinking about or attempting suicide at least once in the past year.

This study is being conducted by Dr. Ian Cero and the University of Rochester Medical Center (URMC) at Strong Memorial Hospital.

Purpose of Study

The purpose of this study is to understand the benefits of a program to prevent suicide attempts among teens with recent histories of suicide-related concerns. The program is called Youth-nominated Support Teams (YST). It involves your child nominating 3-4 trusted adults to provide social support to them for the next 12 weeks. We are interested in learning how this program might promote social support, emotion regulation, and increased help seeking between your child and trusted adults in their life. Lastly, we are interested in the general mental health of parents and other adults who are supporting children with recent suicide-related concerns.

This study asks: can adding a Youth-focused Module (YM) - involving three interactive sessions and weekly text messages to the standard YST package (YST+YM) - improve your child's social support, emotion regulation, and their comfort seeking help from trusted adults?

Description of Study Procedures

1. If you decide to allow your child to participate in the study (and your child also agrees), we will help the two of you choose roughly 3-4 trusted adults in your child's life who might want to be on their Support Team for the next 12 weeks. We will begin this nomination process with you as soon as possible. We will also help you and your child schedule your child's first interactive session with us. Altogether, the nomination and scheduling process usually takes about 30 minutes.

2. After you and your child agree on the adults to nominate for your child's support team, we will contact those adults. We will provide them with an overview of our program and inform them that your child has nominated them to be on their support team. We will ask basic questions about whether they are appropriate and willing to serve on the support team, including whether they have enough time to talk to your child at least once a week for 12 weeks.

3. If the nominated adult agrees to be a part of your child's support team, we will provide them with 60-90 minutes of education on how to provide social support, tailored specifically to your child. We will ask them to attempt to contact your child to provide that social support at least once a week for the first 12 weeks after discharge.

    a. We will further explain that their role will be only to utilize broad social and emotional support skills, but not to attempt to provide psychotherapy.

    b. However, to tailor this session to your child's specific needs and to be prepared if there is an emergency, this will include information on your child's recent mental health diagnosis and experiences, as well as their history with suicidal thoughts and behavior. It will also include discussion of your child's safety plan (which we will share with each support team member) and information on what to do in the event of an emergency with your child.

4. Adults on your child's support team will receive weekly phone check-ins from us (3-15 minutes) for the next 12 weeks. During these calls, we will ask whether they have contacted your child in the past week and how the conversation went. We will then provide those adults with encouragement and help them think through any difficulties or concerns that may have come up in conversation with your child.

5. In addition to your child's participation, if you also choose to participate in the study, we will also send you a survey via email or text message at this time (10-15 minutes). That survey will ask you about your general impressions of the intervention so far. We will also ask you about your perception of your child's mental health, as well as your own recent mood and stress levels.

6. Around the same time as the adults receive their psychoeducation training, your child will have their first interactive session with one of our study staff. All study staff have prior mental health training and are supervised by Dr. Cero. All interactive sessions will of two parts:

    a. Social and emotional assessment (30-60 minutes): You child will complete secure, online surveys that give us information about their current emotional and social health. These surveys will be similar to surveys your child took during their time in the partial hospital program at CAPHS.

    b. Strengths-focused interactive discussion (45-60 minutes): Your child will engage in a series of interactive activities and discussion topics, designed to emphasize opportunities for growth and change in the time after discharge. They will learn about how to incorporate three specific strengths to help them work through the post-discharge adjustment period, including working on social connection, maintaining emotional balance, and activities that promote meaning and purpose in their life.

7. Your child will start receiving automated text messages about once a week until their final interactive session (about 12 weeks total). Some of these text messages will be for your child alone. Some of them will be group texts involving your child and one of the adults on their support team. The text messages will focus broadly on promoting reflection on the strengths discussed in the first interactive session (e.g., "How has working on social connections helped you in the last week?") and promoting interaction with supportive adults (e.g., "What has been the most helpful for finding purpose this week for each of you?").

8. After discharge, your child will complete two interactive sessions (45-60 minutes; one at 4-6 weeks after discharge and the other at 10-12 weeks after discharge). One or more of your child's adult support team members may also be invited to join them. During both of these interactive sessions, your child will first complete a social and emotional assessment (30-60 minutes) along. The remainder of the session will focus on the key strengths from the first session (e.g., connection,

balance, purpose). Your child and any supportive adult(s) will then be lead through a guided conversation about how they have used those three strengths in the past, and how they might work on those strengths together in the future. At the end of the final session, we will also ask your child for general feedback about the program, including things they might think should be changed for future teens in the program.

9. Around the same time that your child completes their final interactive session, you will also be asked to take a short (15-20 minute) survey about the program. We will ask you questions related whether you think the program was helpful to your child, and whether the amount of effort it required was workable for you. We will also ask about your recent mood and stress levels, as well as whether there is anything you recommend that we should change for future teens in the program.

10. Lastly, about 22-24 weeks after discharge, we will meet with your child for their final social and emotional assessment. Note that this last meeting will involve assessment only. The assessment will be the same as all previous assessments, except it will not be paired with another interactive program session because the program has already ended by this point. The purpose of this assessment is to help us understand what your child's experiences are like after the program ends.

Number of Subjects

Approximately 65 youth subjects will take part in this study, along with roughly 65 of their parents / legal guardians and about 200 adult subjects who will make up the youths' support teams.

Duration of the Study

The total duration of the study for your child will be between 6 and 7 months. This includes roughly 12 weeks to complete the support team program and then a 12 week follow up period. The total duration of the study for you as a parent / legal guardian is roughly 3 months. The table below depicts study activities over that 6-month period.

	Pre-discharge	Post- discharge week				
		1-3	4 – 6	7-10	10-12	22-24
Teen	• **Child pre-screening (with therapist)** • **Consent & contact information** • **Adult team pre-screening & nominations** • **Social & emotional survey** • **Interactive Session 1 (only teen)**	• **Weekly texts** • **Weekly contact with support team**	• **Weekly texts** • **Weekly contact with support team** • **Social & emotional survey** • **Interactive session 2 (can bring adult team members)**	• **Weekly texts** • **Weekly contact with support team**	• **Weekly texts** • **Weekly contact with support team** • **Social & emotional survey** • **Interactive session 3 (can bring adult team members)** • **Feedback survey & semi-structured interview**	• **Social & emotional survey** • **Feedback survey & semi-structured interview**
Parent / Guardian	• **Consent & contact information** • **Adult team pre-screening & nominations**	• **Adult experience and feedback survey**			• **Adult experience and feedback survey**	
Supportive Adults	• **Consent & contact information**	• **Adult experience and feedback survey** • **Education session** • **Weekly contact with teen** • **Weekly phone check-ins with study staff**	• **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	• **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	• **Adult experience and feedback survey & semi-structured interview** • **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	

Study Phases

Part of the purpose of this study is to use the feedback from our participants to revise and improve the content of the YST+YM intervention (e.g., make text messages easier to read, add or subtract activities

based on participants' reported interest in them). The study thus has two phases, (1) an initial phase where we will utilize participant feedback to change the YST+YM intervention in approximately real-time and (2) a second phase where we will still ask for your feedback, but will not revise the intervention.

Risks of Participation

There are a few risks of participating in the surveys and interviews.

1. The questions in the surveys and interviews could cause some emotional stress to you or your child due to the personal nature of the material. For example, you and your child will be asked about emotional health and that may bring up difficult memories or feelings. You will also be asked about the program's appropriateness and perceived benefit for your child, which may also bring up difficult memories or feelings for you. All the questionnaires and interview questions have been used in previous research with adults and adolescents. No lasting negative effects are expected from the evaluations. You are free not to answer any question(s) for any reason at any time.

2. The questions in the surveys or interview could make you or your child tired due to the length of the interview. You are free to stop the interview if you become tired.

3. Some of the survey and interview questions ask about psychiatric symptoms (e.g., depression, anxiety), recent stressful experiences, and suicide. If we become concerned about your child's safety (or the safety of others), we will notify Dr. Cero (or an on-call associate) for recommendations within 24 hours. One action we may take is to notify you about your child's safety concerns. We may also contact your child's emergency contact person or contact emergency medical services (911) or the police, in the event of immediate concerns about your child's safety. We will also notify your child's therapist. In addition, the researchers are required to report information regarding potential child abuse or neglect reported by you or your child.

There are a few risks of participating in the YST+YM program:

1. Although the focus of the YST+YM program involves an optimistic and strengths-based focus, the content may still remind your child of difficult memories. Your child may feel emotionally stressed due to the topics discussed in the interactive session or with their supportive adults each week. We have utilized similar program content with both children and adults in the past and no lasting effects are expected. Your child is free to skip any topics they do not feel comfortable with during interactive sessions. They are also free to decline to interact with any of their support team members at any time.

2. There are also some risks to privacy and confidentiality involving text messages. These are described in detail below.

Remember: for this study, neither you nor your child are expected to do anything that either of you is uncomfortable with. You or your child are free to stop either the YST+YM program or the surveys/interviews at any point.

Use of Text Message Communication for Research

Text messages by mobile/cell phones are a common form of communication. The YST+YM program in this study involves sending your child (and members of their support team) text messages.

These text messages are designed to promote reflection on the content and broad themes of the YST+YM program, as well as to promote communication between your child and their support team. Some of these text messages may be personalized to your child's stated interests during interaction sessions (e.g., "Last time we met, you said playing soccer really helped you stay emotionally balanced. What can you do to make sure you play soccer at least once this week?"). When your child and a support team member receive group text messages from us, they will be designed to promote conversation and mutual reflection on the YST+YM program content (e.g., "What is something that has helped each of you stay emotionally balanced this week?").

Importantly, texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information your child or a support person sends or receives by text message (a) could be intercepted, or (b) viewed by an unintended recipient, or (c) viewed by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- We will never ask your child or a support person about your child's mental or physical health over text. We will never ask any questions that ask about any other private health information over text. All text messages are designed to prompt reflection on strengths-based YST+YM themes.

- All text messages are automated. None of them are actively monitored by a member of the study staff in real-time. We will therefore remind your child and all support team members that they should not ask for emergency or safety-related assistance via text messages. We will not be able to receive those requests. Instead, they will be instructed to follow the steps listed on the safety plan constructed for your child before discharge.

- Text messages are not encrypted, and therefore carry security risks. This research study and the University of Rochester are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and the University of Rochester are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messaging should not be used for sensitive medical information, or in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number (585-684-3597) a text message that says "unsubscribe."

- Your agreement, and any request to stop text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

Your consent below indicates that you understand the risks associated with text message communication.

Use of Email Communication for Research

Email communication will be limited to scheduling (e.g., appointment reminders) or providing resource information. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this

risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

Audio-video recordings

YST+YM interactive sessions may include audio-video recordings, collected via URMC supported video conference software (e.g., Zoom). These recordings will be labeled only with a code number, which will be kept in a URMC secure data storage system. These recordings will be used to evaluate how well the intervention is going and ways we might improve it in the future.

If you agree to participate in this study, your signature on this consent form gives the researchers permission to make and retain the audio/video recordings for this study. You have the right to review the recordings and to request that all or any portion of the recording be erased.

Safety plan

For your child to participate in this study, we will to acquire a copy of their safety plan from their current therapist / their medical record. We will also need to share it with their adult support team, so that the team is equipped with the information they need to help your child in the event of an emergency. Your signature below means you give us permission to acquire the safety plan from your child's therapist and share it with the supportive adults on this study.

Benefits of Participation

Your child might not benefit from being in this research study. The potential benefit to your child from being in this study might be increased sense of well-being and a reduced risk of future suicide attempts.

Sponsor Support

The University of Rochester is receiving funding from The National Center for Advancing Translational Sciences (NCATS) to conduct this study.

Costs

There are no costs to enroll in this study. However, it is possible there are fees related to text messaging that will be charged by your child's cell service carrier plan.

Payments

Your child will be paid $100 for completing the entire study. Payment will be administered in $25 increments after each of the four social and emotional assessment points. All payments will be delivered in the form of Amazon e-gift cards.

Parents/guardians and adult support team members will not be paid.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you and your child private. In order to do so, we have trained all of our study interviewers in confidentiality procedures. We will enter and store the information you and your child share with us using coded identification labels. Your named file is stored in a locked filing cabinet in a locked office, kept separate from your coded file. We will maintain project computers in secure locations with restricted access by enforced password protection. Sometimes, however, researchers need to share information that may identify you and your child with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask study staff for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past or present medical records or e-records to make sure the study is a good fit for you and your child

Who may use and give out information about you and your child?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- National Center for Advancing Translational Sciences (NCATS)

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you and your child will not be used.

What if I decide not to give permission to use and give out my health information?

Then you and your child will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this be permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?

You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you and your child will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
If you withdraw your permission to be in the study, no new health information identifying you and your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you and your child. At most, the Web site will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you and your child in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used

as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You and your child should understand that a Certificate of Confidentiality does not prevent you and your child or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you, your child, and your family must also actively protect your own privacy.

Finally, you and your child should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Future contact after the conclusion of this study

We may want to contact you in the future about this study. You can decide now whether you want to be contacted. You can also change your mind later.

If you agree, we may contact you for several reasons. For example, we may contact you to update basic information.

Contact Persons

For questions related to your participation, for more information concerning this research, if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Cero at youth_connect@urmc.rochester.edu.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642-8315, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You or your child wish to talk to someone other than the research staff about your or your child's rights as a research subjects;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You and your child are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you and your child are entitled. In the event that you and your child do withdraw from this study, the information you and your child have already provided will be kept in a confidential manner.

****

SIGNATURE/DATES

After reading and discussing the information in this consent form you and your child should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you and your child;
- Other options you and your child may have instead of being in the study;
- How your personal information will be protected;
- What to do if you and your child have problems or questions about this study.

****

Parent / Legal Guardian Permission

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

___ *I consent to the use of email in this study.*

___ *I consent to the use of text messaging in this study.*

___ *I consent to being contacted in the future about this study.*

___ *I consent to my own participation in this study.*

___ *I consent to my child's participation in this study.*

_____
Child's Printed Name

_____
Parent / Legal Guardian Name (Printed by Subject)

_____ _____
Signature of Subject (Parent / Legal Guardian) Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date

ASSENT FORM

Network health intervention for adolescents leaving acute psychiatric care

Principal Investigator: Ian Cero, PhD
Co-Investigators: Peter Wyman, PhD, Anthony Pisani, PhD
Sub-Investigator: Annamarie Defayette, MA

What are some general things you should know about research studies?
You are being asked to take part in a research study. Your parent or guardian needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. You are free to choose whether or not to be in this study. You may decide not to join, or, if you join, you may decide to stop being in the study, at any time, for any reason, without penalty.

What is the purpose of this study?
The purpose of this study is to understand the benefits of a program to prevent suicide attempts among teens with recent histories of suicide-related concerns. The program is called Youth-nominated Support Teams (YST). It involves you naming 3-4 trusted adults to provide social support for you during the next 12 weeks. You are being asked to take part in this study because you are about to complete treatment at the Child & Adolescent Partial Hospitalization Program (CAPHS) and are between the ages of 12 and 17. You are also being asked because you have also reported thinking about or attempting suicide at least once in the past year.

What will happen if you take part in the study?
Support Team. If you decide to participate in the study (and your parent / legal guardian also agrees), we will help the two of you choose roughly 3-4 trusted adults in your life who might want to be on your Support Team for the next 12 weeks. As part of the study, your support team will be given information about your recent mental health experiences so that they can best support you. We will start this process with you as soon as possible. We will also help you schedule your first interactive session with us. The whole process of choosing your trusted adults and scheduling your first interactive session usually takes about 30 minutes.

Interactive sessions and surveys. You will complete three interactive sessions with one of our study staff during your study participation. All study staff have mental health training and are supervised by Dr. Cero. You will have your first interactive session about one week before discharging from CAPHS. Only you and one of our study staff will be at the first interactive session. You will have your second interactive session about 4-6 weeks after discharging from CAPHS and your third interactive session about 10-12 weeks after discharging. For interactive sessions that happen after discharge, we may also invite one or more of your support team members to join.
There are two parts to all interactive sessions:

1. *Surveys (30-60 minutes)*: You will complete secure, online surveys about your current emotional and social health. These surveys will be similar to surveys you took during your time in the partial hospital program at CAPHS. At the end of the third session, we will also ask you for feedback about the program, like things you think should be changed for teens in the future.
2. *Strengths-focused interactive discussion (45-60 minutes)*: You will participate in a series of interactive activities and discussion topics. You will learn about how to use three specific strengths to help you work through growth and change after discharging from CAPHS. The strengths include working on social connection, emotional balance, and activities that build meaning and purpose in your life. During the second interactive session, when one of your support team members is there, you will also talk about how you both have used those three strengths in the past, and how you both might work on those strengths together in the future.

You will also complete one final survey about 22-24 weeks after discharging. The survey will be the same as the other surveys you completed, except you will not have an interactive discussion at this meeting. This survey is to help us understand how things have been for you after the program ends.

Text messages. After discharging from CAPHS, you will start receiving automated text messages about once a week until your third interactive session (about 12 weeks total). Some of these text messages will

be for you alone. Some of them will be group texts for you and one of the adults on you support team. The text messages will focus broadly on helping you reflect on the strengths you learned about in the first interactive session (e.g., "How has working on social connections helped you in the last week?") and helping you to interact with your supportive adults (e.g., "What has been the most helpful for finding purpose this week for each of you?").

Audio-video recordings. YST+YM interactive sessions may include audio-video recordings, collected via URMC supported video conference software (e.g., Zoom). These recordings will be labeled only with a code number, which will be kept in a URMC secure data storage platform. These recordings will be used to evaluate how well the intervention is going and ways we might improve it in the future.

Agreeing to participate in this study means that you agree to the research team making and retaining the audio/video recordings for this study. You have the right to review the recordings and to ask that all or any part of the recording be erased.

Safety plan. For you to participate in this study, we will ask for a copy of your safety plan from your current therapist or your medical record. We will also share it with your adult support team, so that the team has the information they need to help you in the event of an emergency. Agreeing to participate in this study means you give us permission to get the safety plan from your therapist and share it with the supportive adults on this study.

Study conditions. Part of the purpose of this study is to use the feedback from our participants to improve the content of the YST+YM intervention (e.g., make text messages easier to read, add or subtract activities based on what you liked or didn't like). The study therefore has two conditions: (1) an early condition where we will use participant feedback to change the YST+YM intervention as the study takes place; and (2) a later condition where we will still ask for your feedback, but will not revise the intervention anymore until after the whole study is completed. You will be assigned to one of these two conditions based only on your start date. You are not able to choose which condition you are in. You will not be told which condition you are placed in.

Who will be told the things we learn about you in this study?
We will make every effort to keep the information collected from you private. Only the people working on this study will be able to look at the information we collect. It will not affect how your doctor or therapist treats you. In order to help keep your information private, we have trained all of our study team members in confidentiality procedures. We will enter and store the information you share with us using coded identification labels. Your named file is stored in a locked filing cabinet in a locked office, kept separate from your coded file. We will keep project computers in secure locations with restricted access by enforced password protection. Sometimes, however, researchers need to share information that may identify you with people that work for the University, the government or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

In addition, if we become concerned about your safety (or the safety of others), we will notify Dr. Cero (or an on-call associate) for recommendations within 24 hours. One action we may take is to notify your parent / legal guardian about your safety concerns. We may also contact emergency medical services (911) or the police, in the event of immediate concerns about your safety. The researchers are also required to report information regarding potential child abuse or neglect reported by you or you.

How long will your part in this study last?
Your participation in this study will last between 6 and 7 months.

What are the possible risks or discomforts involved from being in this study?
There are a few risks of participating in this study.

1. The questions in the surveys and interviews could cause some emotional stress to you due to the personal nature of the material. For example, you will be asked about your emotional health and that may bring up difficult memories or feelings. You will also be asked about the program's match and

perceived benefit for you, which may also bring up difficult memories or feelings. All the questionnaires and interview questions have been used in previous research with adults and adolescents. No lasting negative effects are expected from the evaluations. You are free not to answer any question(s) for any reason at any time.

2. The questions in the surveys or interview could make you tired due to the length of the interview. You are free to stop the interview if you become tired.

3. Some of the survey and interview questions ask about mental health symptoms (e.g., depression, anxiety), recent stressful experiences, and suicide. If we become concerned about your safety (or the safety of others), we will notify Dr. Cero (or an on-call associate) for recommendations within 24 hours. One action we may take is to notify your parent / legal guardian about your safety concerns. We may also contact emergency medical services (911) or the police, in the event of immediate concerns about your safety. In addition, the researchers are required to report information regarding potential child abuse or neglect reported by you or about you.

There are a few risks of participating in the YST+YM program:

1. Although the focus of the YST+YM program involves an optimistic and strengths-based focus, the content may still remind you of difficult memories. You may feel emotionally stressed due to the topics discussed in the interactive session or with your supportive adults each week. We have used similar program content with both children and adults in the past and no lasting effects are expected. You are free to skip any topics you do not feel comfortable with during interactive sessions. You are also free to decline to interact with any of your support team members at any time.

2. There are also some risks to privacy and confidentiality involving text messages. These are described in detail below.

Remember: for this study, you are not expected to do anything that you are uncomfortable with. You are free to stop either the YST+YM program or the surveys/interviews at any point.

What should you know about using text messages for research?

Text messages by mobile/cell phones are a common form of communication. The YST+YM program in this study involves sending you (and members of your support team) text messages. These text messages are designed to help you reflect on the content and broad themes of the YST+YM program, as well as to help you and your support team communicate. Some of these text messages may be personalized to your interests that you share during interaction sessions (e.g., “Last time we met, you said playing soccer really helped you stay emotionally balanced. What can you do to make sure you play soccer at least once this week?”). When you and a support team member receive group text messages from us, they will be designed to encourage conversation and shared reflection on the YST+YM program content (e.g., “What is something that has helped each of you stay emotionally balanced this week?”).

You should know that texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted (protected). This means that information you send or receive by text message (a) could be intercepted, or (b) viewed by an unintended recipient, or (c) viewed by your mobile/cell phone provider or carrier.

You should also know that:

- We will never ask you or a support person about your mental or physical health over text. We will never ask any questions that ask about any other private health information over text. All text messages are focused on reflecting on the strengths-focused YST+YM themes.
- All text messages are automated. None of them are actively monitored by a member of the study staff in real-time. Therefore, you should not ask for emergency or safety-related assistance via text messages. We will not be able to receive those requests. Instead, you will be instructed to follow the steps listed on the safety plan constructed before discharge.
- You/your parent/legal guardian will be responsible for all fees charged by your/your teen's carrier's service plan for text messaging. This research study and the University of Rochester are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messaging should not be used for sensitive medical information, or in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number (585-684-3597) a text message that says "unsubscribe."
- Your agreement, and any request to stop text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

By agreeing to using text messages in this study, you are agreeing that you understand the risks of text message communication.

Can you use email to communicate with the research team?
You have the option to receive communications about this study via email, by indicating your agreement at the end of this form. We will only email about scheduling (e.g., appointment reminders) or to provide resource information. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your agreement below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email.

What are the possible benefits from being in this study?
You might not benefit from being in this research study. The potential benefit to you from being in this study might be increased sense of well-being and a reduced risk of future suicide attempts.

Will you get any money or gifts for being in this study?
You will receive $25 via an Amazon.com e-gift card after completing each of the survey points (interactive session 1; interactive session 2; interactive session 3; final survey). This means that you can earn up to $100 in e-gift cards for participating in survey points. You will not receive a payment for a missed survey point.

What if you have questions about this study?
For more information concerning this research or if you feel that being in the study has resulted in any research related injury, emotional or physical discomfort please contact: Ian Cero, PhD at youth_connect@urmc.rochester.edu.

What if you have questions about your rights as a research subject?
Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject
- To voice concerns about the research
- To provide input concerning the research process
- In the event the study staff could not be reached

Do I have to be in this study?

Taking part in this research study is your choice. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are otherwise entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

****

SIGNATURE/DATES

Subject Assent

I have read (or have had read to me) the contents of this assent form and have been encouraged to ask questions. I have received answers to my questions. I agree to take part in this study. I have received (or will receive) a copy of this form for my records and future reference.

___ *I agree to the use of email in this study.*

___ *I agree to the use of text messaging in this study.*

_____

Print name if you agree to be in the study

_____ _____

Sign name if you agree to be in the study Date

Person Obtaining Assent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a copy of this assent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the assent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Assent Date

CONSENT FORM

Network health intervention for adolescents leaving acute psychiatric care

Principal Investigator: Ian Cero, PhD
Co-Investigators: Peter Wyman, PhD, Anthony Pisani, PhD
Sub-Investigator: Annamarie Defayette, MA

This consent form describes a research study, what you may expect if you decide to take part, and important information to help make your decision.
Please read this form carefully.

The study staff will explain this study to you. Please ask questions at any time and about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends. However, you must decide whether to participate WITHIN ONE WEEK of discussing this form with our study staff.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop it at any time.
- If you choose not to take part, your care through the Strong health system will not be changed in any way.
- There are some risks from participating and you should understand what these mean.

Introduction

You are being asked to take part in this study because an adolescent you know nominated you to serve on their Youth Support Team. They indicated you specifically as an adult they trust and would like to receive social support from while they may a difficult transition.

This study is being conducted by Dr. Ian Cero and the University of Rochester Medical Center (URMC).

Purpose of Study

The purpose of this study is to understand the benefits of a program to prevent suicide attempts among teens with recent histories of suicide-related concerns. The program is called Youth-nominated Support Teams (YST). It involves a teen nominating 3-4 trusted adults to provide social support for them during the next 12 weeks. We are interested in learning how this program might promote social support, emotion regulation, and increased help seeking between that teen and trusted adults in their life. We are interested in the general mental health of parents and other adults who are supporting children with recent suicide-related concerns.

This study asks: can adding a Youth-focused Module (YM) - involving three interactive sessions and weekly text messages to the standard YST package (YST+YM) - improve the teen's social support, emotion regulation, and comfort seeking help from trusted adults?

Description of Study Procedures

1. If you decide to participate in the study, we will provide you with 60-90 minutes of education on how to provide social support, tailored specifically to the teen who nominated you. We will ask you to attempt to contact that teen to provide that social support at least once a week for the first 12 weeks after discharge.

    a. We will further explain that your role will be only to utilize broad social and emotional support skills, but not to attempt to provide psychotherapy.

b. Additionally, this education session will include information on your teen's recent mental health diagnosis and experiences, as well as their history with suicidal thoughts and behavior. It will also include discussion of their safety plan and information on what to do in the event of an emergency (e.g., self-hard, suicide-related concern).

2. Shortly after the education session is complete, we will also send you a survey via email or text message (10-15 minutes). That survey will ask you about your general impressions of the intervention so far. We will also ask you about your perception of your youth's mental health, as well as your own recent mood and stress levels.

3. Once the education session is complete, you will also receive weekly phone check-ins from us (3-15 minutes) for the next 10-12 weeks. During these calls, we will ask whether you have contacted your teen in the past week and how the conversation went. We will then provide you with encouragement and help you think through any difficulties or concerns that may have come up with the teen in the last week.

4. Around the same time as the education session, we will also ask you to complete a brief survey (under 30 minutes) about your recent life experiences and expectations for the program.

5. Depending on scheduling and a range of other factors, some adult support team members may also be asked to participate in 1-2 60-minute interactive sessions with the teen who nominated them and a member of our study staff. In this session, you and the teen you support will be lead through a guided conversation to explore how you both have used three key strengths (social connection, emotional balance, and finding purpose) in the past, and how you both might work on those strengths together in the future. Not all adults on the support team will be required to complete this extra session and you can decline it with no penalty.

6. Adults who complete the extra interactive session with their teen will also be asked to participate in weekly guided text messages with the teen for the remainder of the program (roughly 6-8 weeks, totaling 6-8 text messages). These messages are designed to be brief and to promote reflection on the content you and the teen learned together (e.g., "Which of the three strengths you learned about has helped each of you the most over the past week? How do you plan to work on that strength in the coming week?").

7. About 10-12 weeks after your initial education session, we will again ask you to complete a survey about some of your life experiences and invite you to an interview for general feedback about the program (under 30 minutes total). The program ends with this final survey.

Number of Subjects

Approximately 65 youth subjects will take part in this study, along with roughly 65 of their parents / legal guardians and about 200 adult subjects who will make up the youths' support teams.

Duration of the Study

The total duration of the study for you will be 12 weeks. Note, the study will last longer for the teen you are supporting, even though your time in the study has ended. The table below depicts all study activities over that 6-month period.

	Pre-discharge	Post- discharge week				
		1-3	4 – 6	7-10	10-12	22-24
Teen	• **Child pre-screening (with therapist)** • **Consent & contact information** • **Adult team pre-screening & nominations** • **Social & emotional survey** • **Interactive Session 1 (only teen)**	• **Weekly texts** • **Weekly contact with support team**	• **Weekly texts** • **Weekly contact with support team** • **Social & emotional survey** • **Interactive session 2 (can bring adult team members)**	• **Weekly texts** • **Weekly contact with support team**	• **Weekly texts** • **Weekly contact with support team** • **Social & emotional survey** • **Interactive session 3 (can bring adult team members)** • **Feedback survey & semi-structured interview**	• **Social & emotional survey** • **Feedback survey & semi-structured interview**
Parent / Guardian	• **Consent & contact information** • **Adult team pre-screening & nominations**	• **Adult experience and feedback survey**			• **Adult experience and feedback survey**	
Supportive Adults	• **Consent & contact information**	• **Adult experience and feedback survey** • **Education session** • **Weekly contact with teen** • **Weekly phone check-ins with study staff**	• **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	• **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	• **Adult experience and feedback survey & semi-structured interview** • **Weekly contact with teen** • **Weekly phone check-ins with study staff** • *Some adults also receive weekly texts with teen*	

Study Phases

Part of the purpose of this study is to use the feedback from our participants to revise and improve the content of the YST+YM intervention (e.g., make text messages easier to read, add or subtract activities based on participants' reported interest in them). The study thus has two phases, (1) an initial phase

where we will utilize participant feedback to change the YST+YM intervention in approximately real-time and (2) a second phase where we will still ask for your feedback, but will not revise the intervention.

Risks of Participation

There are a few risks of participating in the surveys and interviews.

4. The questions in the surveys and interviews could cause some emotional stress to you due to the personal nature of the material. For example, you will be asked about your emotional and social health and that may bring up difficult memories or feelings. You will also be asked about the program's appropriateness and perceived benefit for you, which may also bring up difficult memories or feelings. All the questionnaires and interview questions have been used in previous research with adults and adolescents. No lasting negative effects are expected from the evaluations. You are free not to answer any question(s) for any reason at any time.

5. The questions in the surveys or interview could make you tired due to the length of the interview. You are free to stop the interview if you become tired.

There are a few risks of participating in the YST+YM program:

3. Although the focus of the YST+YM program involves an optimistic and strengths-based focus, the content may still remind the teen of difficult memories. You may feel emotionally stressed due to the topics discussed in the interactive session or with the teen you are supporting each week. We have utilized similar program content with both children and adults in the past and no lasting effects are expected. You are free to skip any topics you do not feel comfortable with during interactive sessions.

4. There are also some risks to privacy and confidentiality involving text messages. These are described in detail below.

Remember: for this study, you are not expected to do anything that you are uncomfortable with. You are free to stop either the YST+YM program or the surveys/interviews at any point.

Use of Text Message Communication for Research

Text messages by mobile/cell phones are a common form of communication. The YST+YM program in this study may involve sending you (and the teen you support) text messages to respond to.

These text messages are designed to promote reflection on the content and broad themes of the YST+YM program, as well as to promote communication between you and your supported teen. If you receive group text messages from us, they will be designed to promote conversation and mutual reflection on the YST+YM program content with the teen you support (e.g., "What is something that has helped each of you stay emotionally balanced this week?").

Importantly, texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you or a support person sends or receives by text message (a) could be intercepted, or (b) viewed by an unintended recipient, or (c) viewed by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- We will never ask you about your mental or physical health over text. We will never ask any questions that ask about any other private health information over text. All text messages are designed to prompt reflection on strengths-based YST+YM themes.

- All text messages are automated. None of them are actively monitored by a member of the study staff in real-time. We will therefore remind you that you should not ask for emergency or safety-related assistance via text messages. We will not be able to receive those requests. Instead, you will be instructed to follow the steps listed on the teen's safety plan, which will be made available to you during the education session.

- Text messages are not encrypted and therefore carry security risks. This research study and the University of Rochester are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and the University of Rochester are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messaging should not be used for sensitive medical information, or in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number (585-684-3597) a text message that says "unsubscribe."

- Your agreement, and any request to stop text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

Your consent below indicates that you understand the risks associated with text message communication.

Use of Email Communication for Research

Email communication will be limited to scheduling (e.g., appointment reminders) or providing resource information. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

Audio-video recordings

YST+YM interactive sessions may include audio-video recordings, collected via URMC supported video conference software (e.g., Zoom). These recordings will be labeled only with a code number, which will be kept in a URMC secure data storage system. These recordings will be used to evaluate how well the intervention is going and ways we might improve it in the future.

If you agree to participate in this study, your signature on this consent form gives the researchers permission to make and retain the audio/video recordings for this study. You have the right to review the recordings and to request that all or any portion of the recording be erased.

Benefits of Participation

There are no known benefits to you from participating in this study.

Sponsor Support

The University of Rochester is receiving funding from The National Center for Advancing Translational Sciences (NCATS) to conduct this study.

Costs

There are no costs to enroll in this study. However, it is possible there are fees related to text messaging that will be charged by your cell service carrier plan.

Payments

Participation in this study is voluntary. There is no monetary compensation for your participation.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we have trained all of our study interviewers in confidentiality procedures. We will enter and store the information you share with us using coded identification labels. Your named file is stored in a locked filing cabinet in a locked office, kept separate from your coded file. We will maintain project computers in secure locations with restricted access by enforced password protection. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask study staff for one.

What information may be used and given to others?

The study doctor will get your personal and information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institute of Health

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this be permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?

You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you, you, and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Future contact after the conclusion of this study

We may want to contact you in the future about this study. You can decide now whether you want to be contacted. You can also change your mind later.

If you agree, we may contact you for several reasons. For example, we may contact you to update basic information, recent life experiences, or to request information about your health.

Additionally, we may want to contact you to see if you want to participate in other research. For example, we might want to ask you to fill out a survey or complete a phone interview with a researcher or doctor. If a study like this is approved, someone from this project will contact you. We will tell you about the study so you can decide if you want to receive more information. There will be a new consent process just for that study. You can decide then to take part or not take part. If at any time you decide you no longer want to be contacted about future studies, you can notify Dr. Cero at youth_connect@urmc.rochester.edu.

Contact Persons

For questions related to your participation, for more information concerning this research, if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Cero at youth_connect@urmc.rochester.edu.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642-8315, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subjects;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

****

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

****

Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study and agree to my child's participation in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

___ *I consent to the use of email in this study.*

___ *I consent to the use of text messaging in this study.*

___ *I consent to being contacted in the future about this study.*

_____
Support Person's Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date

CONSENT FORM

Network health intervention for adolescents leaving acute psychiatric care

Principal Investigator: Ian Cero, PhD
Co-Investigators: Peter Wyman, PhD, Anthony Pisani, PhD
Sub-Investigator: Annamarie Defayette, MA

This consent form describes a research study, what you may expect if you decide to take part, and important information to help make your decision.
Please read this form carefully.

The study staff will explain this study to you. Please ask questions at any time and about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends. However, you must decide whether to participate BEFORE you are discharged from the Child and Adolescent Partial Hospital Program (CAPHS).

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop it at any time.
- If you choose not to take part, your care through the Strong health system will not be changed in any way.
- There are some risks from participating and you should understand what these mean.

Introduction

You are being asked to take part in this study because you are about to complete acute complete treatment at the Child & Adolescent Partial Hospitalization Program (CAPHS) and are 18 years old. You are also being asked because you have also reported thinking about or attempting suicide at least once in the past year.

This study is being conducted by Dr. Ian Cero and the University of Rochester Medical Center (URMC).

Purpose of Study

The purpose of this study is to understand the benefits of a program to prevent suicide attempts among teens with recent histories of suicide-related concerns. The program is called Youth-nominated Support Teams (YST). It involves you naming 3-4 trusted adults to provide social support for you during the next 12 weeks.

Description of Study Procedures

Support Team. If you decide to participate in the study, we will help you choose roughly 3-4 trusted adults in your life who might want to be on your Support Team for the next 12 weeks. As part of this study, your support team will be given information about your recent mental health experiences so that they can best support you. We will start this process with you as soon as possible. We will also help you schedule your first interactive session with us. The whole process of choosing your trusted adults and scheduling your first interactive session usually takes about 30 minutes.

Interactive sessions and surveys. You will complete three interactive sessions with one of our study staff during your study participation. All study staff have mental health training and are supervised by Dr. Cero. You will have your first interactive session about one week before discharging from CAPHS. Only you and one of our study staff will be at the first interactive session. You will have your second interactive session about 4-6 weeks after discharging from CAPHS and your third interactive session about 10-12 weeks after discharging. For interactive sessions that happen after discharge, we may also invite one or more of your support team members to join.

There are two parts to all interactive sessions:

3. *Surveys (30-60 minutes)*: You will complete secure, online surveys about your current emotional and social health. These surveys will be similar to surveys you took during your time in the partial hospital program at CAPHS. At the end of the third session, we will also ask you for feedback about the program, like things you think should be changed for teens in the future.
4. *Strengths-focused interactive discussion (45-60 minutes)*: You will participate in a series of interactive activities and discussion topics. You will learn about how to use three specific strengths to help you work through growth and change after discharging from CAPHS. The strengths include working on social connection, emotional balance, and activities that build meaning and purpose in your life. During the second interactive session, when one of your support team members is there, you will also talk about how you both have used those three strengths in the past, and how you both might work on those strengths together in the future.

You will also complete one final survey about 22-24 weeks after discharging. The survey will be the same as the other surveys you completed, except you will not have an interactive discussion at this meeting. This survey is to help us understand how things have been for you after the program ends.

Text messages. After discharging from CAPHS, you will start receiving automated text messages about once a week until your third interactive session (about 12 weeks total). Some of these text messages will be for you alone. Some of them will be group texts for you and one of the adults on you support team. The text messages will focus broadly on helping you reflect on the strengths you learned about in the first interactive session (e.g., "How has working on social connections helped you in the last week?") and helping you to interact with your supportive adults (e.g., "What has been the most helpful for finding purpose this week for each of you?").

Safety plan. For you to participate in this study, we will ask for a copy of your safety plan from your current therapist or your medical record. We will also share it with your adult support team, so that the team has the information they need to help you in the event of an emergency. Agreeing to participate in this study means you give us permission to get the safety plan from your therapist and share it with the supportive adults on this study.

Study conditions. Part of the purpose of this study is to use the feedback from our participants to improve the content of the YST+YM intervention (e.g., make text messages easier to read, add or subtract activities based on what you liked or didn't like). The study therefore has two conditions: (1) an early condition where we will use participant feedback to change the YST+YM intervention as the study takes place; and (2) a later condition where we will still ask for your feedback, but will not revise the intervention anymore until after the whole study is completed. You will be assigned to one of these two conditions based only on your start date. You are not able to choose which condition you are in. You will not be told which condition you are placed in.

Number of Subjects

Approximately 65 youth subjects will take part in this study, along with roughly 65 of their parents / legal guardians and about 200 adult subjects who will make up the youths' support teams.

Duration of the Study

The total duration of the study will be between 6 and 7 months. This includes roughly 12 weeks to complete the support team program and then a 12 week follow up period.

Risks of Participation

There are a few risks of participating in this study.

6. The questions in the surveys and interviews could cause some emotional stress to you due to the personal nature of the material. For example, you will be asked about your emotional health and that may bring up difficult memories or feelings. You will also be asked about the program's match and perceived benefit for you, which may also bring up difficult memories or

feelings. All the questionnaires and interview questions have been used in previous research with adults and adolescents. No lasting negative effects are expected from the evaluations. You are free not to answer any question(s) for any reason at any time.

7. The questions in the surveys or interview could make you tired due to the length of the interview. You are free to stop the interview if you become tired.

8. Some of the survey and interview questions ask about mental health symptoms (e.g., depression, anxiety), recent stressful experiences, and suicide. If we become concerned about your safety (or the safety of others), we will notify Dr. Cero (or an on-call associate) for recommendations within 24 hours. One action we may take is to notify your parent / legal guardian about your safety concerns. We may also contact emergency medical services (911) or the police, in the event of immediate concerns about your safety. In addition, the researchers are required to report information regarding potential child abuse or neglect reported by you or you.

There are a few risks of participating in the YST+YM program:

5. Although the focus of the YST+YM program involves an optimistic and strengths-based focus, the content may still remind you of difficult memories. You may feel emotionally stressed due to the topics discussed in the interactive session or with your supportive adults each week. We have used similar program content with both children and adults in the past and no lasting effects are expected. You are free to skip any topics you do not feel comfortable with during interactive sessions. You are also free to decline to interact with any of your support team members at any time.

6. There are also some risks to privacy and confidentiality involving text messages. These are described in detail below.

Remember: for this study, you are not expected to do anything that you are uncomfortable with. You are free to stop either the YST+YM program or the surveys/interviews at any point.

Use of Text Message Communication for Research

Text messages by mobile/cell phones are a common form of communication. The YST+YM program in this study involves sending you (and members of your support team) text messages. These text messages are designed to help you reflect on the content and broad themes of the YST+YM program, as well as to help you and your support team communicate. Some of these text messages may be personalized to your interests that you share during interaction sessions (e.g., “Last time we met, you said playing soccer really helped you stay emotionally balanced. What can you do to make sure you play soccer at least once this week?”). When you and a support team member receive group text messages from us, they will be designed to encourage conversation and shared reflection on the YST+YM program content (e.g., “What is something that has helped each of you stay emotionally balanced this week?”).

You should know that texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted (protected). This means that information you send or receive by text message (a) could be intercepted, or (b) viewed by an unintended recipient, or (c) viewed by your mobile/cell phone provider or carrier.

You should also know that:

- We will never ask you or a support person about your mental or physical health over text. We will never ask any questions that ask about any other private health information over text. All text messages are focused on reflecting on the strengths-focused YST+YM themes.

- All text messages are automated. None of them are actively monitored by a member of the study staff in real-time. Therefore, you should not ask for emergency or safety-related assistance via text messages. We will not be able to receive those requests. Instead, you will be instructed to follow the steps listed on the safety plan constructed before discharge.
- You/your parent/legal guardian will be responsible for all fees charged by your/your teen's carrier's service plan for text messaging. This research study and the University of Rochester are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messaging should not be used for sensitive medical information, or in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number (585-684-3597) a text message that says "unsubscribe."
- Your agreement, and any request to stop text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

By agreeing to using text messages in this study, you are agreeing that you understand the risks of text message communication.

Use of Email Communication for Research

You have the option to receive communications about this study via email, by indicating your agreement at the end of this form. We will only email about scheduling (e.g., appointment reminders) or to provide resource information. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your agreement below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email.

Audio-video recordings

YST+YM interactive sessions may include audio-video recordings, collected via URMC supported video conference software (e.g., Zoom). These recordings will be labeled only with a code number, which will be kept in a URMC secure data storage platform. These recordings will be used to evaluate how well the intervention is going and ways we might improve it in the future.

Agreeing to participate in this study means that you agree to the research team making and retaining the audio/video recordings for this study. You have the right to review the recordings and to ask that all or any part of the recording be erased.

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you from being in this study might be increased sense of well-being and a reduced risk of future suicide attempts.

Sponsor Support

The University of Rochester is receiving funding from The National Center for Advancing Translational Sciences (NCATS) to conduct this study.

Costs

There are no costs to enroll in this study. However, it is possible there are fees related to text messaging that will be charged by your cell service carrier plan.

Payments

You will receive $25 via an Amazon.com e-gift card after completing each of the survey points (interactive session 1; interactive session 2; interactive session 3; final survey). This means that you can earn up to $100 in e-gift cards for participating in survey points. You will not receive a payment for a missed survey point.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we have trained all of our study interviewers in confidentiality procedures. We will enter and store the information you share with us using coded identification labels. Your named file is stored in a locked filing cabinet in a locked office, kept separate from your coded file. We will maintain project computers in secure locations with restricted access by enforced password protection. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask study staff for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past or present medical records or e-records to make sure the study is a good fit for you

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institute of Health

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this be permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?

You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer

use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you, you, and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Future contact after the conclusion of this study

We may want to contact you in the future about this study. You can decide now whether you want to be contacted. You can also change your mind later.

If you agree, we may contact you for several reasons. For example, we may contact you to update basic information.

Contact Persons

For questions related to your participation, for more information concerning this research, if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Cero at youth_connect@urmc.rochester.edu.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642-8315, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subjects;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

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Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study and agree to my child's participation in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

___ *I consent to the use of email in this study.*

___ *I consent to the use of text messaging in this study.*

___ *I consent to being contacted in the future about this study.*

_____
Subject's Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date