STUDY PREREGISTRATION

Study Preregistration: Testing a Digital Suicide Risk Reduction Platform for Adolescents: A Pragmatic Randomized Controlled Trial

Clinical trial registration information: A Digitally Assisted Risk Reduction Platform for Youth at High Risk for Suicide; https://clinicaltrials.gov/; NCT05920252.

STUDY SYNOPSIS

Introduction Summary

Suicide is the second leading cause of death among adolescents, and rates of suicidal thoughts and behaviors (STBs) are climbing.[1] Promising interventions such as dialectical behavior therapy (DBT) are available to treat suicidal youth, and new approaches may facilitate greater intervention engagement, adherence, and effectiveness.[2] Digital tools (eg, personal smartphones) are a particularly promising avenue and could enhance existing, evidence-based interventions by providing new opportunities for assessment and intervention between sessions.

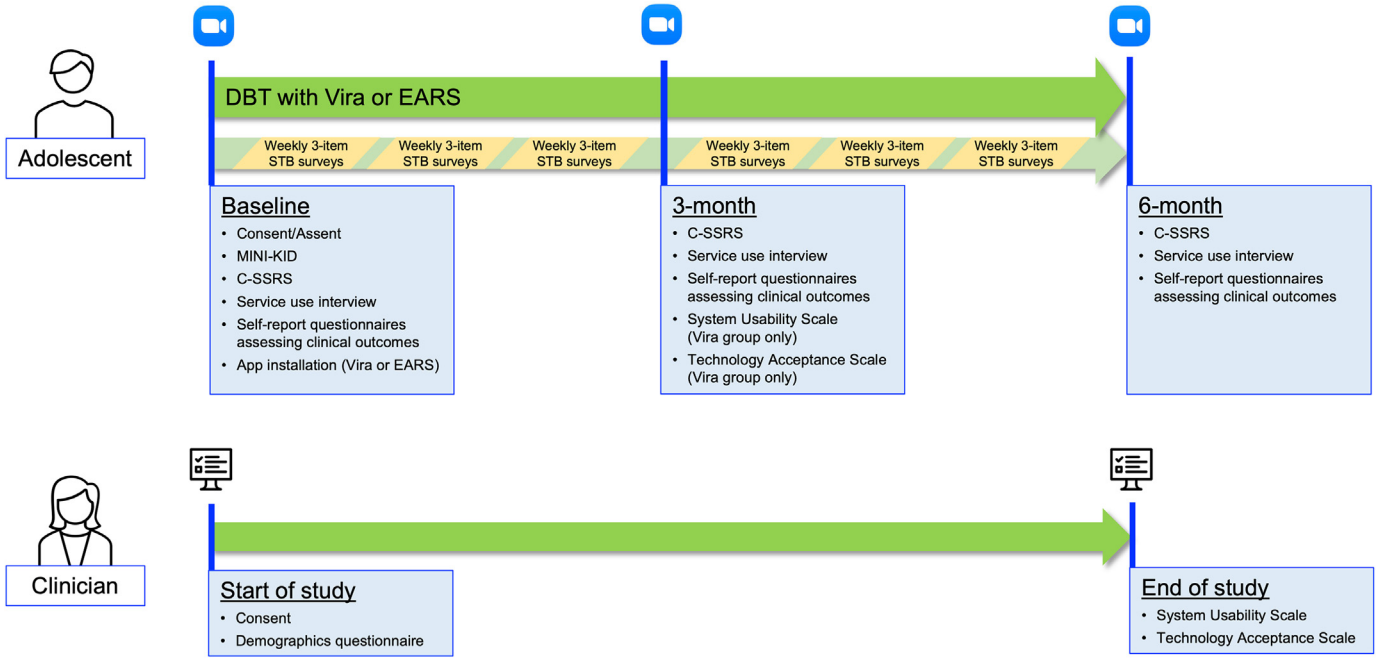
To this end, Ksana Health has developed the Vira digital behavior change platform, which consists of a patient-facing smartphone app and a linked, Health Insurance Portability and Accountability Act (HIPAA)–compliant Web portal for clinicians. The smartphone app monitors patients' proximal suicide risk factors (eg, sleep disturbance, low mood) using mobile sensing and brief self-report surveys. The Vira app allows patients to access these data 24 hours a day, 7 days a week, and offers patients insights into passively sensed behavioral patterns associated with their mood. These data are collected continuously, objectively, and with minimal burden to the patient and clinician, thus addressing key barriers to routine outcome monitoring and measurement-based care.[3] Clinicians can use the Web portal to view these data and to gain insight into patients' behavior, mood, and risk between sessions. The clinician portal also enables clinicians to schedule personalized push notifications based on therapy plans to be delivered to a patient's smartphone in everyday life. These notifications may increase therapeutic skill utilization and "homework" completion between sessions, which improve treatment outcomes[4] but are variable among youth.[5] These notifications also enable clinicians to provide enhanced support between sessions, which is important for reducing suicide risk in adolescents.[6] The Vira platform is built on principles of behavioral activation and DBT, and has previously been optimized through user-centered design activities. It has also demonstrated feasibility, acceptability, and preliminary effectiveness for reducing depressive symptoms in young adults with elevated depressive symptoms.[7]

The present study is a 2-arm, pragmatic randomized controlled trial that will test the Vira platform's feasibility, acceptability, and effectiveness in an intensive outpatient DBT service for adolescents at risk for suicide. Adolescents beginning treatment will be randomly assigned to receive DBT with either the Vira platform or a standalone app that acquires mobile sensor and self-report data (ie, a measurement-only comparison condition). We hypothesize that the Vira platform will have high usability, acceptability, and utilization by adolescent patients and their clinicians. Our primary clinical hypothesis is that, compared to adolescents in the comparison group, adolescents receiving DBT with Vira will demonstrate greater reductions in STBs at 3- and 6-month follow-up assessments. As secondary aims, we will test whether adolescents receiving DBT with Vira experience greater reductions in psychiatric symptoms or suicide risk factors compared to those in the comparison group. Exploratory analyses will test whether adolescents receiving DBT with Vira demonstrate greater engagement in DBT treatment (eg, higher session attendance) or are more likely to utilize crisis care.

Method Summary

Figure 1 provides an overview of the study protocol. Adolescents (N = 200) 13 to 18 years of age will be recruited upon admission to the Intensive Adolescent and Family DBT Program at Columbia University Irving Medical Center. Adolescents will be randomly assigned to either DBT utilizing the Vira platform (n = 100) or a comparison condition (n = 100) involving DBT as usual along with a standalone, measurement-only smartphone app called Effortless Assessment of Risk States (EARS).[8,9] EARS obtains mobile sensing data and will deliver the same survey prompts as the Vira app, but does not allow patients to

FIGURE 1 Overview of the Study Protocol



Note: *The duration of dialectical behavior therapy (DBT) treatment is determined by the treatment team and typically is between 2 and 6 months. The Vira or Effortless Assessment of Risk States (EARS) apps are uninstalled following treatment termination.*

access these data and does not offer personalized insights into behavioral patterns associated with mood. This study will also include approximately 20 clinicians providing services within this program. All clinicians and patients using the Vira platform will receive training about its features and how to use them.

Implementation outcomes (eg, acceptability, usability, utilization) will be assessed at the 3-month follow-up. Clinical outcomes (eg, STBs, suicide risk factors, psychiatric symptoms) will be assessed at baseline and at the 3- and 6-month follow-ups. In addition, weekly 3-item surveys will probe STBs in the prior week. Differential group changes from baseline to the follow-ups will be examined using multilevel modeling following an "intent-to-treat" approach.

Significance Summary

Novel strategies that improve the effectiveness of preventive interventions for adolescents at risk for suicide are needed. Results from this pragmatic randomized controlled trial will indicate whether a promising candidate—comprehensive, digitally enhanced delivery of an evidence-based intervention for high-risk youth—can be implemented in a real-world clinical setting and can improve the management of suicidal thoughts, behaviors, and risk factors.

CRediT authorship contribution statement

Carter J. Funkhouser: Writing – review & editing, Writing – original draft, Conceptualization. **Trinity C. Tse:** Writing – review & editing. **Lauren S. Weiner:** Writing – review & editing, Conceptualization. **Danielle deLuise:** Conceptualization, Writing – review & editing. **David Pagliaccio:** Conceptualization, Writing – review & editing. **Katherine Durham:** Writing – review & editing, Conceptualization. **Colleen C. Cullen:** Writing – review & editing, Conceptualization. **Zachary K. Blumkin:** Writing – review & editing, Conceptualization, Writing – review & editing, Conceptualization. **Nicholas B. Allen:** Writing – review & editing, Conceptualization. **Randy P. Auerbach:** Conceptualization, Writing – original draft, Writing – review & editing.

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Consent has been provided for descriptions of specific patient information.

Drs. Funkhouser and Auerbach served as the statistical experts for this research.

Disclosure: Drs. Weiner and Allen and Ms. deLuise are employed by, and hold equity in, Ksana Health, which developed and commercialized the Vira platform. Dr. Auerbach has reported being an unpaid scientific advisor for Ksana Health and paid scientific advisor for Get Sonar, Inc. Drs. Funkhouser, Pagliaccio, Durham, Cullen, Blumkin, and O'Brien and Ms. Tse have reported no biomedical financial interests or potential conflicts of interest.

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