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A Multi-Site, Non-Intervention Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings

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1. Synopsis

Protocol Title: A Multi-Site, Non-interventional Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings

Rationale: Evaluating alternatives to inpatient treatment for suicidal adolescents is urgently needed. An unprecedented use of telehealth crisis services are being utilized during the COVID-19 pandemic. Evaluation of outcomes for telehealth care is greatly needed. To address the unmet need of optimizing the treatment and management for adolescent suicidality, we propose to compare treatment outcomes of Telehealth Crisis Intervention Services (CIS) to in-person Outpatient Crisis Intervention Clinic (OCIC) and inpatient treatment.

Objective and Endpoint

Objective	Endpoint
Primary	
▪ Evaluate the safety of CIS-telehealth relative to inpatient and OCIC-in-person among children with similar CHRT scores.	▪ Time to first recurrence of a suicidal event ▪ Number of suicidal events ▪ Severity of suicidal ideation
Secondary	
▪ Examine the effectiveness of CIS-telehealth relative to inpatient and in-person OCIC among children with similar CHRT scores.	▪ Score from PROMIS Short Form v 1.0-General Life Satisfaction-Short Form 5a (to assess the parent's well-being) ▪ Score from PROMIS Parent-Proxy Life Satisfaction-Short Form 8a ▪ Score from PROMIS Pediatric Life Satisfaction-Short Form 4a ▪ Score from CHRT-SR at baseline and follow-up visits
▪ Assess patient and parent treatment satisfaction with CIS-telehealth relative to inpatient and in-person OCIC among children with similar CHRT scores.	▪ Score from Client Satisfaction Questionnaire (CSQ-8)
Tertiary/Exploratory	
▪ Does Telehealth CIS lead to greater reduction of emotional arousal or perceived stress levels in response to COVID-19 the pandemic	▪ Scores from the COVID-19 survey

Overall Design: Observational Design
Number of Participants: CCHMC- 61; other 3 sites- 61 each; total- 244 from all 4 sites
Treatment Groups: Inpatient Psychiatric Treatment vs. Outpatient Crisis Intervention Clinic (OCIC) vs. Telehealth Crisis Intervention Services (CIS)

Duration: 12 Months (1 Years)

2. Introduction

Suicide is a leading cause of death for adolescents in the United States.[1-5] Inpatient psychiatry, a frequent treatment setting for adolescents with suicidality [6-9], is problematic because it can lead to a burden on families [10-13], disruption in school [14], financial cost to society [15, 16], a substantial increase in the risk of suicide attempts after short psychiatric hospitalizations [17-23], assault by other patients [24-26], and poor self-esteem from the stigma.[27-29] Indeed, alternatives to inpatient psychiatric treatment need to be explored due to bed shortages [8, 30], access issues [31-35], and boarding of adolescent psychiatric patients in medical units and Emergency Departments.[36-39] Taken together, evaluating alternatives to inpatient treatment for suicidal adolescents is urgently needed. Outpatient Crisis Intervention Clinic (OCIC) is an alternative treatment option that provides a more intensive level of short-term (two to six weeks) support with multiple therapeutic visits for patients and families each week promptly starting within three days of the crises (the Emergency Department (ED) visit). OCIC provides these services for the adolescents and their families who are waiting for outpatient services without exposing these adolescents to the above-mentioned disadvantages of inpatient psychiatry treatment. [40-43] Due to the worldwide pandemic, the mental health community has shifted many of its services to telehealth, including crisis intervention. More research is needed to assess the effectiveness of this treatment modality compared to inpatient and OCIC services.

2.1. Study Rationale

The COVID-19 pandemic has led to disruptions throughout medicine, including psychiatry. The vast majority of psychiatric services at institutions across the country have rapidly shifted to telehealth-based services. This includes services for adolescents with suicidal ideation. Although this shift was done to provide services in a time of crisis that all but eliminated face-to-face services, the mental health community is left with questions regarding safety and effectiveness of telehealth. This is especially true for adolescents with suicidal thoughts. Previous research that explored the use of telehealth in mental health services has focused primarily on rural populations where services are limited (Roberts et al 2017, Saurman et al, 2014). Research has not specifically examined the effectiveness and safety of telehealth for adolescents with suicidal thoughts. This is partly attributable to restrictions on telehealth like state regulations, licensing, insurance, and equipment (Mace et al, 2018). However, the US response to COVID-19 has effectively eliminated these barriers. Currently, there is an unprecedented use of telehealth across US health systems. Yet, there is a deficiency of research indicating that telehealth for adolescents with suicidal thoughts is safe *and* effective. Given the current changes and their potential for long-term or permanent implementation, knowledge is urgently needed establish whether telehealth is a safe and effective approach for adolescents with suicidal thoughts. The START study is in a unique position to evaluate telehealth services relative to the current standards of care. By integrating an enhancement project into our current START study, we will be able to make a critical contribution to the learning of safe and effective treatment for adolescents experiencing suicidal thoughts now and in the future. The mental health community needs to determine the factors that can identify the safety of treating adolescents with suicidal thoughts in an outpatient and telehealth setting.

To address the unmet need of optimizing the treatment and management for adolescent suicidality, we propose to evaluate the effectiveness and safety of telehealth services compared to inpatient and OCIC for suicidal adolescents in our target population. To achieve this goal, we propose a multi- site study to compare telehealth, OCIC, and inpatient care, and see which can lead to a lower risk of a suicidal event (primary outcome) as well as higher treatment satisfaction (TS) and satisfaction with life (SL) (secondary outcomes) of both the legal guardians/parents and patients.[11, 44, 45] Furthermore, we will assess which clinical and socioeconomic factors at baseline may affect the treatment outcomes. With the results from our proposed study, we will be able to reduce the family and clinician decisional uncertainty about the best treatment setting for suicidal adolescents in our target population. The results will significantly help patients, families, and clinicians with this decision-making process and improve outcomes for suicidal adolescents.

2.2. Background

Suicide is a leading cause of death for adolescents in the United States. [1-5] Adolescent suicidality includes suicidal thoughts, intent, plans, and attempts. [73] Suicidality does not include nonsuicidal self-injury (NSSI) because it does not include intent to die. [74] The primary outcome measure for this proposed research will be the time to first recurrence of a suicidal event. [75] A suicidal event is defined as: a suicide attempt, interrupted attempt, hospitalization because of suicidal risk, an emergency/urgent evaluation because of suicidal risk, and a death by suicide. NSSI is not our primary target and we will focus on adolescents who present with suicidal thoughts and suicide attempts which can also include NSSI. Therefore, to improve generalizability, we will collect data on NSSI even though it is not part of our primary outcome.

Our stakeholder partner, Heather Turner, Executive Director, NAMI of Southwest Ohio, clarified that the most acceptable terminology is death by suicide or died by suicide rather than committed or completed suicide.[76] For adolescents in the United States in 2015, suicide was the third leading cause of death between the ages of 10 and 14, and the second leading between the ages of 15 and 34. [2, 4, 5] For girls (ages 15 to 19), the suicide rate doubled from 2007 to 2015 and was at its highest peak in 40 years in 2015 with a rate of 5.1 per 100,000. For males (ages 15 to 19), the suicide rate increased by 31% between 2007 and 2015 when the rate was 14.2 per 100,000.[3] The Youth Risk Behavior Surveillance Survey estimated that of high school students, 16% reported seriously considering suicide, 13% reported creating a plan to kill themselves, and 8% reported trying to kill themselves in the previous 12 months. [77] Adolescent suicidal behavior is common, with more than 1 million attempts and 4,600 deaths by suicide each year. [52] There is a clear need for development of treatment programs both aimed at preventing adolescent suicide attempts, as well as addressing recurrent suicidal ideation and promotion of safety following an attempt. [78, 79]

The Problems with the Current Standard Treatment for Adolescent Suicidality: The standard and common treatment for adolescents with suicidality is inpatient psychiatry [6-9], which includes therapy (individual and group), improving coping skills, family meetings, close monitoring of safety, and medication management. [81] It is important to note that the Standard of Care at Cincinnati Children's Hospital Medical Center has improved, as OCIC interventions have been introduced. CCHMC, Northwell Health, Nationwide Children's and Children's Health **(in Dallas**), along with at least 10 other locations across America have introduced OCIC interventions.[1-2, 4-5] Inpatient psychiatry is a short term intensive treatment method that is commonly used in clinical practice for suicidal adolescents and is seen as an important

component in the treatment of adolescents with mental illness.[6-9] However, there are no direct studies on the efficacy of inpatient hospitalization in reducing adolescent suicidal behavior. Not all adolescents brought to the ED for suicidality are acutely suicidal. Suicidal ideation runs on a spectrum of increasing severity and intensity of the ideation and behavior. The following scale displays the increasing severity nature of suicidal ideation: 1) Wish to be dead, 2) Non-Specific Active Suicidal thoughts, 3) Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act, 4) Active Suicidal Ideation with Some Intent to Act, without Specific Plan, 5) Active Suicidal Ideation with Specific Plan and Intent. (Columbia-Suicide Severity Rating Scale 2016). While the demand for inpatient psychiatric treatment is high, the number of inpatient beds has been decreasing in the U.S. in the past decade. [8, 30] Studies have shown that inpatient hospitalization may not be effective in the linkage of patients to outpatient treatment. [82]The time period after discharge from inpatient hospitalization can be a time for increased risk for suicidal behavior. The first month following discharge from an inpatient psychiatric hospitalization has been identified as the greatest period of risk for reattempt. [17] In addition, despite the importance of continued outpatient care, previous research shows that the majority of adolescents who attempt suicide receive limited follow up care with less than 40% receiving a follow-up visit within 30 days. [75, 83] A study from 2017 found that children's hospital admissions for suicidality more than doubled from 2008 to 2015. [84] Inpatient psychiatry is problematic because it can cause worsened depression [85], be a burden to families [10-13], disrupt school [14], increase the risk of suicide attempts after short psychiatric hospitalizations [17-23], and lead to poor self-esteem from the stigma of inpatient treatment. [27-29] Moreover, adolescents whom have suicidal thoughts that return may not seek help if they had a negative experience with inpatient psychiatry. [86, 87] Indeed, alternatives to inpatient psychiatric treatment need to be explored due to bed shortages [8, 30], access issues [31-35], and boarding of adolescent psychiatric patients on medical units and Emergency Departments. [36-39]

Alternative Treatment to Standard Treatment of Adolescent Suicidality: Telehealth services encompass an emerging intervention due to the need for social distancing measures. They encompass crisis interventions that include safety planning, therapeutic interventions and emergency medication consultations. Telehealth services will not be the same at all sites, but involve similar services.

At CCHMC, our study team developed the term Outpatient Crisis Intervention Clinic (OCIC) to encompass the programs from the 4 individual sites, CCHMC, Northwell Health, Nationwide Children's and Children's Health, that provide similar, but not the same, services. The 4 programs that encompass the term OCIC have some variation in treatment approaches and duration, however all 4 programs have crisis intervention work in common, including appointments that occur soon after emergency department visits for crisis intervention. In comparison to inpatient psychiatry, Outpatient Crisis Intervention Clinic (OCIC) provides more intensive therapeutic services for adolescent suicidality with frequent family focused mental health appointments, specific therapeutic interventions for suicidality while outside of the hospital, and more thorough safety planning to prevent future suicidal events. OCIC has advantages because it provides a more intensive level of short-term (about two to six weeks) support with multiple therapeutic visits for adolescents with suicidality and their families each week starting within three days of the crises. OCIC provides these services for the adolescents and their families who are waiting for outpatient services without exposing these adolescents to the above-mentioned disadvantages

Gaps in Knowledge about Outcomes of Alternative Treatment of Adolescent Suicidality: Few programs have been developed that bridge the vulnerable period of time spanning between Emergency Room evaluation for adolescent suicidality to outpatient care,[88-90] and even fewer that provide intensive treatment in an outpatient setting for teens.[17] As such, there is tremendous need to develop and test optimal treatment strategies for adolescents during this high risk period, as highlighted in Objective 8.4 of the National Strategy for Suicide Prevention, to "promote continuity of care and the safety and well-being of all patients treated for suicide risk in emergency departments or hospital inpatient units." [91]

This study aims to evaluate treatment outcomes for Telehealth CIS, In-Person OCIC and Inpatient treatment. The gap in knowledge is that it is unknown if telehealth services or OCIC will lead to better outcomes than inpatient psychiatry. Clinical trials have not examined the effectiveness of telehealth or OCIC in treating adolescent suicidality. The last publication on the American Academy of Child and Adolescent Psychiatry Practice Parameters (AACAP) for the treatment of children and adolescents with suicidal behaviors was from 2001. [54, 92] Our proposed research will provide the needed evidence to update these practice parameters for adolescents with suicidal behaviors. Although there are no randomized controlled trials to determine the effectiveness of admitting suicidal adolescents, the AACAP parameters recommended inpatient psychiatry for adolescent suicide attempters with persistent suicidal thoughts. Since the time of the last AACAP parameters publication, standard of care for the treatment of adolescent suicidality has improved to include OCIC interventions. This improvement has led to a decrease in unnecessary inpatient hospitalizations.[1-2, 4-5]

Although the National Action Alliance for Suicide Prevention released evidence-based recommendations for standard care for adults with suicide risk on April 17, 2018, no recommendations for standard care were provided for adolescents with suicide risk.[94]The adult recommendations are as follows:

Primary Care	• Identify and assess the risk for suicide among all patients who have mental illnesses, misuse substances, have been prescribed psychiatric medication or have a substance use disorder an stratify them according to risk level. ➢ For those with elevated risk • Provide information on crisis hotlines which include the National Suicide Prevention Lifeline. Work with family and significant others to reduce patient's access to lethal means. • Work with behavioral health professionals to engage with the patient. • Follow up with patient within 24 hours after discharge.
Emergency Depart-ment	• Assess all patients for suicide risk and stratify patients according to risk level. Pay close attention to any injuries sustained and the nature of those injuries since this may affect risk level. • Determine risk level and treatment type (Discharge with support, Outpatient or Inpatient treatment). • Provide a safe, monitored space and remove items that could be used to do bodily harm. • For those with elevated risk who will be discharged with support • Provide information on crisis hotlines which include the National Suicide Prevention Lifeline number (1-800-273TALK). • During the visit, complete a safety plan that focuses on reducing access to lethal methods and ask for assistance from loved ones. • Engage the patient with a licensed mental health provider after discharge. • Make "caring contact" with the patient 24 hours after discharge and again 7 days after discharge.
InpMental Health	• Assess all patients for suicide risk and stratify patients according to risk level • Completely safety plan on admission • Develop a collaborative safety plan for the environment the patient will return to. This should include individuals that can help support the patient after discharge. • Provide crisis hotline information (Preferably someone with training in assessment ad safety planning). • Engage the patient with a licensed mental health provider after discharge. • Make "caring contact" with the patient 24 hours after discharge and again 7 days after discharge.
Outpatient Mental He	• Assess all patients for suicide risk and stratify patients according to risk level ➢ If risk is Elevated • Complete a collaborative safety plan as part of the treatment plan during the visit. • Provide crisis hotline information (Preferably someone with training in assessment ad safety planning). • Reassess risk and review and/or update the safety plan at every visit until risk levels decrease to less threatening levels.

The standard care for adolescents with suicidality is expected to be different because adolescents often have a built-in safety net with their families who can provide supervision. Hence, OCIC is more feasible for adolescents with suicidality than adults. Additionally, with the COVID-19 safety measures in place around the country, telehealth services are more widely used service in treating mental health crises. With the results from our proposed study, we will be able to eliminate the family and clinician decisional uncertainty about standard care and the best treatment setting for suicidal adolescents and improve treatment outcomes. We will address the comparative clinical effectiveness research (CER) question regarding the evidence gap about which treatment setting is most effective. We will compare the effectiveness of: telehealth CIS, OCIC and inpatient treatment at reducing adolescent suicidality by assessing the time to first recurrence of a suicidal event, the number of suicidal events, treatment satisfaction (TS), and satisfaction with life (SL).

Most Relevant Preliminary Data: In 2017, out of 401 adolescent patients with suicidality who were in the Cincinnati Children's Hospital's OCIC, only 25 (6%) returned to the ED for psychiatric reasons within 90 days of their first OCIC appointment. Also, the treatment satisfaction ratings by parents were higher for OCIC than inpatient in 2017. For example, significantly more parents (88%) rated that they felt that they participated as much as they should have in OCIC in comparison to inpatient psychiatry (74%). Upon completion of the Dallas OCIC, one of our four sites, teens and parents completed the Client Satisfaction Questionnaire (CSQ-8) CSQ to assess satisfaction. Both patient and parent satisfaction were very high. In response to the question, "In an overall, general sense, how satisfied are you with the service you have received?", 99% of parents and 96% of teens responded that they were mostly satisfied or very satisfied. When asked if they would refer a friend, 89% of parents and 67% of teens responded "definitely yes" while only 1% of parents and 2.3% of teens responded "don't think so". The average score across items on the CSQ for those who were enrolled in the program was 3.78 (SD=.33) for parent (n=290), and 3.54 (SD=.49) for teen (n=302) on a 4 point scale (with 4 indicating the highest level of satisfaction). The findings suggest that OCIC for adolescents with suicidality is both acceptable and feasible as well as efficacious as an alternative to inpatient psychiatry treatment. However, a randomized trial is needed in order to determine the efficacy of OCIC compared to inpatient psychiatry. At our site in Dallas, Drs. Kennard and Emslie saw 364 eligible adolescents (aged 12 to 17 years; mean age 14.9 ±1.4 years) from January 1, 2014 and December 31, 2015 who had a worsening of suicidal ideation or a recent suicide attempt were enrolled in a newly-developed OCIC and attended at least 1 appointment. Suicidality (CHRT-SR) was assessed at baseline and discharge from the program. The majority of patients completed the OCIC program (81.04% over a 4 week period). Patients were improved at the time of discharge on depressive symptoms and suicidal ideation and behavior. Both parents and patients reported significant improvement in depression severity based on the QIDS-A at exit (7.67±4.87 and 8.65±5.58, respectively) compared to baseline (13.22±4.81 and 13.65±5.98, respectively), $p<.0001$.

Scores on the CHRT were also significantly reduced by discharge with propensity scores (26.01±10.43 vs. 16.72±10.03; $p<.0001$) as well as active suicidal ideation scores (4.85±3.63 vs. 1.91±2.40; $p<.0001$) showing a marked improvement compared to baseline. Preliminary clinical outcomes at discharge from Drs. Kennard and Emslie's OCIC and at six month follow-up were positive. Patients were improved at the time of discharge on self-report of depressive symptoms

and suicidal ideation and behavior. 286 of the 364 adolescents (or 78.57%) responded to the 6 month follow up questions. In total, 8.7% and 27.3% of the 286 respondents reported a suicide attempt and event, respectively, within 6 months of discharge from OCIC. Reattempt rates at 6 months were at 8.7%, with almost half these occurring within one month after discharge. Suicidal events (includes attempts, emergency room visits or hospitalization) at 6 months were at 27.3%. It is possible that the suicidal events were higher than attempts because the adolescents were following their safety plan and reaching out for professional support when suicidal ideation increases. Patients who made an attempt within the 6 month follow up period had a history of more previous attempts, higher self-report of depressive symptoms at discharge, and higher levels of active suicidal ideation (CHRT) at entry and exit.

Those patients who had a suicide event at follow-up were more likely to be female, had more previous attempts, and had higher self-reported and parent reported depression at entry in the program. Those with a suicidal event also had higher self-reported active suicidal ideation at entry into the program.

Due to the fact that telehealth CIS is only currently being widely used for mental health services in this population group, CHRT-SR and other follow up data is not currently known. This research will seek to fill in this gap of knowledge.

2.3. Benefit/Risk Assessment

Potential Benefits to Participants: The benefits of participation include having an increased level of safety monitoring which involves gathering data from parents and participants every two weeks for up to180 days. Participants and their parents will receive monitoring that is likely to be more intensive than what would be available in the community. Overall, safety may improve for participants in all treatment groups when compared to adolescents with suicidality who are not in this study. All of this monitoring will be provided at no cost to the participants and their families. Research project staff will be on call during business hours for participants in all treatment groups. We will check in with patients in person or with phone calls as needed. Phone calls or in person visits will occur depending on whether research staff feel that it is needed based on participant responses to scales and questionnaires. If safety concerns are identified during follow survey completion, including suicidal behavior or an increase in suicidal ideation based on questions 13-14 on the CHRT-SR, an automated text message or email will be sent to guardians identifying the safety concern and providing emergency numbers if needed. Research staff will then attempt to contact legal guardian to encourage follow up with patient's clinical team and provide referrals if needed. If serious safety concerns are identified, including significantly worsening suicidal thoughts or suicidal behaviors, family will be referred to the ED. Text messaging may also be used as a reminder of study participation and/or to notify that further communication by phone or in person is needed. Study related questions or safety concerns may be addressed via text messaging, email, phone calls or in person communication. Participants may derive a sense of accomplishment from participation in research and contributing to the knowledge of treatment of adolescents with suicidality.

Potential Benefits to Others: Potential benefits to society may be considerable. Information will be provided about the outcomes and treatment satisfaction of telehealth CIS, OCIC, and inpatient for adolescents with suicidality. If telehealth CIS and/or OCIC is found to have the same or better outcome to inpatient within our study population group of patients with

low to moderate suicidal ideation, this could help inform patients, parents, and clinicians about the best treatment. We will also learn about which factors influence outcomes within each treatment group. Finally, we will learn about barriers to treatment by assessing the "no show" group. Our research is expected to reduce decisional uncertainty about the best treatment setting for adolescents with suicidality. Given the careful assessment and monitoring for safety, and the potential benefits to adolescents with suicidality, we believe that this study has a favorable risk to benefit ratio. With the above significant benefits to participants and others, the minimal risks to the participants are reasonable.

By comparing outcomes from telehealth CIS versus OCIC versus inpatient treatment, we will significantly help patients, families, and clinicians with the decision-making process and improve outcomes. Important knowledge gained about HTE's (clinical and sociodemographic factors) will help with future decision making about treatment options. Furthermore, important knowledge will also be gained concerning barriers to treatment for the "no show" group. The minimal risks to the participants are reasonable in relation to the importance of the knowledge to be gained since telehealth CIS, OCIC and inpatient provide a higher level of care. Our proposed research (with minimal risks) will provide important evidence to fill in the knowledge gap regarding standard care for adolescents with suicidality.

Risks and Discomforts

A potential risk is the possible disclosure of PHI during the gathering and assessment of the data. The risk of PHI being disclosed to unintended recipients is minimal and secured systems have been in place at each location that will ensure the protection of any information from any unauthorized releases. In order to further enhance our data security measures, we are limiting access to the data to our Data management team located at CCHMC.

Also, surveys and assessments can cause burden and potentially trigger feelings of sadness in the participants. Since this research is working with a vulnerable population (adolescents with suicidal thoughts), there is a risk of a possible increase in suicidal thoughts if a participant becomes more sad. Follow up surveys will be reviewed by study staff to assess if intervention and/or referral is needed due to triggered emotions.

Breach of confidentiality: There is a potential risk of loss of confidentiality. Consistent with the Federal guidelines, all patients and guardians will be informed of the federally mandated reporting laws for child abuse and neglect, verbally and in the written consent form. Therefore, if abuse or neglect is suspected, per institutional and legal standards and requirements, the Department of Human Services may be called if appropriate and indicated. Risks associated with this reporting include embarrassment, legal consequences, and removal of the child from home.

3. Specific Aims and Hypothesis

Specific Aims	Hypothesis
SA1: Evaluate the safety of CIS-telehealth relative to inpatient and OCIC-in-person among children with similar CHRT-SR scores.	• Our working hypothesis is that CIS-telehealth is associated with a greater risk of suicidal event relative to inpatient and in-person OCIC. • Response is defined by a delay in first recurrence of a suicidal event and a lower number of suicidal events over 90 days and 180 days. • **Clinical Features:** 1. Severity of suicidal ideation at baseline and over 180 days 2. number of suicidal events at baseline only 3. Substance use at baseline and over 180 days. • **Sociodemographic features**: Age, Gender, Gender Identity, Type of insurance (Public, Private or none), Ethnicity, Race, or living with one biological parent, two biological parents, a stepparent, a relative, or other.
SA2: Examine the effectiveness of CIS-telehealth relative to inpatient and in-person OCIC among children with similar CHRT scores.	▪ Our working hypothesis is that CIS-telehealth will be associated with poorer reduction in emotional arousal and perceived stress levels in response to COVID-19 the pandemic relative to CIS-inpatient and CIS-in-person.
SA3: Assess patient and parent treatment satisfaction with CIS-telehealth relative to inpatient and in-person OCIC among children with similar CHRT scores.	▪ Our working hypothesis is that CIS-telehealth is associated with less patient satisfaction than inpatient and in-person OCIC among children with similar CHRT scores.
Exploratory Aim	

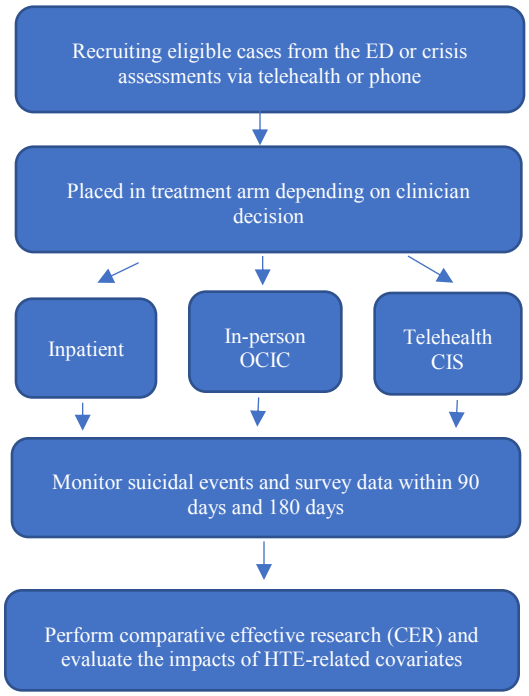
Specific Aims	Hypothesis
SA4: As an exploratory aim, assess the demographics and potential barriers to treatment for a third comparator of the "no show" group who were placed in Telehealth, OCIC or inpatient treatment but never showed up or left the inpatient unit against medical advice (AMA). Please see section 6.2 Treatment Compliance to view plan regarding follow up for this "no show" group. SA5: As an exploratory aim, assess the impact of the COVID-19 pandemic on social and emotional functioning.	• The no show group (the third comparator) who did not arrive for any OCIC appointments or left AMA from inpatient treatment will differ from the other comparators with respect to the following barriers to treatment: 1) Age 2) Gender [53-56] 3) Type of Insurance (public insurance/no insurance/private) [61-63] 4) Ethnicity (Hispanic/Non) [64]; 5) Race (African-American (AA) versus non-African American) [65-67]; 6) Living with one biological parent, two biological parents, a stepparent, a relative, or other [68, 69] • The no show group will have significantly shorter time to first recurrence of a suicidal event and a larger number of suicidal events over 90 days and 180 days in comparison to the other patients. • We hypothesize that the levels of perceived stress and depressed mood have been increased amidst the COVID-19 pandemic.

4. Study Design

4.1. Overall Design

The study conceptual framework is illustrated in Figure 1. Briefly, we have proposed an observational design. Eligible individuals will be identified during a crisis assessment, either in the emergency department or during an emergency phone or telehealth assessment. Once the individual has been assessed and assigned to the clinician for treatment, study staff will assess if the patient is appropriate for the study using the study eligibility criteria. Individuals who receive treatment in one of the following treatment arms will be eligible for this observation study: inpatient, in-person OCIC or telehealth crisis intervention service. Eligible individuals will be contacted by study staff to introduce and offer the study. If patient and guardian agree, they will complete surveys at baseline and every 2 weeks for 6 months to evaluate outcomes.

Figure 1



Clinical features will be measured with the CHRT-SR, Suicidal Event Form for START, and our short START-Clinical Features (CF) form at baseline and every two weeks (see Schedule of Events) to evaluate HTE's. A one time survey will be completed at week 2 that collects information related to the impact of COVID-19 on the family. To decrease clinician, patient, and family burden, the scales are self- report short forms. All START follow up forms will be sent to participants and guardians every 2 weeks via email prompts in REDCap and data will be collected upon return from participants. Study CRCs will make best efforts to contact families for reminder to complete data within the study milestone window, however completion at each milestone marker is not ensured due to nature of population group. Data will be collected when available. The research coordinators, a research team member, or clinicians will ensure the

completion of the Suicidal Event Form for START and the brief START-CF form based on EHR review and/or other sources of information (family and patients) within 72 hours of admission (baseline) to inpatient, telehealth CIS, or OCIC and every two weeks. The research coordinators will search the EHR for all hospitals (with permission and consent) on weekly basis for suicidal events which may have ICD-10-CM code. [100] We developed this plan based on feedback from patients, families, and clinicians.

The following sociodemographic data will be gathered by our research coordinators or a research team member at baseline (within 72 hours of admission to inpatient, telehealth CIS, or OCIC) with our Demographic Form from our prior and current research on school safety: 1) Age 2) Gender [53-56] 3) Gender Identity [57-60] 4) Type of Insurance (public Insurance/no insurance/private) [61-63] 5) Ethnicity (Hispanic/Non[64]; 6) Race (African-American (AA) versus non-African American) [65-67]; 7) Living with one biological parent, two biological parents, a stepparent, a relative, or other. [68, 69]

4.2. Number of Participants

We proposed to recruit approximately 244 eligible cases that will be placed in 3 treatment arms: inpatient, in-person OCIC and telehealth CIS. We expect to recruit a small proportion of the suicidal adolescent group in the ED or who receive crisis assessment from telehealth or via phone. To test Aim 1, we will use Cox proportional regression model (CPR) to test whether the telehealth only CIS; outpatient, in-person CIS; and in-patient CIS groups have different incidence rates for recurrent episodes within 3 months. We expect that the sample sizes for the three arms will be *at least* 75, 75, and 70 respectively. To test Aims 2 and 3, we will use the generalized linear model (GLM) to evaluate whether telehealth only CIS; outpatient, in-person CIS; and in-patient CIS groups have different levels of changes in emotional arousal (Aim 2) and treatment satisfaction (Aim 3) at 3 months, after adjusting for several covariates (e.g., age, gender, triage "location"). For CPR, we will have power for our pilot study greater than 0.70 assuming a hazard ratio of 2.8 and greater than 0.8 for our GLM analyses assuming f2 = 0.1 and correcting for multiple comparisons.

Recruitment Plan for Prospective Studies

. Estimated number of potentially eligible study participants	500
. Total number of study participants expected to be screened:	300
. Total number of study participants expected to be eligible of those screened:	270
. Target sample size (use same number stated in milestones):	244
. Total number of practices or centers that will enroll participants:	4
. Projected month first participant enrolled (month after project initiation):	2nd Month

. Projected month last participant enrolled (month after project initiation):	10st Month
. Projected rate of enrollment (anticipated number enrolled per month of enrollment period):	2-10/month
. Estimated percentage of participant dropout:	10%

4.3. End of Study Definition

The end of the study is defined as the date, October 1, 2021, or when the last participant completes the last study visit.

5. Study Population

The study population and the study settings are appropriate for the proposed research question as we will include adolescents (ages 12 to 18) who present in the ED or for crisis assessment with suicidal ideation and who have been recommended from treatment in one of the following treatment arms: inpatient, in-person OCIC, and telehealth CIS. After discussion with our patient/parent partners and site clinicians, we determined that the appropriate study population is patients presenting to the ED in a mental health crisis with a history of suicidal-related symptoms and behaviors who are clinically judged to require a mental intervention following the ER visit or crisis assessment that could be safely treated in inpatient care or intensive outpatient management, in-person or telehealth.

5.1. Workflow

The START Non-intervention study workflow is as follows:

- Patient presents in the ED or crisis assessment with chief complaint of suicidal ideation.
- Patients will be assessed by a mental health clinician and treatment will be determined. The CHRT-SR will be clinically obtained or during baseline data gathering at crisis assessment.
- If a patient is determined to need inpatient, in-person OCIC or telehealth CIS, they are eligible for the study and will be contacted by research staff to introduce the study.
- If patient and guardian agree to be in the study, they will be remotely consented and complete baseline surveys.
- Patient will be contacted every 2 weeks for up to 6 months to complete surveys.

Consistent with Informed Consent standard operating procedures a guardian can withdraw consent at any time in the study.

5.2. Informed Consent

To avoid causing undue stress and burden to patients and their families, research coordinators will use a script when gaining consent that is specifically designed to minimize burden and stress. Research coordinators will be provided with extensive formal training regarding the proper administration of the informed consent process. This will be documented in the Study Staff Checklist.

We will be obtaining documented consent for this study. Consent will be obtained either in person or through REDCap. Study personnel will initiate the e-consent process and explain the study and the e-consent/assent forms. Participants will have the opportunity to ask questions prior to deciding whether to continue with enrollment or to decline. All participants will have the capacity to provide e-consent.

For this study, the IRB approved consent/assent document has been uploaded into the REDCap database. The IRB approved document has been modified to an electronic format, but will include all of the same elements as the IRB approved document (i.e. IRB number, approval dates, and CCHMC logo, etc.). The electronic informed consent form includes fields for full name, signature, and date and time of the signature for the consenter and witness, along with text that states that all signatures are associated with the Subject ID# registered in the database. When completed, REDCap will generate a footer that contains the long date and time the document was submitted and "Confidential" listed in the header as an added precaution to preserve the research participants' confidentiality.

The HIPAA Consent is queued to automatically open once the consent has been signed and all logic is satisfied.
For the HIPAA and Notice of Privacy Practices the IRB approved consent document will be uploaded into the database instrument. The instrument includes fields to capture full name, signature, and date and time of the signature for the consenter, and witness and conditional text that states that all signatures are associated with the Subject ID# registered in the database.
Signature process:
Participants and Witnesses will type their first and last name into a text box, sign their name in the signature field with a stylus or finger and then click "Now" by the date field to automatically enter the date and time. A copy will be printed or sent electronically to the subject per their preference.

5.3. Payment for Participation

Study participants (i.e. the adolescent patient) will be paid $20 for each survey completion for up to 6 months for their time and effort. Payments will be given upon completion of each milestone survey. Participants will receive payment for this study in the form of a reloadable debit card (Clincard).

5.4. The CHRT-SR and Recruitment

The CHRT-SR will be obtained at baseline and at all follow up milestones. The baseline CHRT-SR will be used to help identify a consistent population group for analysis across all treatment

arms. The baseline CHRT-SR will be clinically obtained and can be accessed through the medical record or will be obtained during baseline data gathering. The distributions of CHRT-SR scores from the beginning months, November 2019 to March 2020, of the START study are shown in Figure 2. One-way ANOVA was used to evaluate whether the three disposition groups differ by CHRT-SR scores. The results suggest that CHRT-SR scores did not vary by the disposition outcome ($F = 0.23$, p-value = 0.7921, Barlett's test for equal variance $\chi^2 = 4.55$, p-value = 0.103). We further used multinomial logistic regression model to examine whether CHRT-SR scores could predict the disposition outcome, and results also indicate that the outcome was independent of the score ($p > 0.05$ for two comparisons: Bridge vs. Outpatient and Inpatient vs. Outpatient, separately).

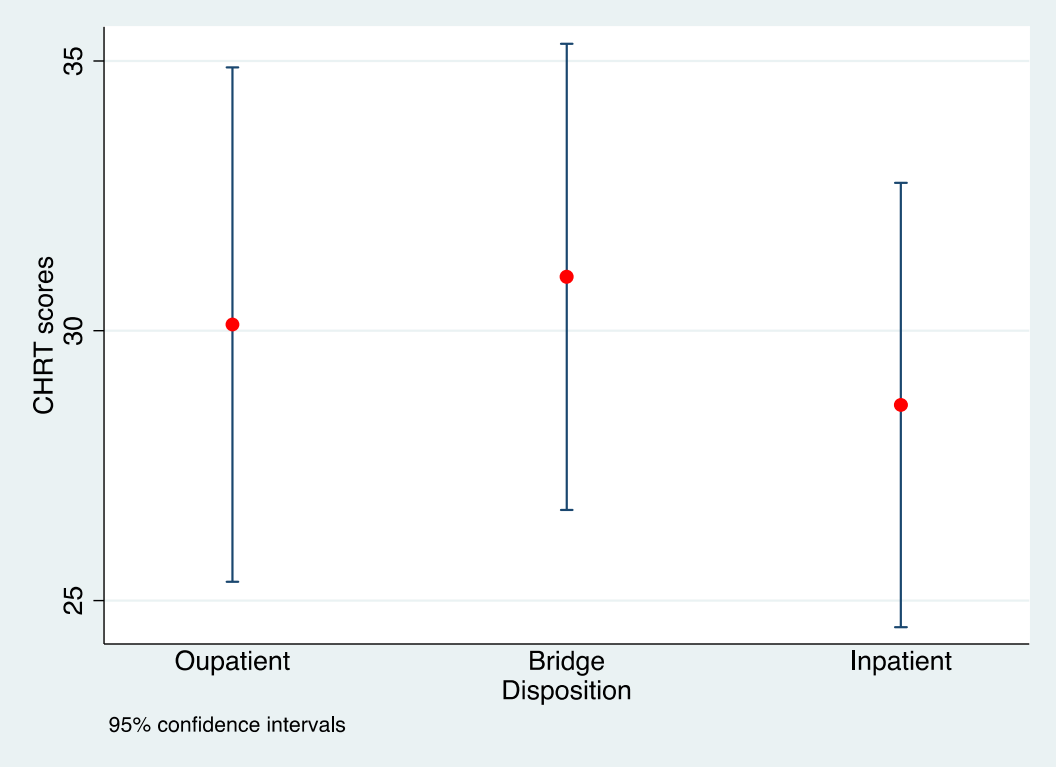


Figure 2. CHRT-SR scores stratified by disposition status.

Participant's ability to understand and read English may be determined through screening questions during initial recruitment before the consenting process. If participants are able to understand English but have difficulty with reading, then questionnaires and surveys may be read to them.

5.5. Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

1. Adolescents that are 12 through 18 years old.

2. Are brought to the Emergency Department (ED) or for crisis evaluation due to suicidal thoughts or behaviors
3. Require a higher level of care (In-person OCIC, Inpatient, or Telehealth CIS)
4. The presence of a legal guardian for consent
5. Capable of giving signed informed consent/assent, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

5.6. Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

1. Adolescents with suicidal thoughts who had prior OCIC treatment in the past 12 months
2. Adolescents without the ability to answer survey questions
3. Adolescents that are non-English speaking due to the scales and surveys that are used for this study only being available in English.

5.7. Screen Failures

Screen failures are defined as participants who consent to participate in the clinical study but are not subsequently included in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants to meet the Consolidated Standards of Reporting Trials (CONSORT) publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any serious adverse events (SAE).

Individuals who do not meet the criteria for participation in this study (screen failure) may be rescreened. Rescreened participants will be assigned the same participant number as for the initial screening.

6. Treatments

Study treatment is defined as psychiatric treatment within either Outpatient Crisis Intervention Clinic (OCIC), on an Inpatient unit, or telehealth crisis intervention services. Participants will be placed in the treatment setting by the assessing clinician. These therapeutic interventions are available whether or not the subject agrees to participate in the study.

Telehealth crisis intervention services (telehealth CIS) is defined as psychiatric services provided via telehealth services that is expected to be scheduled within 7 business days of the crisis assessment. Interventions can be with a social worker, therapist or psychiatrist. Services are not in person and occur over a computer video/phone system.

Inpatient treatment includes supportive individual therapy, improving patient's coping skills, family meetings about safety planning, and medication management. [6-9, 81]

OCIC services include crisis psychotherapy/intervention, evidence-based screening/risk assessments, coordination of care/referral to an ongoing provider, short-term therapy/crisis treatment, safety planning, and/or referral and linkage to follow-up care. Treatment in OCIC may include group therapy, individual therapy, and/or family therapy, depending on the site. Please

see below for full description of services by site. Adolescents in OCIC will be referred to a psychiatrist for medication management as needed. OCIC provides crisis intervention therapy and/or components of Cognitive Behavior (CBT), Dialectical Behavior Therapy (DBT), mindfulness CBT, Relapse Prevention CBT, and/or Supportive Psychotherapy. The length of time in OCIC and telehealth CIS can range from around one to six weeks depending on the needs of the patients and families. Due to the pragmatic approach to the research design, interventions provided will be site specific but all sites will include the crisis intervention component, including crisis stabilization (therapeutic intervention) and safety planning and assessment. Additionally, patients will have the expectation of being scheduled to be seen within 7 business days of the ED visit for follow up care. The charts below outline a description of the OCIC program, Inpatient services, and Telehealth CIS services provided at each of the four sites. [4043] The following is an explanation of services provided in the treatment arms. All treatment is clinically based and data will be collected. No decisions on treatment will be part of this study and the data from this study will not be shared with clinicians to alter care.

Site	Describe intervention with patient	Describe intervention with family	Length of visit	Length of treatment	Staff performing treatment	Plan if subject has increased risk of suicide
Cincinnati	A crisis intervention appointment will entail: 1.Identification of current crisis and precipitants 2.Exploration of feelings/emotions using components of CBT, DBT and other therapies 3.Identification and exploration of coping skills and resources 4.Safety planning and assessment	1.Family support 2.Safety assessment and planning 3.Referral to psychiatric provider for evaluation for need of medication 4. Referral and connection to outpatient provider for continued care.	60 min or longer as needed	Average 1-3 sessions, longer as needed	Licensed Independent Social workers, Clinical Counselors, APRNs and child and adolescent psychiatrist for medication management	Pt would be referred to the ED for evaluation or admitted to inpatient by clinical staff.

Site	Describe intervention with patient	Describe intervention with family	Length of visit	Length of treatment	Staff performing treatment	Plan if subject has increased risk of suicide
New York	A crisis intervention appointment will entail: 1.Identification of current crisis and precipitants 2.Exploration of feelings/emotions using components of CBT and other therapies 3.Identification and exploration of coping skills and resources 4.Safety planning and assessment	1.Family support and psychoeducation 2.Safety assessment and planning 3.Psychopharmacology 4. Referral and connection to outpatient provider for continued care.	60 min or longer as needed	Average 1-3 sessions, longer as needed	Licensed Independent Social workers, Clinical Counselors, APRNs and child and adolescent psychiatrist and fellows under supervision for medication management	Pt would be referred to the ED for evaluation or admitted to inpatient by clinical staff.

Site	Describe intervention with patient	Describe intervention with family	Length of visit	Length of treatment	Staff performing treatment	Plan if subject has increased risk of suicide
Columbus	A crisis intervention appointment will entail: 1.Identification of current crisis and precipitants	1.Family support 2.Safety assessment and planning 3.Referral to psychiatric provider for evaluation	60 min or longer as needed	Average 1-3 sessions, longer as needed	Licensed Independent Social workers, Clinical Counselors, APRNs and child and adolescent	Pt would be referred to the ED for evaluation or admitted to inpatient by clinical staff.

	2.Exploration of feelings/emotions using components of CBT, DBT and other therapies 3.Identification and exploration of coping skills and resources 4.Safety planning and assessment	for need of medication 4. Referral and connection to outpatient provider for continued care.			psychiatrist for medication management	

Site	Describe intervention with patient	Describe intervention with family	Length of visit	Length of treatment	Staff performing treatment	Plan if subject has increased risk of suicide
Dallas	A crisis intervention appointment will entail: 1.Identification of current crisis and precipitants 2.Exploration of feelings/emotions using components of CBT, DBT and other therapies 3.Identification and exploration of coping	1.Family support (on an individual level) 2.Safety assessment and planning 3. Multi-family group, which includes family wellness, communication, strength building 4. Referral and connection to outpatient provider for continued care.	Group (9 hrs/week, which includes two teen groups and one multi-family group), Once weekly individual therapy (60 minutes)	Treatment duration is 4-6 weeks, Follow-up assessment phone calls at 1 month and 6 months post-discharge	Licensed Clinical Social workers, Licensed Professional Counselors, and child and adolescent psychiatrists for medication management; All of the above include trainees performing treatments under the supervision of licensed providers	First preference is direct admission to Inpatient Unit (either at our site or in the community); if after hours, refer patient to ED

	skills and resources 4.Safety planning and assessment 5. Psychiatric evaluation and medication management, as needed *Note: #2 and #3 above are done in both individual and group format throughout the course of treatment					

Treatment Components
Inpatient

	Medication evaluation and management	Safety planning	Individual and family therapy	Skills groups	DBT program with skills group	Length of stay
Dallas	X	X	X	X		7 days
New York	X	X	X		X	8 days
Nationwide Children's	X	X	X	X		8 days
Cincinnati	X	X	X	X		6 or 7days

Outpatient (OCIC)

	Group therapy	Individual and family therapy	Referral to psychiatrist for med management	Crisis stabilization/ safety reassessment	Safety Planning	Parents attend skills class	Length of treatment
Dallas	X	X	X	X	X	X	4-6 weeks
New York		X	X	X	X		3 visits
Nationwide Children's		X	X	X	X		1-6 weeks
Cincinnati		X	X	X	X		1-6 weeks

Telehealth Crisis Intervention Services CIS

	Individual and family therapy	Referral to psychiatrist for med management	Crisis stabilization/ safety reassessment	Safety Planning	Length of treatment
Dallas	X	X	X	X	4-6 weeks
New York	X	X	X	X	1-3 visits
Nationwide Children's	X	X	X	X	1-6 weeks
Cincinnati	X	X	X	X	1-6 weeks

Once a patient has agreed to participate in the study, meets eligibility, and has given consent/assent, they will be followed in their treatment group. The patient's treatment will be done by social workers, doctors (MD), and/or other mental health professionals.

6.1. Method of Treatment Assignment

All eligible individuals will be followed in three treatment arms: OCIC versus inpatient treatment versus telehealth groups. Potential participants will be identified once they have been assigned to a treatment setting by a licensed clinician at each institution (Cincinnati, Dallas, Columbus, and New York). Research coordinators will be in contact with clinicians who complete the assessments to identify appropriate participants. The CHRT-SR will be reviewed to identify participants who meet study criteria (i.e. need higher level of treatment due to suicidal thoughts). Once a potential participant is identified, research coordinators will contact guardians via phone to introduce the study and complete remote enrollment and consenting procedures.

6.2. Treatment Compliance

For this study, treatment compliance is defined as adhering to appointments assigned by assessing clinician to telehealth or OCIC and not leaving against medical advice (AMA) if assigned to inpatient treatment. For patients who are not treatment compliant, attempts will be

made by the study staff to follow up and encourage recommended treatment. Study staff will work with PIRC or equivalent to complete up to two phone calls or text messages to attempt to contact patients who do not show for scheduled telehealth appointments, OCIC appointments, or inpatient recommendation. If we are unable to contact these patients or they refuse any or all follow up treatment (including telehealth, OCIC, inpatient or outpatient recommendations), we will continue to follow them until they withdraw from the study. If patients refuse telehealth, OCIC or inpatient treatment from the emergency department or crisis assessment, we will continue to follow these patients until they withdraw from the study. For patients who are AMA from the inpatient unit, this process of following up regarding services will be addressed by the inpatient treatment team. It is standard of care for inpatient treatment teams to not provide prescriptions and follow up services for AMA's but this practice varies based on the inpatient treatment team. If the AMA (from inpatient treatment) patient remains in our study, we will encourage the AMA patient to return to treatment (inpatient, OCIC, and/or telehealth outpatient).

6.3. Treatment After the End of the Study

Follow up care after the end of this study will be decided by the participants' parents'/guardians', therapist, mental health professional, and/or physician.

7. Discontinuation Criteria

It is unlikely that a patient will be discontinued from the study during the inpatient, telehealth, or OCIC phase of the study. If patient experiences worsening symptoms while inpatient, this treatment will be extended to meet their needs as identified by inpatient clinicians. Patient in the OCIC or telehealth treatment arms with worsening symptoms may be recommended for evaluation in the ED, referral for inpatient, and/or connected to outpatient services as identified by a qualified mental health clinician. If a patient is involved in an adverse event that is associated with study procedures, leading to harm, the DSMB and external medical monitor may identify the need for removal from the study for safety concerns. This is unlikely but will be monitored by the DSMB, EMM and IRB

7.1. Discontinuation from the Study

- A participant may withdraw from the study at any time at his/her own request, or may be withdrawn at any time at the discretion of the investigator for safety, behavioral, or administrative reasons.
- If the participant withdraws consent for disclosure of future information, the sponsor may retain and continue to use any data collected before such a withdrawal of consent.
- Refer to the Schedule of Events (SoE) in the Appendix for data to be collected at the time of study discontinuation and follow-up and for any further evaluations that need to be completed.

7.2. Lost to Follow Up

A participant will be considered lost to follow-up if he or she repeatedly fails to complete surveys and/or fails to return for scheduled visits and is unable to be contacted by the study site.

The following actions must be taken if a participant fails to return to the clinic for a required study visit or fails to complete the surveys/questions that occur about every 2 weeks:

- The site must attempt to contact the participant and reschedule the missed survey or visit as soon as possible and counsel the participant on the importance of maintaining the assigned survey or visit schedule and ascertain whether or not the participant wishes to and/or should continue in the study. Text messaging may be used as a method of communication with the participant to encourage survey completion and/or to notify that further communication by phone or in person is needed.
- In cases in which the participant is deemed lost to follow up, the investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's research record.

- Should the participant continue to be unreachable, he/she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8. Study Assessments and Procedures

- Study procedures and their timing are summarized in the SoE (Appendix). Surveys are administered and requested for completion every 2 weeks. Data will be collected upon return of surveys. If surveys are not completed within 10 days of milestone window, that window will be skipped and study team will request data at the next milestone window.
- Baseline data and follow surveys/forms will be completed through REDCap and/or paper forms. CCHMC REDCap can collect almost any type of data, and is particularly designed to support online and offline data capture for research studies and operations.
- Adherence to the study design requirements, including those specified in the SoE, is essential and required for study conduct.
- All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria. The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.
- Time to first recurrence of a suicidal event and number of suicidal events will be measured with the Suicidal Event Form for START (appendix), a short supplemental form (developed by our team), at baseline and every two weeks (see Schedule of Events; appendix)
- Severity of suicidal ideation will be measured with the self-report scale: CHRT-SR (appendix) at baseline and every two weeks (see Schedule of Events; appendix).
- The Suicidal Treatment AlteRnatives for Teens (START)-Clinical Features (CF) form (appendix), a short supplemental form with 13 questions (developed by our team), will be completed at baseline (within 72 hours of admission to inpatient or OCIC) and every two weeks to monitor substance use based on information from patient, parent, and/or EHR.
- The C-SSRS Self-Report form, included in the CF survey, will be completed at baseline and every 2 weeks by the participant to assess for suicidal thoughts and behaviors.
- Satisfaction with Life (SL) will be measured with self-report scales including the PROMIS Short Form v 1.0-General Life Satisfaction-Short Form 5a (to assess the parent's well-being), PROMIS Parent-Proxy Life Satisfaction-Short Form 8a, and PROMIS Pediatric Life Satisfaction-Short Form 4a every 2 weeks.
- Treatment satisfaction (TS) data about, telehealth CIS, OCIC and inpatient psychiatry will be collected only after two weeks and/or subsequent to completion of inpatient psychiatry or OCIC. TS will be measured once with the Client Satisfaction Questionnaire (CSQ-8) 95 after completion of telehealth, OCIC or inpatient treatment which is typically completed by week 3 (but could be completed by week 2 to week 6).
- COVID-19 Impact survey will be completed at week 2 and will gather information regarding the impact of the pandemic on the participant and families social, emotional, and economic functioning.

- The Self-Assessment Manikin (SAM) questionnaire will be completed at baseline and week 12 follow up survey.

8.1. Efficacy Assessments

- Time to first recurrence of a suicidal event and number of suicidal events will be measured with the Suicidal Event Form for START (appendix), a short supplemental form (developed by our team), at baseline and every two weeks (see Schedule of Events; appendix)
- Severity of suicidal ideation will be measured with the self-report scale: CHRT-SR and C-SSRS (appendix) at baseline and every two weeks (see Schedule of Events; appendix).
- The Suicidal Treatment AlteRnatives for Teens (START)-Clinical Features (CF) form (appendix), a short supplemental form with 13 questions (developed by our team), will be completed at baseline (within 72 hours of admission to inpatient, telehealth CIS, or OCIC) and every two weeks to monitor substance use based on information from patient, parent, and/or EHR.
- Satisfaction with Life (SL) will be measured with self-report scales including the PROMIS Short Form v 1.0-General Life Satisfaction-Short Form 5a (to assess the parent's well-being), PROMIS Parent-Proxy Life Satisfaction-Short Form 8a, and PROMIS Pediatric Life Satisfaction-Short Form 4a every 2 weeks.

8.2. Adverse Events

The primary outcomes in this study, suicidal ideation or a recent suicide attempt, are AEs that will be reported to the DSMB. In addition, youth at risk for suicide often engage in multiple health risk behaviors (e.g., alcohol/drug use, interpersonal violence) and consequently, are at increased risk for accidental injury and death, all of which constitute AEs or SAEs. We expect AEs and SAEs in this population, but not related to study procedures.

Prior to recruitment, the DSMB will meet in the first month to review the protocol, outcomes, AE and SAE definitions, and treatment components to ensure there are no concerns.

AE will be reported by the participant (or, when appropriate, by a caregiver, surrogate, or the participant's legally authorized representative).

If the AEs and SAEs are related to study procedures, then we will review with the DSMB. We will also review the proportion of observed suicidal-related AEs in our study compared to the rate of suicidal ideation and suicide attempts we would expect in this population, based on the extant literature.

8.2.1. Time Period and Frequency for Collecting AE and SAE Information

All AE and SAE will be collected from the start of treatment until 180 day follow-up or when the participant completes milestones.

For serious adverse events that result in injury, disability, death or significant functional impairment, each site is required to notify the DSMB and the IRB within 24-48 hours of the knowledge of the occurrence one of these SAE's, how the site personnel became aware of it, and

the response. The DSMB will make a determination as to whether the risks and benefits of the study are altered by the event.

8.2.2. Method of Detecting AE and SAE

Clinical worsening of suicidal ideation/behavior is assessed similarly at each site. On the inpatient units at each site, clinical worsening of suicidal ideation/behavior is assessed daily with observation and by interviewing the patient. For patients in the OCICs and telehealth outpatient clinics at every site, clinical worsening of suicidal ideation/behavior is assessed by the treating clinician during each visit or if the parent/legal guardian calls to discuss the patient. The Dallas OCIC uses a clinical approach and assessment tools to evaluate worsening of suicidal ideation/behavior while the other sites use a clinical approach (with collateral information and interviews of the patient). Furthermore, clinical worsening of suicidal ideation/behavior will be assessed through the use of surveys and questionnaires that patients and/or guardians will fill out about every 2 weeks.

The risk of lack of improvement or worsening of psychiatric illness will be addressed by monitoring subjects closely during assessments.

For this proposed research, we will plan to have the research coordinator at each site contact the legal guardians and patients by phone (or in person) within 24-48 business hours of the baseline assessment to review the referral to either inpatient psychiatric treatment, telehealth, or OCIC treatment and to review safety planning and identify any concerns or needs for referral. At Nationwide Children's Hospital (NCH), they also plan to have text message outreach to patients within the 48 hours after discharge. Text messaging may also be considered as a potential method within 48 hours of discharge at other sites if phone calls are not successful in reaching the legal guardians and patients.

During the baseline ED visit or assessment, all patients and families who receive telehealth or OCIC will receive safety planning, lethal means restriction education, emergency contact numbers, and will be advised that if a situation of potential harm should arise that they should go to the nearest ED by their assessing clinician. During the period between ED discharge and their first appointment in telehealth or OCIC, based on clinical judgment of the research team, patients and their families may be contacted by a research team member to further discuss safety planning, provide lethal means restriction education, provide emergency contact numbers, and/or advise that if a situation should arise that they should go to the nearest ED. Families will also be directed that they can contact research staff (during business hours) if they have any of the above stated needs and research staff can provide referrals. If patients in the inpatient arm of the study show signs they are clinically worsening, the patient will remain on the inpatient unit and hospital protocol will be used to determine the most appropriate safety measures. If the patient showed signs of worsening in the telehealth or OCIC arm of the study or while in the outpatient setting, the patient will be admitted into inpatient psychiatry, will attend partial hospitalization and/or will be evaluated in the ED. All decision on treatment and care will be decided by the patient's treating clinician. Study staff will follow and document outcomes.

8.2.3. Follow-up of AE and SAE

The main adverse events (AEs) discerned during the 180 day follow--up interviews will be suicidal ideation with intent, or a recent suicide attempt. All AEs and SAEs will be documented

by the site manager and will be reported to the DSMB and IRB as needed. Dr. Barzman will be notified because part of his role as overall PI of all AEs and SAEs.

8.2.4. Regulatory Reporting Requirements for SAE

- Prompt notification by the investigator to the sponsor of SAE is essential so that legal obligations and ethical responsibilities towards the safety of participants and the safety of a study treatment under clinical investigation are met.
- The sponsor has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of a study treatment under clinical investigation. The sponsor will comply with country-specific regulatory requirements relating to safety reporting to the regulatory authority, Institutional Review Boards (IRB)/Independent Ethics Committees (IEC), and investigators.
- The Institutional Review Boards of each site will be responsible for monitoring risks to human subjects and assessment of ethical issues related to this study, and will have approved the consent form and protocol prior to initiation of the study. The consent form will be scripted to minimize burden and stress. All unexpected AEs and SAEs will be reported to the IRB's per institutional and regulatory requirements as well as the DSMB. If the AEs and SAEs are related to study procedures, then we will review with the DSMB. This will be part of our safety monitoring and DSMB charter.
- Overall data monitoring will be the responsibility of the PIs. During the course of the study, the PIs will follow the progress of the clinical study and data entry to ensure utmost accuracy of the data and to detect any possible errors at an early time point. The research coordinators will generate weekly reports, which will include suicidality, and adverse events for each subject for review during weekly project meetings as well as an ongoing CONSORT diagram. DSMB reports will include recruitment data, demographic information, serious adverse events, early termination, and protocol deviations, as well as any other information requested by the DSMB.

9. Statistical Considerations

9.1. Sample Size Determination

We proposed to recruit approximately 244 eligible cases that will be followed in three treatment arms: telehealth CIS, in-person OCIC, and inpatient. We expect that the sample sizes for the three arms will be *at least* 75, 75, and 70 respectively. These numbers account for an expected 10 % dropout rate; 220 participants are expected to complete study procedures. Prior evidence suggests that the 6-month inpatient readmission rate for adolescents with a prior history of suicidality is approximately 19%. [108] Preliminary data suggest that almost 10% of adolescents who received OCIC treatment following a suicidal event could have recurrent suicidal attempts during the following 6 months after OCIC treatment (preliminary unpublished data from the sites from Dallas and Cincinnati). Therefore, if we assume the hazard ratio (inpatient group vs. OCIC group) will be approximately 2.8 and the readmission rates over 6 months for the two groups will be 19% (for the inpatient group) vs. 10% (for the OCIC group), we will be able to achieve the statistical power at 0.70 given the two-side alpha value = 0.05. We expect numbers for the

Telehealth CIS to be larger than the inpatient group. We will achieve similar power when we compare the Telehealth CIS group with the inpatient group. The power is likely lower than 0.6 when we compare Telehealth CIS with the OCIC group since the effect size (i.e., hazard ratio < 2). The power calculation, based on the assumption that 19% (inpatient group) vs. 10% (Telehealth CIS or OCIC group) will be the averaged recurrence rates for the two arms across the four sites, was performed using the powerSurvEpi package in the software R. For continuous outcomes, we expect that the two-group comparison can achieve the power at 0.84 when the effect size Cohen's *d* is 0.5 and sample sizes for the first and second group are 75 and 70, respectively. Alternatively, we will achieve the power at 0.76 if we use ANOVA to evaluate whether the continuous outcome differs among the three groups given the effect size $f^2 = 0.2$

For purposes of analysis, the following populations are defined:

Population	Description
Enrolled	All participants who sign the ICF
Observational	All patients will be followed in three treatment arms (telehealth CIS, in-person OCIC, and inpatient)
Evaluable	Inclusion: 1) Adolescents (12 to 18 years old) who were brought to the ED due to suicidal thoughts or behaviors and require a higher level of care (Telehealth, OCIC or inpatient); 2) The presence of a legal guardian. Exclusion: 1) Adolescents with suicidal thoughts who had prior OCIC treatment in the past 12 months will be excluded; 2) Adolescents without the ability to answer survey questions will be excluded.
Safety	Participants will be analyzed according to the treatment they actually received.

9.2. Statistical Analyses

The statistical analysis plan will be developed and finalized before database lock and will describe the selection of participants to be included in the analyses, and procedures for accounting for missing, unused, and spurious data. Below is a summary of planned statistical analyses of the primary and secondary endpoints.

9.2.1. Efficacy Analyses

Endpoint	Statistical Analysis Methods
Primary	The primary outcome measure for this proposed research will be the time to first recurrence of a suicidal event. We will examine if the treatment option can predict the "time to the first suicidal event" using the Cox-proportional hazard model.
Secondary	The secondary outcome is Satisfaction with Life (SL), which will be measured every two weeks. The treatment effect on such time-series

	data will then be analyzed using mixed-effect ordinate logistic regression model.
Exploratory	Will be described in the statistical analysis plan finalized before database lock

9.2.2. Safety Analyses

All safety analyses will be performed on the Safety Sample.

Endpoint	Statistical Analysis Methods
Primary	Our primary outcomes are direct measures related to safety. Our treatments will not be associated with any safety concerns other than the primary outcome that will be analyzed in the treatment efficacy research.
Exploratory	Will be described in the statistical analysis plan finalized before database lock

9.2.3. Other Analyses

We will also evaluate heterogeneous treatment effects (HTE) to better understand whether the treatment effect depends on clinical or socioeconomic features. The overarching goal of the HTE analysis is to identify the factors that can predict if telehealth CIS and OCIC leads to different treatment outcomes compared to the inpatient treatment, which could shed some light on how individual characteristics might influence the treatment response, and pave the way for personalized medicine. The core hypothesis for our HTE analysis is that individual features correlated with poorer adherence with outpatient appointments (e.g., lower socioeconomic status) or psychiatric disturbances associated with poorer prognosis (e.g., severe suicidal thoughts) may at least partially determine who may have better treatment outcomes. The HTE's include three clinical features: 1) Severity of suicidal ideation at baseline and over 180 days; 2) number of suicidal events at baseline only; 3) Substance use at baseline and over 180 days. [46-52] The HTE's also include seven sociodemographic features at baseline: 1) Age 2) Gender [53-56] 3) Gender identity [57-60] 4) Type of Insurance (public insurance/no insurance/private) [61-63] 5) Ethnicity (Hispanic/Non) [64]; 6) Race (African-American (AA) versus non-African American) [65-67]; 7) Living with one biological parent, two biological parents, a stepparent, a relative, or other. [68, 69] A past suicide attempt (suicidal event) is one of the strongest risk factors for future suicide attempts and death by suicide in adolescence. [65, 101- 104] Adolescents who attempted suicide are 18 times more likely to attempt suicide compared to adolescents with no prior suicide attempts. [101] About 11% of adolescents who attempt suicide will eventually die by suicide. Although female adolescents have a higher rate of suicidal thoughts and attempts, the deaths by suicide are higher for male adolescents. [53-56] In addition, substance use [46-52] and gender dysphoria in adolescence substantially increase the risk for suicide. [57-60] Type of insurance will allow us to obtain an approximation of income level. Adolescents from lower socioeconomic backgrounds have an

increased risk of serious suicide attempts and suicide. [61-63] The cultural context of adolescent suicidal behavior and help-seeking is important and differs among races and ethnic groups. [105] For example, in the Hispanic community, families are much less likely to seek mental health professionals in help seeking and prefer to rely on family first. [64] Ethnic groups and races differ in rates of adolescent suicidal behaviors. [105, 106] However, the gap has been decreasing between white adolescent suicides and African American suicides due to an increase in male African American deaths by suicide. [65-67] Living situation (living with one biological parent, two biological parents, a stepparent, a relative, or other) is an important HTE for adolescents because living with one parent or the presence of a stepparent was correlated with an increased risk of suicidal thoughts and suicide attempts by adolescents. [68, 69]

The analysis plan:

To test Aim 1, we will use Cox proportional regression model (CPR) to test whether the telehealth only CIS; outpatient, in-person CIS; and in-patient CIS groups have different incidence rates for recurrent episodes within 3 months. We expect that the sample sizes for the three arms will be *at least* 75, 75, and 70 respectively. To evaluate Aims 2 and 3, we will use the generalized linear model (GLM) to evaluate whether telehealth only CIS; outpatient, in-person CIS; and in-patient CIS groups have different levels of changes in emotional arousal (Aim 2) and treatment satisfaction (Aim 3) at 3 months, after adjusting for several covariates (e.g., age, gender, triage "location"). For CPR, we will have power for our pilot study greater than 0.70 assuming a hazard ratio of 2.8 and greater than 0.8 for our GLM analyses assuming $f^2 = 0.1$ and correcting for multiple comparisons.

The main objective of the analysis plan for the COVID-19 survey is to evaluate whether the changes of levels of emotional dysregulation, anxiety, depressed mood, perceived stress levels, and other indicators of well-being, during the pandemic, are associated with the treatment outcome. Furthermore, we will evaluate whether the changes of these indicators are associated with the perceived level of social support, disruptions in life events, and electronic media habits. First, the changes of levels of emotional dysregulation, anxiety, depressed mood, perceived stress levels, and other indicators of well-being, will be treated as covariates in the analysis under Aims 1-3 (comparative treatment effect analysis). Second, we will then use generalized linear model to evaluate the relationship between continuous outcomes and predictors and ordinal logistic regression model to evaluate the relationship between ordinal outcomes and predictors. The outcomes include the changes of levels of emotional dysregulation, anxiety, depressed mood, perceived stress levels, and other indicators of well-being, and the predictors include perceived levels of social support, disruptions in life events, and electronic media habits.

Interim analysis:

We propose to evaluate the progress of the project at the end of the 6th month. The goal of the interim analysis is to examine the following outcomes: 1) scores from PROMIS Short Form v 1.0-General Life Satisfaction-Short Form 5a (to assess the parent's well-being), 2) scores from PROMIS Parent-Proxy Life Satisfaction-Short Form 8a, 3) Score from PROMIS Pediatric Life Satisfaction-Short Form 4a, 4) Score from CHRT-SR at baseline and follow-up visits. Specifically, the change in CHRT-SR scores will be used to facilitate the decisions for revising the protocol. If any of the three treatment groups is found to have statistically significant lower

levels of changes in CHRT-SR scores within the first six months with an effect size Cohen's $d >$ 1.2 (which is considered as a "very large" effect size according to Sawiloski (2009)[109] in comparison with another treatment group, we will discuss the results with all steering committee members and the DSMB to decide whether we should recommend to psychiatry leadership that the treatment group with overtly inferior treatment outcomes should be discontinued at the four sites.

10. References

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11. Appendices

1. Schedule of Events (SoE) / Milestones

11.1. Appendix 1: Schedule of Events (SoE) / Milestones

Schedule of Events

Table X. Schedule of Events	Visit (Weeks)												
Measures	Baseline	2	4	6	8	10	12	14	16	18	20	22	24
Age/Gender/Gender Identity/Insurance Type(Public, Private, No Insurance)/Ethinicity (Hispanic, Non Hispanic)/ Race (African American, Non African American)/ Living Situation (One Parent, Both Parents, Other)													
Demographics Form	x												
Severity of Suicidal Ideation													
CHRT-SR (self-report)-14 item	x	x	x	x	x	x	x	x	x	x	x	x	x
Suicidal Events													
Suicidal Event Form for START	x	x	x	x	x	x	x	x	x	x	x	x	x
Substance Use													
Clinical Features (CF)	x	x	x	x	x	x	x	x	x	x	x	x	x
Treatment Satisfaction													
Client Satisfaction Questionnaite (CSQ-8)		x											
Satisfaction with Life													
PROMIS Short Form-Life Satisfaction (SL)	x	x	x	x	x	x	x	x	x	x	x	x	x
PROMS Parent-Proxy SL-Short Form 8a	x	x	x	x	x	x	x	x	x	x	x	x	x
PROMIS Pediatric SL-Short Form 4a	x	x	x	x	x	x	x	x	x	x	x	x	x
Other													
COVID-19 Survey		x											
Self Assesment Manikin (SAM)	x						x						