Study Protocol

Official Title: Text2Connect, Component 2 of iCHART (Integrated Care to Help At-Risk Teens) (T2)

ClinicalTrials.gov ID (NCT number): NCT03982043

Protocol Date: 02/02/2021

Scientific Background

Connecting depressed and suicidal adolescents with mental health (MH) treatment can play a critical role in reversing the alarming trend of suicide. Currently, rates of linkage with treatment among depressed and suicidal youth identified in primary care are as low as 18%, and, in one survey, increase only to 32% with integrated MH services. Aside from structural barriers such as treatment availability and cost, the major barriers to MH care among at-risk adolescents are motivational. In order to be motivated to engage in care, an individual must first perceive themselves to be susceptible to depression and suicide, and understand that treatment can help reduce these risks. Even then, there may still be significant stigma around depression labels and MH treatment that keep them from acting. Digital interventions using mobile communication such as text messaging (TM) could be useful to address motivational barriers to MH care initiation in depressed/suicidal adolescents and their parents. Potential benefits include the ability to repeatedly prompt awareness of treatment targets in daily life and deliver on-demand tailored support. Recent studies suggest TM interventions may improve retention in MH care for depressed adolescents already in treatment. Yet, effective approaches to enhancing MH care initiation among adolescents remains unknown.

Study Objectives

To increase rates of MH care initiation, we propose an automated TM intervention, "Text to Connect" (T2C), that aims to increase motivations in at-risk adolescents and their parents. We will develop and examine T2C using dissemination and implementation science principles, specifically, the RE-AIM framework, for balancing internal and external validity and optimizing uptake and sustainability. We will select the most salient of the following behavior change techniques: psychoeducation, cued mood monitoring, adolescent-parent communication prompts, cognitive bias modification, and cues to action. Intervention material will be tailored to baseline characteristics. We will begin with treatment development. In an initial usability phase, we will develop and iteratively refine the format and content of T2C based on feedback from stakeholders. Data will inform a subsequent feasibility trial comparing T2C with treatment as usual (TAU) using a stepped wedge design.

Aim 1 (Phase 1, Development). To develop T2C, a TM intervention to address motivational barriers to MH treatment initiation for depression and/or suicidal screen-positive adolescents and parents in pediatric primary care. We will collaborate with NuRelm and the Office of Academic Computing at WPIC and the Methods Core to develop T2C based on stakeholder feedback (adolescents, parents, pediatricians, MH clinicians).

Aim 1b (Phase 1b, Feasibility). To examine the feasibility of T2C in pediatric primary care clinics (n=2 clinics, 50 adolescents) using a stepped wedge design.

Hypothesis 1b: Readiness for MH care will be greater among
adolescents in T2C vs adolescents referred during TAU. We will first conduct t tests for continuous variables and chi square tests for categorical variables to examine for baseline differences in demographic

and clinical variables. We will use generalized linear mixed models (nesting for site) to examine for between-intervention differences in readiness. Baseline characteristics that distinguish the groups will be
included as covariates in models examining treatment effects.

Aim 2: Explore differential rates of service utilization (behavioral and physical health services) among youth who receive Text2Connect (T2C) versus Treatment As Usual (TAU).

Study Design & Methods

T2C aims to increase perceived susceptibility/severity of depression/suicidality and decrease stigma in at-risk adolescents and their parents. We hypothesize that modification of patient beliefs leads to change talk, thereby increasing the experience of discrepancy which affects motivation for change. These experiences in turn influence decisional balance away from ambivalence toward readiness for change.

We propose the following behavior change techniques: psychoeducation, cued mood-monitoring, adolescent-parent communication prompts, cognitive bias modification, and cues to action. Psychoeducation will be used to increase understanding of: 1) how mood and behavioral symptoms signal depression/suicidality; and 2) the availability and benefits of MH services. Cued mood monitoring (i.e. daily mood reports) will raise awareness of personal severity of depression. Cognitive bias modification will shift beliefs around depression/suicidality, and stigma regarding MH treatment. Cues to action will strengthen the link between intentions and action. Prompts will include contact information and reminders to target barriers to scheduling and attending MH appointments.

Tailoring is the method of personalizing characteristics of an intervention (e.g., content, timing) to maximize receptivity and engagement. Tailoring within digital interventions has been shown to be an important to optimize effectiveness. In T2C, intervention material will be tailored to adolescents' and parents' baseline characteristics; based on characterization, we will prioritize specific T2C intervention material. For example, if an adolescent perceives themselves to have low readiness, the TM intervention will give greater weight to psychoeducation and cognitive bias modification.

A stepped wedge design was selected for both ethical considerations and feasibility. First, the T2C intervention is unlikely to cause harm, and PCP stakeholders have expressed the need and desire for these tools. Thus, we will offer these interventions to all practices to maximize stakeholder feedback and optimize opportunities for implementation. In the proposed stepped wedge design, all practices start with Treatment As Usual-TAU-(i.e.,PCP referral to Mental Health care) and are randomized to transition to implement T2C at different times. All clinics will be initially monitored for at least 2 months during TAU, followed by a staggered adoption of T2C. During each time period, a new clinic will begin to use T2C (order determined by block randomization. A web-based system will randomly assign the next clinic to begin.

Consent:
Within about 24-48 hours, the ETUDES Assessment & Recruitment Center (ARC) assessors will call an eligible teen to complete informed consent with teen and parent, conduct baseline assessment measures, and onboard the T2C program on the cell phone. A waiver to document consent will be used to obtain consent from parents and assent from minors (12-17 yo) over the phone with the ARC assessor. If a minor participant turns 18 yo during the course of the study, a waiver to document consent will be used to identify if the minor wishes to continue their participation in the study. Date and time of the informed consent & assent phone conversation will be recorded. Prior to this phone call the RA in the primary care practice will have provided the family with a copy of the informed consent wording and HIPAA authorization to review (See recruitment methods section). The ARC assessor will review any areas of concern or question before obtaining family consent and moving on with the Baseline data collection. Consenting will take about 15 minutes.

Baseline assessment phone call:
Following the informed consent, the ARC assessor will conduct the baseline assessment measures. The measures include collecting sociodemographic questions, the CSSRS scale & suicide scales, quality of life ratings, treatment history, barriers to treatment, readiness for treatment, attitudes toward seeking psychological help, anxiety & mania adaptive scales via the K-CAT mental health adaptive screen, substance use, depression history, treatment preferences, and if there's a family history of bipolar disorder that impacts the youth's risk for mental health problems. A waiver of HIPAA authorization to collect permission verbally over the phone will be used to access and collect medical record data. Electronic medical record information will be used to supplement treatment and service utilization and uptake of the T2C intervention via the RE-AIM framework described in statistical analysis. Parents will respond to questions about their child, not themselves and youth will answer about themselves. Phone calls will take about 30-60 minutes.

Onboarding T2C:
The ARC assessor will use the provided cell phone number on a text-capable device to onboard the T2C program, verify the youth received initial messages, and troubleshoot technological problems with starting the intervention. Upon study entry, the youth will receive a series of welcome messages describing what to expect over the intervention period, expectations for response, and ways to reduce breach of privacy. For example (adolescent): “Welcome to the T2C Program. Over the next week we’ll send you daily texts. Set up a password on your phone and erase messages you do not want anyone to see after reading them.” We will indicate they can drop out of the T2C program at any time by texting “Quit.” Dr. Suffoletto has successfully used this onboarding process in prior studies.

T2C intervention
Text messages will last for about 1 week and participants will be asked to respond to up to 2 text message queries daily. Psychoeducation will be provided in the form of true/false or multiple choice questions. For example, “True or False: If someone has depression as a teen, they will always have it.” To alter false beliefs about treatment, texts will focus on what treatment entails, e.g., “Which of the following happens when you talk to a therapist about depression? (a) They make you tell them all your secrets; (b) They judge you; or (c) they help you understand your

feelings." Correct responses will be reinforced with a congratulatory message. For incorrect responses, a statement will validate their concern, and then the correct answer will be provided. Questions will be drawn from resources available in the public domain (e.g., SAMHSA). To promote symptom self-monitoring, we will use the single item "How often have you felt down, depressed or sad today on a scale 1 (not at all) to 5 (all day)? To decrease stigma, we will use cognitive bias modification strategies used successfully in prior research. Specifically, T2C will present individuals with a series of text statements regarding beliefs about using MH services (e.g., "Seeing a therapist means that I am weak"). Individuals can select "true" or "false" in response to each statement. Incorrect responses (i.e., indicating help-seeking stigma) are followed by corrective feedback (i.e., the correct answer); correct responses (i.e., promoting help seeking) are positively reinforced. Individuals repeat these tasks to facilitate internalization of more adaptive cognitions, consistent with cognitive therapy principles. T2C will send adolescents communication prompts weekly (or as requested when teens voluntarily check their self-reported mood ratings) to discuss ongoing mood symptoms with their parent, e.g., "Try to talk with your parent about these symptoms."

T2C for Parents: Parent subjects will receive similar psychoeducation and cognitive bias modification about depression/suicidality and MH treatment about their child, except focused on typical parental cognitive barriers. Tailoring is the method of personalizing characteristics of an intervention (e.g., content, timing) to maximize receptivity and engagement. Tailoring within digital interventions has been shown to be an important to optimize effectiveness. In T2C, intervention material will be tailored to adolescents' and parents' baseline characteristics; based on characterization, we will prioritize specific T2C intervention material. The tailoring will occur based on the text responses the parent offers about their child, not their personal characteristics about attending treatment for themselves.

Follow Up assessment phone calls:
During each follow up assessment phone call during week 4 and week 12 following the baseline phone call and onboarding to T2C, the ARC assessor will update demographic & contact information, ascertain continuing consent and assent to participate in study, and collect measures on depression, anxiety, mania, and suicide symptoms, the CSSRS, quality of life ratings, barriers to treatment, readiness for treatment, depression literacy, treatment utilization and history since last assessment, substance use, and additionally information on client satisfaction and usability processes with the T2C intervention once the family has completed the program. The youth will respond to questions about themselves and the parent about their child. Phone calls will take about 30-60 minutes.

Eligibility Criteria

Youth Inclusion Criteria:
- Youth aged 12-26 yo
- Own a cell phone with text message capability
- Biological or adoptive parent is willing to provide informed consent for teen to participate
- Youth speaks and understands English

-Positive PHQ score or provider determines youth has depressive symptoms based on clinical interaction and refers youth to the study (in cases when PHQ is not available and study staff will complete the PHQ during the screening) OR Provider can refer if they are unclear if symptoms are depressive and PHQ scoring will be used to determine youth's eligibility. OR Screening Wizard screening questionnaire (which includes the PHQ and depressive symptom questions) indicates depression OR provider indicates there is a concern that youth has mood or behavioral problem.
-Referred to mental health care OR screening wizard questionnaire (which indicates if provider makes referral to mental health care)

PHQ-9 scores:
Score of 8 or higher on PHQ-8 -or-
Score of 1 or higher on #9 of PHQ-9 suicidality item

Parent inclusion criteria:
- Age 18 or older
- Own a cell phone with text message capability
- Speaks and understands English
- Parent of a youth that scores positive on the PHQ-8 or #9 as described above
- Parent of a youth who has been referred to mental health treatment

Youth Exclusion Criteria:
- Non English speaking
- No parent willing to provide informed consent
- No cell phone with text messaging capability
- Is currently experiencing mania or psychosis
- Evidence of an intellectual or developmental disorder (IDD)
- Life threatening medical condition that requires immediate treatment
- Other cognitive or medical condition preventing youth from understanding study and/or participating.
- Not referred to mental health care

Parent Exclusion Criteria:
- No cell phone with text messaging capability
- Child meets exclusion criteria as described above
- Other cognitive or medical condition preventing parent from understanding study and/or participating.

Statistical Considerations

A stepped wedge design was selected for both ethical considerations and feasibility. A stepped wedge cluster randomized trial design involves the sequential random rollout of an intervention over multiple time periods following a “baseline” period when no cluster has been exposed. The

crossover is typically in one direction, from control to intervention, and continues until all of the clusters receive the intervention with observations taken from every cluster and at each time period. All 3 studies in the ETUDES Center, and specifically, T2C, will utilize this design. Prior to study start, each CCP study practice will be randomly assigned to switch from Treatment As Usual (TAU) to the intervention.

In the proposed stepped wedge design, all practices start with TAU (i.e.,PCP referral to embedded MH care) and are randomized to transition to implement T2C at different times. All clinics will be initially monitored for at least 2 months during TAU, followed by a staggered adoption of T2C. During each time period, a new clinic will begin to use T2C (order determined by block randomization. A web-based system will randomly assign the next clinic to begin.

With regard to Hypothesis 1: We will conduct t tests for continuous variables and chi square tests for categorical variables to examine for baseline differences in demographic and clinical variables. We will use generalized linear mixed models (nesting for site) to examine for between-intervention differences in readiness. Baseline characteristics that distinguish the groups will be included as covariates in models examining treatment effects.

In order to enhance uptake of T2C, we will conduct the proposed work within the RE-AIM framework, as follows. (R)each: The percentage and characteristics of screen-positive adolescents referred for MH treatment who are offered, and agree to participate in, T2C. (E)fficacy: The impact of T2C on MH treatment initiation and engagement. (A)doption: The percentage and characteristics of PCPs who refer to T2C upon making a referral for MH care for a screen-positive adolescent. (I)mplementation: The percentage and characteristics of patients who consent to T2C who complete the TM intervention. (M)aintenance: The percentage and characteristics of PCPs who recommend T2C to appropriate patients upon long-term follow-up, as well as T2C utilization by referred adolescents/parents via de-identified data. The baseline and follow up measures administered are mapped onto each component of the RE-AIM framework.