

# Study Protocol

**Official Title:** Text2Connect-Texting Intervention for Mental Health Treatment Utilization (T2C)

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## Scientific Background

### SIGNIFICANCE

A1. Mental health diagnoses are common and impairing among youth transitioning to college. Recent research indicates that 33% of college freshmen screen positive for at least one mood, anxiety, or substance disorder.<sup>1</sup> Unfortunately, these and other common psychiatric disorders (e.g., Attention Deficit Hyperactivity Disorder ADHD, eating disorders) can profoundly affect successful college transition. College students rank mental health concerns among the top four factors that interfere with their academic performance,<sup>13</sup> and most students who leave college without graduating do so due to mental health reasons.<sup>14</sup>

A2. Engagement in mental healthcare among college students. Despite the prevalence and impairment associated with mental health conditions among college students, treatment rates are low. Research demonstrates that 60% of college students with a mental health problem report the same problem two years later, and within this group (i.e., those whose condition persisted over 2 years), less than half received treatment during that same period of time.<sup>2</sup> Young adults are also more likely to self-discontinue antidepressants than older adults.<sup>15</sup> These data are particularly concerning given that earlier onset of psychiatric disorders is associated with poorer outcomes and greater symptom severity.<sup>16</sup>

A2. The import of mental health self-efficacy among transition age youth. Although many of these youth may have received a range of services in pediatric care (e.g., medication management, psychiatry, therapy) and within the school system (e.g., individualized education plans) prior to college transition, such services often rely on the involvement of parents or guardians in supporting youth, for example, to schedule and attend appointments or refill and administer medications. Once these youth transition to college, they are often on their own, responsible for navigating new systems of care, and must assume responsibility for scheduling appointments, filling medications, and seeking out additional services (e.g., academic accommodations). Furthermore, many college students with pre-existing mental health disorders do not disclose their conditions to their school and/or seek services for other reasons, including lack of awareness of resources, concerns about stigma, and desire for a “fresh start.”

Thus, while many students transitioning to college may benefit from linkage with mental health supports on campus, not all have the knowledge, skills and beliefs to manage their mental healthcare independently, a concept referred to as “mental health self-efficacy.” Not surprisingly, studies show mental health self-efficacy is associated with mental health outcomes and functioning among young adults.<sup>3</sup> Low mental health self-efficacy, together with mental health symptoms, and further exacerbated by common stressors associated with initiating higher education (e.g, academic and social pressures, decreased structure) can culminate in dire consequences for college students including hospitalization, academic probation/failure, and even suicide, rendering mental health self-efficacy an important treatment target for transition-age students.

A3. Interventions to increase mental health self-efficacy. Consistent with cognitive models of help-seeking, interventions to date designed to enhance engagement with mental health services largely

focus on increasing mental health literacy and decreasing stigma. A recent meta-analysis on studies using these approaches found modest improvements in help-seeking cognitions; 1 trial showed small improvements in linkage to mental health care;<sup>17</sup> only 1 targeted adolescents, and most were delivered in-person. Thus, innovative approaches are needed that specifically target mental health self-efficacy among college students to enhance outcomes for this high-risk population.

A4. New Approaches: The Role for Mobile Technology. The ubiquity of mobile communication technology (i.e., cellphones) across age and socio-economic status makes it an ideal platform to reach at-risk individuals. By interacting with individuals in their daily lives over time, mobile digital interventions could be particularly useful to modify cognitive and motivational components of mental health self-efficacy. Text messaging (TM) is a form of digital communication that is especially useful at modifying adolescent health behaviors<sup>18</sup>, including studies by our group on alcohol<sup>10</sup> and risky sexual behavior<sup>11</sup> (see Preliminary Data). Recent evidence also suggests that TM interventions can improve mental healthcare outcomes youth engaged in treatment,<sup>4</sup> yet promise for promoting mental health self-efficacy remains unknown. We will thus develop a TM intervention targeting mental health self-efficacy for youth transitioning to college.

#### INNOVATION

Our TM intervention, “Text to Connect” (T2C), is the first mobile digital intervention to target mental health self-efficacy among transition-age youth with mental health conditions. Because adolescents rely heavily on TM for communication, T2C may be particularly developmentally appropriate. T2C pathways are tailored based on the youth’s needs, thus making material individualized and personal.

#### PRELIMINARY DATA

Text to Connect (T2C) Version 1 for Adolescents. In the context of a Center-funded treatment development phase, the current study team successfully developed and tested a preliminary version of T2C designed to enhance follow-through with mental health treatment for youth (age 12-18) referred for co-located treatment in primary care. The T2C system was successfully built in collaboration with OAC and implemented with 24 youth to date recruited across 4 CCP practices and STAR. From this pilot trial, we determined that the TM intervention itself was highly promising, but also identified an unmet need among transition-age youth for the technology developed, with some modifications. As such, this pilot work demonstrates the team’s success building TM interventions for youth, the resulting intervention serves as a foundation for the T2C system proposed herein, and helped the team identify a significant clinical need and treatment target for this system.

Interactive Text Messaging Interventions Effect Youths’ Health Behavior. Co-I Dr. Suffoletto is an expert in the development, implementation and testing of TM interventions to modify health-related behavior in young people.<sup>10-12</sup> His work demonstrated that for young adults presenting to the emergency department who screen positive for hazardous alcohol use, the TM intervention he developed was associated with greater reductions in binge drinking days (IRR=.69; 95% CI=.59-.79) and lower binge drinking prevalence (OR=.52; 95% CI=.26-.98) compared with controls.<sup>10, 19, 20</sup> He has also applied TM interventions to other youth health behaviors in the emergency department, including sexual risk behaviors<sup>11</sup> and antibiotic adherence.<sup>12</sup>

A Brief Motivational Intervention Improves Medication Adherence for Adolescents with Bipolar Disorder. In a recently completed R34 (MH92424), PI Dr. Goldstein developed and examined an in-person Brief Motivational Intervention (bMI) targeting medication adherence for adolescents with bipolar disorder. A randomized trial demonstrated significant improvement in objective medication adherence among adolescents who received the bMI, vs treatment as usual; the bMI was most potent for adolescents with lower baseline adherence and higher treatment expectancy.<sup>21</sup> Together, these studies demonstrate the team's success examining disseminable motivational interventions and TM platforms for youth health behavior change.

## Study Objectives

This protocol represents the 2nd phase of the ETUDES Center protocol (also known as Study 2 of 3) for Text2Connect Phase 1b. Please reference STUDY18120039 for additional ETUDES Center background leading to the development of this protocol, including the planning toward making adjustments to the initially tested intervention tailored to the real-world settings in which they are implemented.

Over 1/3 of first-year college students screen positive for at least one mood, anxiety, or substance disorder.<sup>1</sup> Unfortunately, despite the prevalence and impairment associated with mental health conditions among college students, treatment rates are low. Research demonstrates that 60% of college students with a mental health problem report the same problem two years later, and less than half received treatment during that time.<sup>2</sup>

This transition period to college presents innumerable challenges that render treatment engagement low for young adults with mental health conditions starting college. Although these youth may have received a range of services in pediatric care (e.g., medication management, psychiatry, therapy) and within the school system (e.g., individualized education plans), such services often rely on the involvement of parents or guardians in supporting youth, for example, to schedule and attend appointments or refill and administer medications. Once these youth transition to college, they are often on their own, responsible for navigating new systems of care, and must assume responsibility for scheduling appointments, filling medications, and seeking out additional services (e.g., accommodations).

As such, not all young adults with mental health conditions have the knowledge, skills and beliefs to manage their own mental health and care independently, a concept referred to as "mental health self-efficacy." Not surprisingly, studies show mental health self-efficacy is associated with mental health outcomes and functioning among young adults.<sup>3</sup> Low mental health self-efficacy, together with mental health symptoms, and further exacerbated by common stressors associated with initiating higher education (e.g. academic and social pressures, decreased structure) can culminate in dire consequences for college students including hospitalization, academic probation/failure, and even suicide.

Digital interventions using mobile communication such as text messaging (TM) could be useful to enhance mental health self-efficacy among young adults during the transition to college. Potential benefits of TM approaches include the ability to prompt awareness of treatment targets in daily life and

deliver tailored knowledge and skills to enhance self-efficacy, thereby improving outcomes. Recent studies suggest TM interventions may improve retention in mental health care for depressed adolescents already in treatment.<sup>4</sup> Yet, effective approaches to enhancing mental health self-efficacy for transition-age youth remains unknown.

To enhance outcomes for transition-age youth with mental health disorders during the vulnerable period that occurs during their first several months of college, we propose an automated TM intervention, "Text to Connect" (T2C), that aims to increase mental health self-efficacy through psychoeducation, self-monitoring of symptoms and stressors, and cues to action for college-bound youth. We propose a pilot randomized controlled trial for 50 youth with a current psychiatric diagnosis who are transitioning to college. Youth will be identified by their treatment providers at 1 of 3 clinics (pediatric primary care clinic, CCP Waterdam; Services for Teens at Risk, STAR Clinic; and Child and Adolescent Bipolar Spectrum Clinic, CABS, Western Psychiatric Hospital) within 6 weeks of starting a higher education program. Consenting participants will be randomized on a 2:1 randomization scheme to either receive T2C (n=30) or a link to brief psychoeducational videos about mental health (PE; n=20). All participants will then complete a brief battery of self-report assessments online at baseline and again monthly through month 4. Youth randomized to receive PE will receive a text message with the link to the webpage with the psychoeducational videos. Youth randomized to receive T2C will be onboarded and initiate the TM intervention that sends automated prompts at minimum monthly through month 4.

Aim 1. To examine the feasibility of T2C for transition-age youth with psychiatric disorders (n=3 clinics, 50 adolescents). Youth randomized to receive T2C will:

Hypothesis 1a. engage with T2C at high rates (>70% response rate to SMS prompts).

Hypothesis 1b. report high levels of satisfaction (>70% satisfaction) and usability with T2C.

Aim 2. To examine the impact of T2C versus PE on mental health self-efficacy, symptoms and functioning, and treatment engagement. Over 4 months, youth who receive T2C, as compared with youth who receive PE, will report:

Hypothesis 2a (Primary). Greater mental health self-efficacy

Hypothesis 2b (Secondary). Lower symptom severity and greater psychosocial functioning

Hypothesis 2c (Secondary). Higher rates of follow-through with mental health services

Our team is ideally suited to conduct the proposed study. PI Dr. Goldstein has extensive experience developing and testing psychosocial interventions for adolescents,<sup>5-7</sup> including motivational interventions for mood-disordered adolescents<sup>8</sup> and mHealth,<sup>9</sup> and Co-I Dr. Suffoletto is expert in developing and testing TM interventions to modify health-related behavior in young people.<sup>10-12</sup> Dr. Gotkiewicz is a pediatrician and community champion devoted to enhancing mental health outcomes for adolescents and young adults.

## Study Design & Method

This study is a randomized trial with a 2:1 allocation in favor of the intervention vs. treatment as usual (TAU).

T2C Onboarding. The participant will be prompted to text a unique keyword to initiate T2C. Upon study entry, participants 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: "Welcome to T2C. Over the next 4 months we'll be checking in by text message. 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 prior studies. Study staff will assist youth with any technical difficulties.

T2C Intervention. T2C aims to increase mental health self-efficacy through psychoeducation, self-monitoring of symptoms and stressors, and cues to action for college-bound youth. Specifically, each monthly check-in starts with a text prompt inquiring about general well-being. Based on the participant's response, the participants then receive either general psychoeducational videos and prompts to continue to monitor mental health (in the event of wellness) or are then prompted to endorse stressors and symptoms they are experiencing to prompt awareness of treatment targets in daily life. A text prompt then assesses the participant's self-reported confidence in ability to manage stressors and symptoms. Tailored knowledge and skills are then texted to the participant to enhance self-efficacy. Participants who endorse stressors/symptoms can opt to receive follow-up texts one week later to re-assess. Participants who endorse low confidence in ability to manage stressors and symptoms are prompted to seek treatment and provided resources.

Psycho-education (PE). The participant will be receive a web link to a library of 4 PE videos. These brief 2-minute videos were created by the study team for this purpose. The videos include general information about self-care during college. Study staff will assist youth with any technical difficulties. The PE videos were developed through a UPMC Quality Improvement project QRC (protocol #2564). A Data Use Agreement is contracted with Clinical Platform (programmers of videos) and CCP Waterdam/UPMC Children's Hospital of Pittsburgh. Videos are currently used in usual care at Children's Hospital in addition to the specific CCP Waterdam videos in this study.

## **Eligibility Criteria**

### **Inclusion Criteria:**

Participants will be at least 18 years of age and:

- 1) engaged in treatment at CCP Waterdam, STAR or CABS clinic;
- 2) have a current psychiatric diagnosis documented in their electronic medical record and/or be in receipt of mental health services within 3 months per self-/parent- or clinician-report;
- 3) recently graduated high school;
- 4) planning to attend college or higher education program within 6 weeks;
- 5) own a text-capable phone; and
- 6) willing and able to provide informed consent.

### **Exclusion Criteria:**

Participants will be excluded if they are under the age of 18 years old, non-English speakers, and have a diagnosis or health condition that would prevent them from participating in the study and/or understanding the intervention and research activities.

## Statistical Considerations

Aim 1. To examine the feasibility of T2C for transition-age youth with psychiatric disorders (n=3 clinics, 50 adolescents). Youth randomized to receive T2C will:

Hypothesis 1a. engage with T2C at high rates (>70% response rate to SMS prompts). We will calculate TM response rates within and between individuals. Per our proposed design, each adolescent will contribute up to 12 responses per timepoint.

Hypothesis 1b. report high levels of satisfaction (>70% satisfaction) and usability (PSSUQ>6) with T2C. We will compute mean satisfaction (CSQ) and usability (PSSUQ) at 4 month follow-up.

Aim 2. To examine the impact of T2C versus PE on mental health self-efficacy, symptoms and functioning, and treatment engagement. Over 4 months, youth who receive T2C, as compared with youth who receive PE, will demonstrate:

Hypothesis 2a (Primary). Greater mental health self-efficacy (MHSES, SE-SMHC).

Hypothesis 2b (Secondary). Lower symptom severity (CCAPS) and greater psychosocial functioning (CAQ).

Hypothesis 2c (Secondary). Higher rates of follow-through with mental health services (C-SRI).

For each of the proposed outcomes (a-c), we will construct mixed-effect models to examine for between-group differences in each outcome. Mixed-effects models are recommended for analysis of repeated-measures data and can properly account for missing data as well as multivariate outcomes.

Power Analysis. The proposed study is a preliminary randomized pilot study. We expect that the small sample will provide sufficient comparison data to guide the design of a larger-scale controlled study that would be sufficiently powered to determine the efficacy of the intervention.

In order to enhance uptake of T2C in relationship to the overall ETUDES Center mission, 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)dooption: The percentage and characteristics of providers who refer to T2C upon making a referral for MH care for a screen-positive adult. (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 young adults via deidentified data. The online survey measures administered are mapped onto each component of the RE-AIM framework.