Comprehensive **A**daptive **M**ultisite **P**revention of **U**niversity student **S**uicide (**CAMPUS**): A Multisite Trial

NCT04728815

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Data Coordinating Center	Duke Data Center (DDC), Duke University Medical Center
sIRB	Duke University Medical Center

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STATEMENT OF COMPLIANCE

This trial will be conducted in compliance with the following protocol, International Conference on Harmonization Guidance for Industry, Good Clinical Practice: Consolidated Guidance (ICH E6), applicable Code of Federal Regulations, and the National Institute of Mental Health (NIMH) Terms of Award. The Principal Investigator (PI) will ensure that no deviation from, or changes to, the protocol will take place without prior agreement from the sponsor and funding agency and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate immediate hazard(s) to trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and Good Clinical Practice (GCP) Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) will be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title: Comprehensive Adaptive Multisite Prevention of University student Suicide (CAMPUS): A Multisite Trial

Study Description: Suicide is the 2nd leading cause of death among college students and suicidal ideation and suicide-related behaviors are a frequent presenting problem at college counseling centers (CCCs), which are overburdened. Studies show that some students respond rapidly to treatment, whereas others require considerably more resources. Evidence-based adaptive treatment strategies (ATSs) are needed to address this heterogeneity in responsivity and complexity. ATSs individualize treatment via decision rules specifying how the type and intensity of an intervention can be sequenced based on risk factors, response, or compliance.

In the wake of the COVID-19 pandemic, CCCs are now offering teletherapy to address the mental health needs of students. This rapid transition to teletherapy service delivery within CCCs has clear implications for the CAMPUS Trial. The goal of the original Collaborative R01 study was to evaluate 4 adaptive treatment sequences (ATSs) when delivered entirely in person. Because of the need for CCCs to begin offering therapeutic services online and the reality that teletherapy will continue beyond the near future, the results from the original CAMPUS Trial would be less relevant and informative to CCCs of the future.

Therefore, we conducted a multi-site feasibility study which was a small-scale, modified version of the larger trial used to 1) evaluate the feasibility and acceptability of the interventions when delivered via a hybrid model and (2) to fine-tune online study procedures, including recruitment, training, supervision, interventions, assessments, data collection, and safety monitoring. Based on data from the feasibility study, we are proposing to modify our original design. Like the feasibility study, the modified CAMPUS Trial will use a hybrid treatment model, which will evaluate the relative effectiveness of treatment when delivered either via telehealth, in person, or a combination, and transition study procedures to an online format. Decisions about what type of sessions to hold will be made by the counselor and based on several factors, including university and CCC policy, location/preference of the student participant, and

location/preference of the counselor participant. In addition, we are proposing modifications to the overall length of the trial and the treatments to better fit within the CCC setting.

The multisite CAMPUS Trial will enroll moderately to severely suicidal college students in the "emerging adulthood" phase (ages 18-25) seeking services at CCCs and evaluate the relative effectiveness of the adaptive treatment strategies (ATSs) when delivered via a hybrid model. The four ATSs will be developed and refined within the context of the current sequential multiple assignment randomized trial (SMART). The SMART will have two stages of intervention. In Stage 1, 480 participants from the participating CCCs will be randomized to 4-6 weeks of: (1) a suicide-focused treatment – Collaborative Assessment and Management of Suicidality (CAMS) or (2) Treatment as Usual (TAU).

Sufficient responders to either intervention will enter the maintenance phase. Non-responders will be re-randomized to one of two Stage 2 higher intensity/dosage intervention options for an additional 1-8 weeks: (1) CAMS (either continued or administered for the first time) or (2) Counseling Center Dialectical Behavior Therapy Dialectical Behavioral Therapy for College Counseling settings (CC-DBT), which includes individual therapy and skills training.

For the CAMPUS Trial, we will also enroll up to 40 CCC counselors who will serve as study counselor participants and periodically complete measures focused on the experience of counselors working with suicidal college students.

Objectives:

The overall purpose of the multisite CAMPUS Trial is to evaluate the relative effectiveness of four adaptive treatment strategies (ATSs) to treat college students who report suicidal ideation when first seeking services at their college counseling center.

The CAMPUS Trial aims to identify which sequence(s) of treatments are most effective on average (average treatment effect or ATE), which treatment sequence(s) are most cost-effective for college counseling centers to provide, and whether outcomes vary based on key student characteristics (heterogeneity of treatment effect or HTE).

Another aim of the CAMPUS Trial is to assess counselor participants' experience of participating in the study and providing treatment to suicidal college students, including examining their expectations for therapy and beliefs about suicide. These analyses will be qualitative and exploratory in nature and will not have specified hypotheses.

Endpoints:	Primary Endpoints/Outcome Measures: The primary endpoint for the CAMPUS Trial is reduction in suicidal risk at the end of Stage 1 treatment, Stage 2 treatment, and at 3-month follow-up. Differences in suicidal risk will be operationally defined as changes in suicidal ideation, non-suicidal self-injury, and suicide attempts, as well as differences in deaths by suicide. Secondary Endpoints/Outcome Measures: Secondary outcomes for the CAMPUS Trial are changes in overall distress, depression, social and generalized anxiety, substance abuse, eating concerns, academic functioning, health care utilization, and student participant ratings of severity and improvement in suicidal risk.
Study Population:	Recruitment of 480 college students (aged 18-25) is the target for randomization to Stage 1 treatments. Up to 40 counselors will also be recruited to participate as study therapists. The number of counselor participants may increase or decrease throughout the project based on turnover, but we expect to maintain approximately 24 participating counselors at any given time across the participating sites in each of the enrollment years.
Phase or Stage:	Phase III Clinical Trial
Description of Sites/Facilities Enrolling Participants:	This multisite study will include the following four primary sites: University of Nevada – Reno, Duke University, University of Oregon, and Rutgers University. Research will be conducted at each site through each College Counseling Center (CCC). The Single IRB will be sponsored and overseen by Duke University. Other CCCs may be added as performance sites in the future to increase enrollment numbers as needed.
Description of Study Intervention/ Experimental Manipulation:	The multisite study will utilize a SMART design. Suicidal college students seeking counseling services through the College Counseling Centers (CCCs) will be recruited. In Stage 1, student participants will be initially randomized into either treatment as usual (TAU) or Collaborative Assessment and Management of Suicidality (CAMS). Student participants receiving TAU will receive the customary treatment they would receive at the CCC. Student participants receiving the CAMS intervention will receive CAMS through weekly sessions with a counselor that will last for 50-60 minutes. Responders to either CAMS or TAU may stop treatment after 4 sessions (minimum dose of treatment), based on counselors' ratings

of improvement of students' symptoms of suicidality. Stage 1 has an intended duration of no more than 6 weeks.

Non-responders to Stage 1 treatments will be re-randomized to one of two Stage 2 treatments: CAMS or College Counseling Dialectical Behavior Therapy (CC-DBT). Student participants receiving CC-DBT will engage in individual therapy and either a skills training group or individual skills training. Stage 2 has an intended treatment duration of 1-8 weeks.

All treatment in Stage 1 and Stage 2 (TAU, CAMS, and CC-DBT) will be administered via a hybrid intervention model, either online or in person. For the purposes of these studies, a hybrid intervention model means that a student participant's course of care may be delivered completely via telehealth, completely in person, or via a combination of in person and telehealth sessions. Decisions about what type or format of sessions to hold will be made by the counselor and based on several factors: university policy, CCC policy, location of student/counselor participants, and preference of the student/counselor participants. Data will be collected on the number of sessions conducted via each modality (captured via EHR). Such data will be explored to inform more richly tailored ATSs.

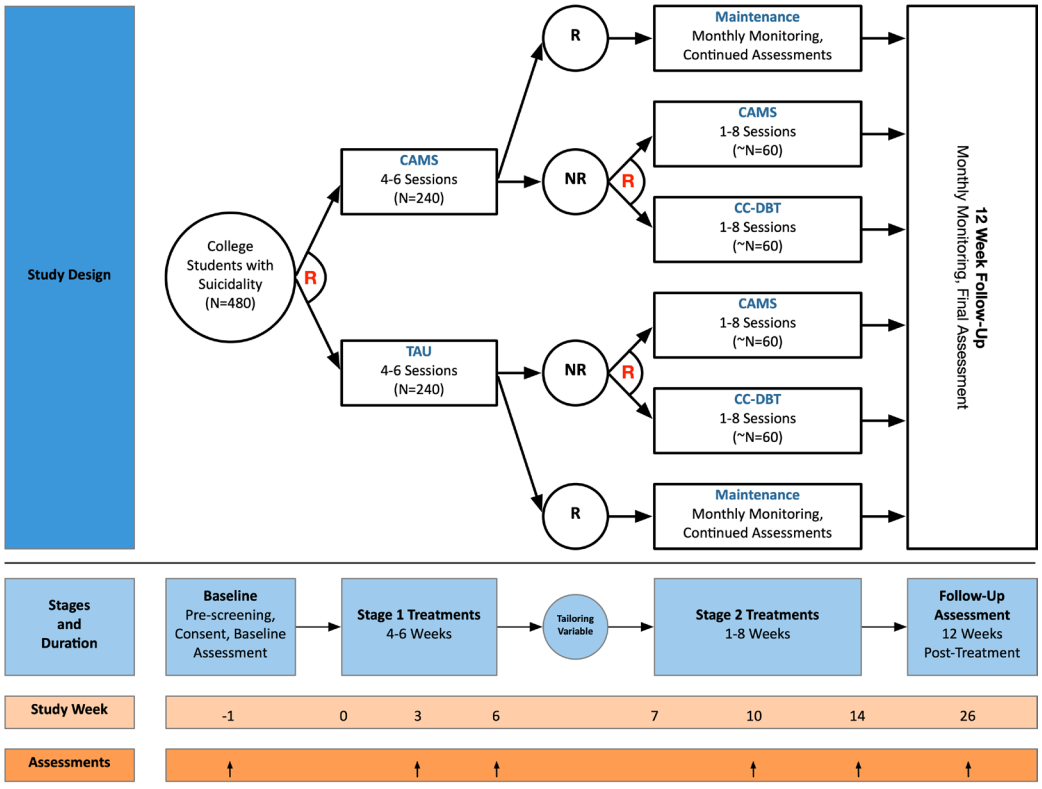
Counselors will provide TAU, CAMS, and CC-DBT to study participants. They will also participate in CAMS and CC-DBT trainings and ongoing consultation teams for each. In addition, counselors will complete questionnaires at regular intervals throughout their participation in the study.

Study Duration: The duration of the CAMPUS Trial is approximately 30 months (2.5 years) total duration from beginning of recruitment until final data collection.

Participant Duration: Total student participant duration is 26 weeks, which includes a 12-week follow-up assessment. Total student participant duration in active treatment can range from 4-14 academic weeks (not including campus holiday breaks or periods where students are ineligible for CCC services due to being out of state). Counselor participant duration will range from 1-2 years.

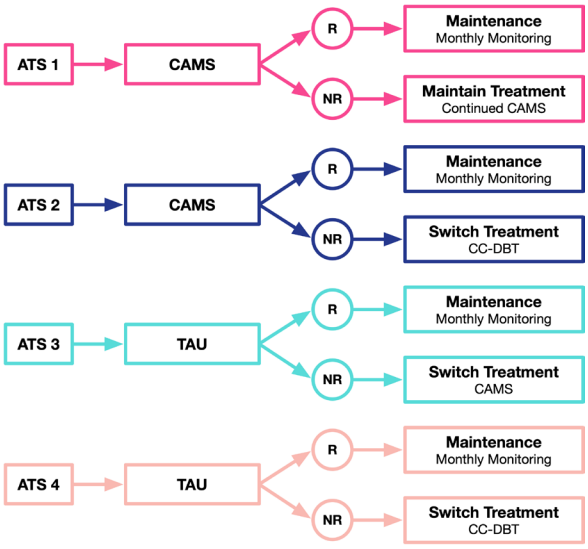
1.2 SCHEMA AND ADPATIVE TREATMENT STRATEGIES

Figure 1. CAMPUS Trial Study Design
(**C**omprehensive **A**daptive **M**ultisite **P**revention of **U**niversity student **S**uicide)



Legend: R=Randomization Point; CAMS=Collaborative Assessment and Management of Suicide; TAU=Treatment as Usual; R=Responder to treatment; NR=Non-responder to treatment; CC-DBT=Counseling Center Dialectic Behavior Therapy

Figure 2. The Four ATSs considered in the CAMPUS Trial



Legend: ATS=Adaptive Treatment Strategy; CAMS=Collaborative Assessment and Management of Suicidality; TAU=Treatment as Usual; R=Treatment Responder; NR=Treatment Non-Responder

1.3 SCHEDULE OF ACTIVITIES

All participants will self-refer to an initial appointment (i.e., intake) at their CCC, and as part of standard operating procedures will meet with an intake counselor, either in-person or remotely following practices of the CCC, as a first step to access CCC services. As part of the CCC's standard clinic workflow, all students seeking services will complete the Counseling Center Assessment of Psychological Symptoms (CCAPS-62). Students who meet inclusion and exclusion criteria will be given a brief explanation of the study by the intake counselor. Interested students will be scheduled for an appointment conducted either in-person or remotely with a member of the research who will review the consent form with each student. Students who sign the consent form will then complete a baseline assessment with the Independent Evaluator (IE), either online or in-person.

The schedule of activities for the CAMPUS Trial is presented in Table 1 on the next page.

Table 1. Schedule of Activities for the CAMPUS Trial																	
			Stage 1						**Stage 2**								
	-1	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**26**
Completed by CCC Intake Counselor																	
Screening Data Form*	X																
Completed by Student Participants																	
Demographic Information		X															
Sexual Orientation and Gender Identity		X															
Counseling Center Assessment of Psychological Symptoms (CCAPS)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Clinical Global Impression – Severity (CGI-S)		X			X			X				X				X	X
Clinical Global Impression – Improvement (CGI-I)					X			X				X				X	X
Adverse Events and Serious Adverse Events (AE/SAE)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Difficulties in Emotional Regulation Scale (DERS)		X						X				X				X	X
DBT Ways of Coping Checklist (WCCL)		X						X				X				X	X
Acceptance and Action Questionnaire (AAQ)		X						X				X				X	X
Suicide Cognitions Scale (SCS)		X			X			X				X				X	X
Self-Efficacy for Managing Emotions		X			X			X				X				X	X
Optimism Hope Scale (OHS)		X			X			X				X				X	X
Personality Assessment Inventory-Borderline Features Scale (PAI-BOR)		X															
Life Stressor Checklist-Revised (LSC-R)		X															X
Drug Abuse Screening Test (DAST)		X														X	X
Alcohol Use Disorders Identification Test (AUDIT)		X														X	X
Student Treatment Credibility Questionnaire (STCQ)			X						X								
Student Treatment Expectations Questionnaire (STEQ)			X						X								
Client Satisfaction Questionnaire (CSQ)								X								X	
Academic Functioning		X														X	X
Completed by Independent Evaluators																	
University of Washington Risk Assessment Protocol (UWRAP)		X			X			X				X				X	X
Clinical Global Impression – Severity (CGI-S)		X			X			X				X				X	X

Table 1. Schedule of Activities for the CAMPUS Trial																	
			Stage 1						**Stage 2**								
	-1	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**26**
Clinical Global Impression – Improvement (CGI-I)					X			X				X				X	X
Scale for Suicidal Ideation (SSI)		X			X			X				X				X	X
Self-Injurious Thoughts and Behaviors Interview (SITBI)		X						X				X				X	X
Global Assessment Scale (GAS)		X			X			X				X				X	X
Treatment History Interview (THI)		X														X	X
Completed by Research Staff																	
Informed Consent		X															
Inclusion/Exclusion Checklist		X															
CAMS Rating Scale-3[1]																	
DBT Adherence Rating Scale[1]																	
Completed by Counselor Participants																	
Reveal Randomization			X						X								
Demographic Information Form (DIF)[2]		X															
Treatment Compliance Item*			X	X	X	X	X	X	X	X	X	X	X	X	X	X	
AE/SAE Summary Form			X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Clinical Global Impression – Severity (CGI-S)[3]			X					X								X	
Clinical Global Impression – Improvement (CGI-I)				X	X	X	X	X	X	X	X	X	X	X	X	X	
Treatment Assignment Reaction Form			X						X								
Counselor Treatment Expectations Questionnaire (CTEQ)			X						X								
Client Satisfaction Questionnaire-Counselor (CSQ-C) and Counselor Satisfaction Rating[3]								X								X	
Reasons for Termination Checklist[3]								X								X	
TAU Questionnaire[3]								X									
Counselor Telehealth Questionnaires (CTSQ)[3]																X	
Zero Suicide Workforce Survey- Abbreviated (ZSWS)[4]		X															X
Focused Interview[5]																	X

Table 1. Schedule of Activities for the CAMPUS Trial

			Stage 1						Stage 2								
	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	26

Notes (1): 1. Research staff will complete this measure on a random sample of therapy sessions. 2. Counselor participants will complete this measure once when they enter the study. 3. Counselor participants will complete this measure following students' last treatment session which may be earlier than Week 14. 4. Counselor participants will complete this measure at the start of their participation in the study and then every six months. 5. Counselor participants will complete this interview at the end of their participation in the study.

Notes (2): §For all assessments collected as part of an Independent Evaluator (IE) visit (i.e., those assessments not collected specifically at treatment visits), there will be a +/-1 week window around the scheduled assessment date for purposes of data collection. IE assessments collected outside of this window will still be collected and values will be imputed based on when the assessment should have occurred.

Notes (3): *These measures are exclusively collected in the Titanium electronic medical record and will be exported at regular intervals throughout the study period.

2 INTRODUCTION

2.1 STUDY RATIONALE

2.1.1 CAMPUS TRIAL

Suicidal College Students Represent a Major Public Health Concern

Among college students, suicide is the second leading cause of death;[20] 10% of college students report having attempted suicide in their lifetime with 2% attempting in the last year alone.[38] Suicidal ideation (SI) is even more frequent: 25% of students report a history of severe SI, including 10% in the last year.[38] These numbers are climbing among college students—not surprising considering that suicide rates among individuals 10-24 years old has been trending up since 2007.[39,40] Some students, particularly those who self-identify as sexual and gender minorities (SGM), such as transgender or non-binary/genderqueer, lesbian, gay, bisexual, and queer (or other self-identity) may be at even higher risk.[18,19]

CCCs are the front line for mental health services for growing numbers of suicidal students.[22,41] Yet CCCs face limited resources[42] and higher demand for services with increasingly complex cases,[21,43] with more than half reporting that waitlists develop within a few weeks and last throughout the term.[25] Despite aspiring to provide only brief therapy,[22] data show that in practice CCCs are providing 20 sessions or more to a segment of their student population,[44] 20% of students have been shown to use 50% of counseling resources,[45] and highly distressed students appear to need a higher number of sessions.[46] Suicidal risk (SR) is likely a key culprit of this crisis: one third of treatment seeking students report SI—20% of those at clinical levels in the last year,[21] SI has become a primary presentation at CCCs,[43] CCC resources devoted to "rapid access" services have increased by 28%,[21] and threat-to-life students use 20-30% more services than other students.[21] Chronically suicidal students greatly strain CCC resources.[21,47] The stakes are also high when suicide occurs on a campus.[26] CCCs are commonly held directly accountable in malpractice litigation and administrators are realizing that untreated suicidality puts the entire institution at risk. Many severely suicidal students remain in school,[21] which, in fact, has suicide-protective benefits at a population level.[48,4] Having a validated, cost-effective, evidence-based approach to treating suicidal students would be very helpful to CCCs.[26] Importantly, suicidal college students are not a homogeneous group. They vary in risk and response to treatment and thus a "one size fits all" approach to treatment is not effective for this heterogeneous population.[50] While many students experience an isolated suicidal episode, 40-50% of severely suicidal students report multiple episodes of SI.[51] In a sample of CCC treatment-seeking suicidal students, 52% quickly resolved suicidality in 6-7 sessions, while others remained suicidal (17%), dropped out of care (22%), or were hospitalized (7%).[27] Thus, some suicidal students require more intensive forms of treatment while most respond to briefer forms of care.[46] It has become imperative to identify an appropriate sequence of evidence-based interventions to address SR in CCCs, matched to different levels of severity and/or responses to treatment, to optimize clinical care and resource efficiency.

Addressing suicidal risk in college students today will help society in the future

There are additional reasons to address SR in college students: 1) evidence-based approaches for this population apply to a large and diverse population given that 49% of 18-to-24-year-olds are enrolled in college and rates of non-white students are rapidly increasing;[52] 2) the emerging adulthood period (18-25 years of age) is developmentally significant[53,54]–with poor adjustment and mental health problems having lifelong consequences,[55,56] thus successful treatment may impact years of downstream public health costs; and 3) today's college students are tomorrow's likely leaders–society at large has a stake in their mental health. Although college students have often been studied as a convenience sample, that's not the case in this study. Something critical is happening with college students right now, that includes increased suicidal thinking and behavior as well as other mental health problems and reduced resilience/skillful behavior, which are thankfully combined with less stigma towards mental health treatment.[57] There are many pathways to suicide,[58] and large-scale studies like this can give us the opportunity not only to prevent suicidal behaviors but also to understand how best to help students.

2.2 BACKGROUND

This Project Will Test Adaptive Treatment Strategies for Suicidal College Students

There is no empirical guidance on how to treat the heterogeneity of suicidal students seeking services at CCCs.[26] CCCs would benefit significantly from understanding how to sequence individualized care—which treatments work best and how intensive do they need to be? In recent years, adaptive treatment strategies (ATSs)[28] have been investigated using methodological innovations such as sequential multiple assignment randomized trials (SMARTs).[17,59] We are proposing to investigate sequences of suicide-focused treatments that could be utilized in CCCs to treat and/or triage a wide range of college students presenting with SR. Moreover, the study will significantly add to the current literature by evaluating treatments when delivered in a hybrid online/in-person format and will better reflect the actual practice within CCCs. Although there are other empirically supported suicide-focused approaches,[60] the two approaches described below were specifically selected for inclusion because they 1) have already been tested at a CCC, 2) have moderate to considerable empirical validation, and 3) complement each other well when implemented in a stepped care fashion.

1) Collaborative Assessment and Management of Suicidality (CAMS)[7] is an evidence-based, suicide-focused approach[61] that was first developed and studied in a CCC specifically for college students.[62] CAMS is a problem-focused treatment that targets client-defined suicidal "drivers" or issues that lead to SI.[7] Central to CAMS is the use of the Suicide Status Form (SSF), a multipurpose clinical assessment, treatment planning, tracking, and outcome tool.[7] The SSF serves as a clinical roadmap to guide collaboration as counselor and client sit next to each other exploring SR through quantitative/qualitative assessments and suicide-specific treatment planning. All CAMS sessions begin with a consideration of the "SSF Core Assessment." Sessions then focus on the CAMS Stabilization Plan (CSP) and the client's suicidal drivers. All sessions end by updating the CSP and problem-focused care targeting suicidal drivers. CAMS is theoretically agnostic; counselors use their own approach to treating patient-identified suicidal drivers. Eight

open clinical trials of CAMS have shown significant reductions in SR and overall distress,[63] two of these with college students.[27,64] Furthermore, four RCTs have found that CAMS reduced SI compared to control care-as-usual,[65] led to reductions in overall distress while increasing hope and patient satisfaction in comparison to control care,[66] performed similarly to DBT in terms of reductions in NSSI and suicide attempts (SAs),[67] and reduced SI and depression more than TAU[4]—the latter specifically with college students.

CCCs need an efficient and effective stepped-care approach to treating suicidal students, delivering more intensive treatments only to those who need it. CAMS is flexible and easy to train and thus may be an ideal first-line intervention; moreover, a large proportion of CCCs report already using CAMS.[43] While there are other empirically-based suicide-focused approaches,[68,69] they have either not been tested within a CCC and/or require more extensive training than CAMS. The adaptive approach we are proposing fits with the recommendations[70] supporting the Zero Suicide policy initiative:[71] (a) target suicidal ideation and behaviors instead of mental disorders, (b) train counselors to deal directly with SR, and (c) base clinical care on SR stratification and evidence-based suicide-specific interventions. We hypothesize that starting with CAMS, then ending treatment/entering maintenance if student participants resolve their SR or switching to a more intensive treatment if there is an insufficient early response would be ideal ATSs for suicidal students.

2) Dialectical Behavior Therapy [8,29] adapted for the college counseling center environment (**CC-DBT**). DBT is an empirically validated treatment for complex clinical presentations, including borderline personality disorder (BPD), SI, and NSSI. Comprehensive DBT (which includes individual therapy, skills group, between-session skills coaching, and peer consultation for counselors) produces gains for suicidal BPD patients across a variety of domains, including SI, BPD, SAs, NSSI, hospitalizations, and social functioning.[15,72] DBT is based on a skills deficit model that suggests that BPD is a disorder of emotion dysregulation stemming from important deficits in interpersonal, emotion regulation, and distress tolerance skills. Suicidal behavior is viewed as maladaptive problem-solving behavior reinforced by either an immediate reduction in emotional arousal and/or by the environment's response.[29] Thus, DBT focuses on teaching skills, particularly emotion regulation, and facilitating the replacement of maladaptive behaviors with skillful behavior.

The team has conducted the only RCT to date using comprehensive DBT for suicidal college students.[10] Compared to an optimized control condition, 7-12 months of DBT led to significantly greater decreases in SI, depression, NSSI events, and BPD criteria, and greater improvements in social adjustment. DBT was particularly effective for suicidal students who were lower functioning at pretreatment. However, some students dropped out before the end of treatment due to improvement, suggesting that a less intensive and shorter approach might be adequate for a few students (see Preliminary Studies). Although there has only been one RCT with DBT at CCCs, open trials have also been conducted with DBT at CCCs,[11,73] and more than a dozen studies have investigated the use of DBT skills groups in CCCs.[9] A recent survey concluded that approximately one third of CCCs already use DBT,[9] and a significant body of

research indicates that DBT is effective for the types of problems treated at CCCs.[74] Our study will evaluate an adaptation of comprehensive DBT for college counseling centers (CC-DBT) as a second stage treatment for students who are insufficient responders to CAMS or TAU.

The Proposed Methodology Is Innovative for Suicidal Risk (SR) Interventions

As treatments for other mental health problems move to a remote format, there is also a critical need to develop best practices and treatments about how to clinically manage students online who are at risk for suicide.

Adaptive Sequences of Care for Suicidal Students Have a High Potential for Subsequent Dissemination

Both CAMS and DBT have been shown to reduce SR in college students[10,75] and are already being implemented in CCCs.[9,43] What remains to be seen is whether a sequence of care can be identified with clearly articulated decision points for optimal outcomes.[25] The adaptive strategy proposed squarely fits within the brief therapy model on which most CCCs operate. Based on our feasibility pilot, we estimate that half of the student participants will resolve their SR in Stage 1 (within 4-6 sessions) comporting with the 6-session average in CCCs.[21] Although providing an additional 1-8 sessions in Stage 2 for insufficient responders might appear to tax CCCs' resources, longer-term care for a segment of the students (20+ sessions) is already happening,[44] students presenting with threat-to-self are already using a third more services,[44] and removing suicidal students from campus incurs litigation risk[76] as well as eliminates a potentially potent protective factor.[26] Our adapted form of DBT (CC-DBT) is designed to disseminate within CCCs. This study will be informative about the most effective sequences of care for suicidal students and may inform which students to refer out to more intensive, longer-term community approaches, such as comprehensive DBT.

Importantly, this study might also identify student characteristics that would help predict who will be responsive to first-line approaches in general, or to specific first- and second-line approaches. Recent research has suggested that first-line suicide-focused approaches, such as CAMS, may be best suited for acute suicidal presentations, with individuals with lower complexity, such as less initial distress,[33] fewer BPD criteria, and fewer than 2 suicide attempts. Other characteristics that might be indicative of greater risk, such as sexual and gender minorities (SGM), can also be explored. Although not many studies have been conducted with SGM and suicidality at CCCs, research has shown that transgender and nonbinary individuals are at higher risk for SI, suicide attempts (SAs), and death than the general population.[18]

The economic cost-benefit ratio of identifying different sequences of care at CCCs to treat different suicidal states or profiles could be significant. It is possible that the implementation of a CAMS+DBT sequence of care may prove cost-effective to CCCs in several different ways. Identifying rapid responders to CAMS, for example, may reduce costs because some of these students may currently be receiving more treatment than needed. The provision of intensive services through DBT may reduce other costs, such as preventing school withdrawals[77] or averting the occurrence of multiple crises at the CCC itself[78] or elsewhere on campus.

To address the generalizability of the current study, we will examine the ATSs across sites that differ in terms of student diversity (ethnic, racial, national origin, sexual and gender identity), type of school (public vs. private), and geographic location (West, Pacific NW, South, and East Coast regions). The multisite trial will employ an effectiveness-implementation Hybrid Type 1 design to examine both clinical effectiveness and implementation outcomes.[37] The hybrid design will also allow the investigation of potential facilitators and barriers to implementing each of the adaptive strategies across the participating CCCs.

This Multisite Study Will Elucidate Mechanisms of Change in Suicide-Focused Approaches

While the identification of transdiagnostic mechanisms of change has become a high priority in suicide research, there is a paucity of research on mechanisms of change within suicide-focused treatments.[79] Bryan[80] has hypothesized that evidence-based treatments for suicidal risk (SR) share three common mechanisms of change: cognitive flexibility, emotion regulation, and cognitive reappraisal. This aligns with the CAMS and DBT literature.[7,81] CAMS purports to create therapeutic change through an intentional collaborative approach to treatment: assessment of SR; suicide-specific treatment planning; deconstruction of, and problem-solving for, patient-defined suicidal "drivers;" and an explicit focus on reasons for living.[7] Thus, CAMS is entirely suicide-focused and known/predicted mediators of change include reductions in suicidal cognitions[82] and suicide-focused attentional bias.[82,83] The putative mechanisms unique to DBT are quite different: hierarchical targeting of problems, mindfulness, dialectical focus, emotion regulation, distress tolerance, counselor self-disclosure, chain analysis, commitment strategies, validation, and telephone consultation.[81] Among these, the research-supported mediators for DBT include skills use,[84] self-efficacy for managing emotions,[188] and emotion regulation/experiential avoidance.[84-86]

The CAMPUS Trial is adequately powered (moderate effect size estimates) to examine known and putative mechanisms of change in CAMS and CC-DBT and whether each works through different or overlapping mechanisms. In addition to known mediators, we will investigate promising exploratory ones identified through RDoC[79] and SR-based[87] reviews.

The Proposed Methodology Is Innovative for Suicidal Risk (SR) Interventions

Although there are a few adaptive strategy studies in the treatment of depression,[88,89] none have examined SR specifically and none have undertaken an evaluation of relative treatment effectiveness via a hybrid online/in-person format that allows for maximal clinical flexibility with respect to the provision of care. Despite the strong relationship between depression and SR,[90] meta-analyses failed to show that depression treatments impact SR specifically.[91] Data suggest that SR should be the focus of care independent of diagnosis.[68,69] This is consistent with NIMH's RDoC framework.[92] There is a clear need for evidence-based guidelines regarding suicide-specific, least-restrictive, and cost-effective clinical care for suicidal individuals.[7,93] Uniform treatment of something as complex and heterogeneous as suicidal thoughts, feelings, and behaviors may not be adequate.[50,7] A recent meta-analysis of 50 years of research shows that our traditional risk factor approach for SR has not yielded desired gains,[94] with authors

suggesting that the field needs to move from a "one size fits all" approach to tailoring clinical work to different suicidal states.

SMART designs provide a rigorous and principled approach to constructing decision rules that guide adaptive interventions, including type, dosage, sequence, and response to treatment.[17] ATSs are recommended when patients vary in response to treatment, the effectiveness of an intervention changes over time due to waxing and waning of symptoms, comorbidity renders treatment more complex, there is a high probability of relapse, and adherence to interventions is difficult to achieve.[17] All of these conditions apply when treating SR at CCCs. Also, ATSs may help bridge the critical gap between research and practice,[17] as ATSs mirror more closely what happens in the real world (e.g., if one treatment does not work, try another).

This study will address critical questions about SR interventions (in CCCs and elsewhere), including, for example: 1) Do we need a suicide-specific approach (CAMS) to address SR or is TAU sufficient as a first stage intervention? 2) Do we need an intensive, suicide-focused approach (CC-DBT) for individuals who do not respond to first-stage interventions? 3) Are the costs incurred by a more comprehensive approach (CC-DBT) worth it relative to the gains? We will also be able to determine differential effects of a particular sequence. We may find, for example, that clients are satisfied with CC-DBT after CAMS, but not after TAU (or vice-versa) or that only CC-DBT reduces SR among insufficient responders to stage 1. Few other designs allow this level of contextual understanding. Thus, this methodological approach (ATSs and a SMART), independent of the context of CCCs, is particularly innovative in terms of its application to SR.

Utilizing CAMS and CC-DBT, Distinct Suicide-Focused Treatments, in a Sequenced Format is Innovative

Examining what theoretically distinct approaches have to offer and then bringing them together in a sequence of care is innovative. CC-DBT might not be needed for all suicidal college students;[10] conversely CAMS, a flexible first-line approach of low intensity and cost, might be all that is needed for many, but not all, suicidal college students.[27] As far as we know, this is the first attempt to bring these two distinct suicide-focused approaches, one that is flexible and theoretically agnostic and one that is multimodal and comprehensive, together in an adaptive, pragmatic, and rigorous scientific manner.

Attempting to Improve the Quality of Mental Health Services in CCCs is Innovative

The NIMH Strategic Plan (Objective 4) acknowledges the need to generate research findings that "will inform the real-world community practice setting." CCCs in the US are becoming a formidable force in mental health treatment delivery.[95] No longer developmentally focused, CCCs now treat a wide gamut of psychological issues. More than 23 million individuals may come into contact with psychotherapy for the first time in a CCC, given that the 18-25 age range targeted in this study is often implicated in the onset/maintenance of psychological disorders.[96] Approximately 10% of college students are served by CCCs.[42] Yet CCCs are continually being tasked to "do more with less."[97] As a result, many CCCs are now using procedures commonly found in community mental health agencies, such as waitlists, session limits, and psychiatric

consultation and referral.[95] Thus, the provision of timely and effective treatments in this context would be of high public health value. We are not aware of any controlled study that focuses specifically on improving the quality of service delivery in this context, despite the dire need and the high number of individuals affected. The bulk of the studies pertaining to CCC services, although useful, are often descriptive,[42] do not use randomization,[21] and the solutions (e.g., session limits) are often guided more by "word-of-mouth" than by evidence-based research. Research at CCCs has been deemed "a necessity" given that "understanding the unique qualities of [CCCs'] environment is fundamental to the development of best practices necessary to serve the mental health needs of college students."[98] This hybrid effectiveness-implementation multisite study proposes to blend components of clinical effectiveness and implementation research for more rapid translational gains for the potential dissemination and scalability of empirically-validated treatments at CCCs.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Risk 1. Worsening of symptoms because of the interventions. With any intervention, there is always the risk that the intervention will affect the individual negatively. There is a slight risk that discussing suicidality specifically or feeling dejected by lack of improvement may increase psychological distress, including suicidal thoughts and behaviors, during and possibly following the completion of the intervention. As there is not an extensive literature on the impact of suicide-focused care via teletherapy, it is unknown whether the remote arrangement of teletherapy in the CAMPUS trial will lead to a greater risk of worsening symptoms because of interventions.

Risk 2. Breach of confidentiality. There is a slight risk that participants will have their privacy violated if information about them is not kept confidential or if participants' online data is accessed by unauthorized users. Participants' discussions of imminent suicidality/homicidality, child abuse/neglect, or elder abuse/neglect may result in a breach of confidentiality (including within the campus) due to counselors' duty to report. In addition, as some clinical care and assessments will be provided through online platforms, there is a risk that private clinical communications could be "hacked" by third parties which might compromise confidentiality. Further, if participants are not alone in private spaces during assessments or therapy sessions, other people may hear personal information about the participant.

Risk 3. Emotional distress associated with assessments. There is a slight risk that assessments with questions about sensitive topics like suicidal ideation and behaviors, substance abuse, gender identity, and sexual orientation may result in increased distress and potentially increased suicidality.

Risk 4. Being involuntarily hospitalized. There is a slight risk that participants in this study, given that they are moderately to severely suicidal, may be civilly committed to a psychiatric setting involuntarily.

Risk 5. Feeling coerced to participate in the study. Because participation in the study will start within a clinical setting (the CCCs), there is a slight possibility that participants will feel pressured to be part of the study.

2.3.2 KNOWN POTENTIAL BENEFITS

There are several potential direct (and indirect) benefits of the CAMPUS trial to the participants and to the greater public. In the wake of the COVID-19 pandemic, there is little empirical knowledge about the effectiveness of online training for clinicians and delivery of suicide-focused care via teletherapy. As pandemically-driven public health requirements include physical distancing and the use of masks, and generally reduce interpersonal contact, there are many compelling arguments for carefully studying the effectiveness of online training and delivery of care.

A hybrid teletherapy/in-person model of treatment delivery would also provide CCCs with the flexibility to move treatment online seamlessly in the event of campus shutdowns in the future or even as part of regular campus operations, given that residential students leave their campuses during academic breaks. As noted previously, considering the level of severity of students presenting to counseling and the relative lower percentage of students (versus those not in counseling) who actually die by suicide, it is thought that campus counseling is associated with a six-fold reduction in suicides among college students — something that can not only save lives and much heartache to parents/family, but also avoid enormous repercussions to the whole campus (e.g., campus being shut down in some instances, classes cancelled, residence hall floors being shut down, friends being distraught and unable to attend classes, copy-cat acts). There are some data from TAU, CAMS, and DBT research to suggest that these treatments are likely to be helpful to a significant number of the participants in this project. Study participation will include careful assessments of suicidal risk at least three times during the study—a level of monitoring far beyond that which CCC clients usually receive, helping raise student participants' awareness of their own suicidal risk. Regardless of treatment assignment, participants may derive a sense of accomplishment from participation in research and contributing to the knowledge of treatment for other students struggling with suicidal ideation. Given the demands and constraints of the pandemic, it is vital for the field to know whether a hybrid teletherapy/in-person format to provide care to suicidal college students can be done safely and effectively.

There are benefits to counselor participants as well, who will receive training in how to help students presenting with suicidal risk. Treating this population can be very distressing to counselors and receiving specialized training and ongoing case consultation was reported as a great benefit of participation by counselors in the pilot and feasibility study. Similarly, the CCCs may benefit from having guidelines on how to treat suicidal students participating in these studies via a hybrid teletherapy/in-person format. As noted in other sections of the proposal, counselors and CCCs are currently treating very distressed—and distressing—suicidal students

without much guidance. Participating in these studies gives them more knowledge and more guidance on how to proceed.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Minimizing Risk 1.

Several strategies are being proposed to help minimize the risk of worsening of symptoms, or to increase the potential to avert emergent crises or quickly detect an adverse event if one should occur:

- Recruitment and consent procedures are expected to help minimize this potential impact. For example, from the outset of each study, prospective participants will be informed by the intake counselor (or member of the research team) about the study and the likely possibility that the treatment will focus on suicidal risk, so they will be less likely to be surprised later by the content of the treatment. This aspect will be reinforced again during the informed consent process.
- Counselor participants will be self-selected based on their experience and interest in working with suicidality in a hybrid teletherapy/in-person format. Not all counselors are skilled and comfortable dealing with suicidal risk, so having counselors who are willing to work with this population and who are not afraid of discussing suicidal thoughts and behaviors, or dealing with potential crisis situations, will greatly increase the quality of care and the likelihood of counselors responding appropriately to imminent suicidal ideation (should it occur), including discerning the waxing and waning typical of suicidality from actual worsening of symptoms.
- Counselor participants will be extensively trained to conduct CAMS and CC-DBT via online/in-person training and consultation. Online and in-person training will be conducted by experts in CAMS and CC-DBT and ongoing expert consultation will address any concerns regarding worsening or lack of improvement in symptoms in a particular participant. Additionally, each CCC has a weekly staff or case management meeting to discuss any cases giving rise to safety concerns—thus this will be available for discussion of TAU treatments.
- All treatments provided as part of the study will allow for the possibility of increasing the frequency of sessions should a particular client need more support for a period of time. It is quite common in clinical care to add an extra session when the client is struggling. [*Note:* All CCC contacts with a student client are documented in the student's CCC treatment file. Therefore, dosage of treatment will be monitored.]
- Several procedures at the participating CCCs, although called by different names, are geared toward addressing crises and detecting adverse events early in the process (although study participants will receive unique treatments and complete research assessments, they will also be treated as regular clinic clients—one of the "effectiveness-based elements" of this study): 1) Students in crisis, regardless of who the counselor is, can contact the CCC at any time during business hours and receive crisis management as needed. 2) All clients are given the number to a 24-hour Crisis Call hotline and the Crisis Text Line. 3) The CCCs are part of University-wide teams that seek, with students' permission, to help students who are involved with multiple departments

campus-wide (e.g., financial aid, judicial affairs, counseling, campus police, disability resource services) and this allows counselors to more effectively help manage certain crisis situations (e.g., students often become suicidal because of loss of financial aid and access to information through the financial aid officer on the team may help prevent a suicidal crisis).

- Because of the remote nature of teletherapy care, student's current location as well as emergency contact numbers for third party involvement (e.g., parents or roommates approved by the client) will be obtained for each client should there be a worsening of symptoms.
- There will also be an understanding of secondary, even tertiary, backup methods for reconnecting with clients should there be technological issues or an unstable internet connection.
- As is routinely done in conventional clinical trials, student participants who worsen significantly may be removed from the study if this is deemed to be in the clinical interests of the student participant (e.g., a student participant may need to withdraw from school to pursue a higher level of care). This is often done in collaborative discussions between student participant and counselor.
- Project Coordinators (PCs), PIs, Co-Is, and consultants will be available for consultation with the participating counselors on a regular basis. Additionally, the PIs or Co-Is in charge of clinical supervision will be available as needed for consultation regarding safety concerns, regardless of current condition assignment, to all participating counselors.
- The NIMH Data Safety and Monitoring Board (DSMB) will monitor all adverse events on a regular basis.

Minimizing Risk 2.

Breach of confidentiality, including unauthorized access to digital data. Several precautions will be taken to protect the confidentiality and privacy of participants from being violated, including unauthorized access to digital data. Risk will be minimized as follows:

- All online clinical care across the four research sites will be provided via videoconferencing on platforms that are fully HIPAA compliant, such as HIPAA-compliant Zoom.
- At the beginning of each session, counselors will make sure that the client is in a secure location where other family members or friends may not be able to listen in on teletherapy sessions. Clients may need to use headphones as part of the effort to minimize what others might hear of any teletherapy session.
- Confidentiality and the limits to confidentiality will be discussed with participants and stated in the informed consent.
- A concern of college student participants might be the release of information about mental health to their academic departments or their families. We will assure participants in the informed consent that we will be unable to disclose this type of information to anyone outside the CCC, unless the student participant has signed a release of information or one of the limits of confidentiality applies. However, we will

explain that even if one of the limits applies (e.g., imminent suicidality), we will make every attempt to discuss this with the client first and only those who absolutely need to know will be informed (e.g., their parents or a roommate if they live in an off-campus apartment). As part of the assessment process, we will collect emergency contact information (parent or other trusted family member/emergency contact adult's name and phone number) and we will also discuss conditions under which a parent or guardian, or this emergency contact person, may be notified for assistance in case of an emergency. Such conditions may include situations such as: the student participant is imminently suicidal and/or is perceived as a danger to themselves or others but does not agree to a safety plan or has missed/cancelled appointments and their commitment to safety cannot be confirmed. Counselors will review these crisis management strategies with student participants during their first therapy session. This aspect is particularly important given the remote nature of teletherapy.

- *Unique ID:* Participants will be assigned a unique study ID and a GUID (Global Unique Identifier) to be used in the completion of all online questionnaires. The individual's name and identifying personal information will not be maintained in computer files that can be accessed via the same system. The GUID is a universal subject ID allowing researchers to share data specific to a study participant without exposing personally identifiable information (PII) and match participants across studies.
- *Security of computers and networking hardware:* The Duke University Medical Center (DUMC) servers hosting the REDCap data repositories are connected to the Duke internal network and protected by the Duke Health Enterprise firewall; access to the repositories is permitted only through properly authenticated web application programming interfaces. REDCap data are encrypted both at rest and in transit. The DUMC database-hosting infrastructure has been audited by the Duke Information Security Office for compliance with HIPAA and Duke Health data security policies. Procedures are in place for rapid recovery from hardware or database failure. All telehealth delivery will be conducted on fully HIPAA-compliant teleconferencing platforms.
- *User authentication/roles:* User access to the REDCap web portal relies on a centrally managed list of users within the Duke Data Center (DDC), their authentication credentials, and their roles and access privileges. The REDCap platform used in the current study will leverage the Duke Health Enterprise authentication system. The DDC will manage user access groups and will provide granular control over specific access permissions, depending on study role (e.g., PC, RA), to specific aspects of the portal, such as eCRFs or study management functions. Password complexity and expiration rules are managed by the Duke ISO to ensure compliance. Usernames will be set for periodic review to make sure that changes to staff roles are audited jointly with the PIs.
- *Security of transmitted data:* All self-report measures will be collected using a secure online survey program relying on SSL (Secure Sockets Layer) encryption such as REDCap or Qualtrics. This technology guarantees the privacy of all data transferred between the participant and data center and assures visitors that the site they are accessing is authentic. To initiate this secure connection, the IEs will register each participant into

the REDCap system, entering their unique study ID, and then ask him/her to complete the self-report measures. For subsequent assessments conducted remotely, the IE will email a unique link to the participant for completing the self-report measures.

- The only individuals who will have access to any information linking participant names to participant codes will be the Principal Investigators (PIs), Project Coordinators (PCs), Independent Evaluators (IEs), Research Assistants (RAs) and, if needed, an overseeing ethical body (IRB or DSMB). Others will only have access to first names (e.g., the PIs while doing case consultations) or the GUID. Moreover, all data published in reports or articles will be described in aggregate form.

Minimizing Risk 3.
Emotional distress associated with assessments. Although studies show that asking about suicidal ideation does not increase the risk of suicidal behavior,[152,30] it is possible that assessments may increase emotional distress. Therefore, the following precautions will be taken:

- The assessments across timepoints will be conducted by well-trained IEs with experience treating suicidal individuals. Assessments of suicidal risk will primarily occur in interview formats (e.g., SSI, SITBI), so the IE conducting the assessments can respond appropriately if the participant becomes emotionally dysregulated. The interview-based assessments will also use validation strategies to ensure that participants feel supported.
- Standard policies (e.g., obtaining current address and an emergency contact) will be developed to manage suicide risk when evaluated remotely.
- Assessments will be limited to those domains essential to conducting the evaluation of treatment response and acceptability.
- The total time spent completing interviews/questionnaires for the CAMPUS Trial for student participants will be 2-3 minutes a week and between 60-180 minutes at baseline and between 45-120 minutes at the middle of Stage 1, the end of Stage 1, the middle of Stage 2, the end of Stage 2, and 3-month follow-up, depending on the assessment timepoint and the student participants' responses to the interview questions (an affirmative answer to a question on suicidality/self-injury/ suicide attempt(s) results in follow-up questions).
- Finally, and importantly, to ascertain the safety of participants during/after scheduled assessments, the IEs will rely on the commonly utilized University of Washington Risk Assessment Protocol (UWRAP).[110] This protocol will guide the IEs through a series of questions and strategies to help ensure that participants are safe prior to ending the assessment session.

Minimizing Risk 4.
Being involuntarily hospitalized. The following precautions will be taken to avoid involuntary hospitalizations:

- When student participants indicate that they are imminently suicidal and are not able/willing to take steps to guarantee they will not hurt themselves, the potential scenarios for voluntary vs. involuntary hospitalization will be discussed in detail.
- Every option for voluntary hospitalization will be explored. In the case of an online assessment or therapy session, these options will also be coordinated with the help of a third party. Often, students will agree to go to the hospital on a voluntary basis. Sometimes, suggesting that they call a friend or a family member who will go with them to the emergency room helps them decide to go voluntarily.
- Consultation with a parent/other trusted family member/emergency contact adult will be explored with the student participant as well.

Minimizing Risk 5.
Feeling coerced to participate in the study. Although this is unlikely to occur based on our experience (plenty of students decline research participation!), the following precautions will be taken:

- Intake counselors and/or members of the research team will describe the study to students who seem interested in hearing about it. They may say something like, "We are currently conducting a study here to help students who may be struggling with suicidality. Would you like to hear more about it?" If a student says no directly or indirectly, the intake counselor will end this discussion and move on to other treatment options.
- The intake counselor will clarify that, "There are other options for treatment. The study is just one of them."
- During the consent process, the member of the research team will ensure that there is enough time for questions and discussion before a student signs the consent form.
- The PI or the PC will make themselves available throughout the study to consult with the participant and/or his/her counselor if there are any concerns about the student participant continuing to participate.
- It will be made very clear both by the intake counselor and by the research staff that participation is voluntary and that declining to participate will have absolutely no impact on the student's ability to receive services at the CCC, now or in the future.

3 OBJECTIVES AND ENDPOINTS

Table 2 provides a summary of the objectives, endpoints, and justification for the endpoints for the CAMPUS Trial that will be conducted immediately following the feasibility study. A more detailed description of the measures can be found in Section 8.1.

Table 2. CAMPUS Trial Objectives, Endpoints, and Justification

Objectives	Endpoints	Justification for Endpoints
Primary Aims of the CAMPUS Trial		
Suicide-Related Behaviors **Aim 1**: To compare four pre-specified ATSs in terms of primary and secondary	Scale for Suicidal Ideation (SSI)	The primary outcomes will be reduction in suicidal risk (SR; suicidal ideation primarily but also non-suicidal self-

Table 2. CAMPUS Trial Objectives, Endpoints, and Justification		
Objectives	**Endpoints**	**Justification for Endpoints**
outcomes. **Hypothesis 1**: The ATS that begins with CAMS and then augments with DBT for insufficient responders will be more effective in reducing SR than the other ATSs. **Aim 2**: To determine whether a suicide-focused first-line intervention (e.g., CAMS) produces greater reductions in SR than a non-suicide focused one (e.g., TAU). **Hypothesis 2**: ATSs that begin with CAMS will be more effective in reducing SR than those beginning with TAU. **Aim 3**: To determine whether providing a comprehensive suicide-focused approach (e.g., CC-DBT) among insufficient responders to Stage 1 treatments will be more effective in reducing SR than a less intensive suicide-focused approach (e.g., CAMS). **Hypothesis 3**: Adding CC-DBT at Stage 2 with insufficient responders to Stage 1 will be more effective in reducing SR compared to adding or continuing CAMS at Stage 2.	Self-Injurious Thoughts and Behaviors Interview (SITBI)	injury, suicide attempts, and suicides) at the end of Stage 1, Stage 2, and at 3-month follow-up. Recognizing that measurement of suicide-related behaviors is fraught with challenges,[112] we are defining SR as "suicidal ideation, attitudes, behaviors and plans which take into account severity, intent, and ability to cope with ideation without engaging in suicidal behaviors, such as planning/rehearsal, non-suicidal self-injury (NSSI), suicide attempts (SAs), and suicide." Our primary assessment measures for SR are two interviews to measure suicidal ideation (SI; defined as self-reported thoughts of suicide-related behavior) and suicidal behaviors, including suicide attempts and NSSI. Suicides will also be tallied.
Secondary Aims of the CAMPUS Trial: Functioning		
*Functioning – Relevant to **Aims 1-3** described above and **Aims 4-5** described below.*	Counseling Center Assessment of Psychological Symptoms (CCAPS-62 or CCAPS-34). Clinical Global Impression for Severity (CGI-S) and Improvement (CGI-I).	Secondary outcome measures will be overall distress, depression, social and generalized anxiety, substance abuse, eating concerns, academic functioning, clinical global impressions by participants and assessors of severity and improvement in suicidal risk.
Secondary Aims of the CAMPUS Trial: Mediation		
Aim 4: To evaluate treatment-specific mediators of change. **Hypothesis 4a**: Treatment effects in CAMS, relative to TAU, will be mediated by improvement in suicide-focused processes, including suicidal cognitions, suicide-focused attentional bias, and hopelessness. **Hypothesis 4b**: Treatment effects in DBT, relative to Stage 2 CAMS, will be mediated by increased emotion regulation, self-efficacy for managing emotions, and improved skills.	The Difficulties in Emotion Regulation Scale (DERS) The DBT-Ways of Coping Check List (DBT-WCCL) The Acceptance and Action Questionnaire II (AAQ-II)	The measures listed include those found in previous studies to mediate outcome in CC-DBT and CAMS.

Table 2. CAMPUS Trial Objectives, Endpoints, and Justification		
Objectives	**Endpoints**	**Justification for Endpoints**
	The Suicide Cognitions Scale (SCS) The Optimism Hope Scale (OHS) PROMIS Self-Efficacy for Managing Emotions	
Secondary Aims of the CAMPUS Trial: Moderation		
Aim 5: To evaluate whether (1) number of lifetime suicide attempts (SAs),[31] (2) Borderline Personality Disorder (BPD) features,[32] (3) baseline distress,[33] (4) sexual and gender minority (SGM) self-identification,[18,19] and (5) comorbid substance and alcohol abuse affect, predict or moderate treatment response. **Hypothesis 5a**: Student participants with >2 prior SAs,[31] more BPD features,[32] and SGM (self-identified)[34] will be less responsive to Stage 1 treatments. **Hypothesis 5b**: Student participants with >2 prior SAs, high baseline distress, more BPD features, and SGM (self-identified) [18,19] will be more likely to respond to CC-DBT than to CAMS in Stage 2.	History of previous suicide attempts (SITBI) The Personality Assessment Inventory – Borderline Features Scale (PAI-BOR) The Optimism Hope Scale (OHS) The Global Assessment Scale (GAS) Sexual orientation and gender identity Alcohol Use Disorders Identification Test (AUDIT) and Drug Abuse Screening Test (DAST)	Aim 5 pertains to the identification of predictors and moderators of treatment response, which could be incorporated as secondary tailoring variables in later studies or during dissemination. Potential predictors and moderators were gleaned from the suicidology literature and/or from CC-DBT and CAMS.
Tertiary/Exploratory Aims of the CAMPUS Trial: Implementation and Process		
Aim 6: To evaluate the ATSs in CCC settings, we will assess implementation outcomes outlined by Proctor[35] employing the Quality Implementation Framework (QIF).[36] A mixed-methods process evaluation will be conducted with CCC stakeholders to identify facilitators/barriers to implementation and sustainability.	The Client Satisfaction Questionnaire (CSQ-8) CSQ-8 (Therapist Version) and Reasons for Termination Checklist Treatment Credibility Questionnaire Treatment Expectations Questionnaire The Treatment History Interview (THI)	The implementation monitoring plan will be guided by 1) critical steps of the Quality Implementation Framework (QIF)[36]; 2) process evaluation and implementation monitoring outlined by Saunders[135]; and 3) implementation outcomes specified by Proctor.[35] The process evaluation will include both quantitative and qualitative assessments to monitor the implementation activities and address barriers that may arise during the study. The mixed methods will include feedback from the student participants, counseling staff, and directors.
Aim 7. To explore counselor experiences working with suicidal college students. All analyses for this aim will be exploratory. Counselors will	CSQ-8 (Therapist Version) and Reasons for Termination Checklist	Aspects of counselor participants' experiences to be explored include their beliefs about suicide, self-identified theoretical orientation and training

Table 2. CAMPUS Trial Objectives, Endpoints, and Justification		
Objectives	**Endpoints**	**Justification for Endpoints**
be separated into clinically relevant groups based on cut-points on key demographic variables. Between-group differences on counselor measures will be explored.	Counselor Treatment Expectations Zero Suicide Workforce Survey (abbreviated) Focused Interview Demographic Information Form TAU Questionnaire	experiences, expectations for and satisfaction with providing different types of therapy during the study, and general experiences of participating in the study.
Aim 8: Within each treatment stage, determine whether CAMS produces greater reductions in SR than TAU (Stage 1) and whether CC-DBT produces greater reductions in SR than Continued CAMS (Stage 2).	Scale for Suicidal Ideation (SSI) Self-Injurious Thoughts and Behaviors Interview (SITBI)	The primary outcomes will be reduction in suicidal risk (SR; suicidal ideation primarily but also non-suicidal self-injury, suicide attempts, and suicides) at the end of Stage 1, Stage 2, and at 3-month follow-up. Recognizing that measurement of suicide-related behaviors is fraught with challenges,[112] we are defining SR as "suicidal ideation, attitudes, behaviors and plans which take into account severity, intent, and ability to cope with ideation without engaging in suicidal behaviors, such as planning/rehearsal, non-suicidal self-injury (NSSI), suicide attempts (SAs), and suicide." Our primary assessment measures for SR are two interviews to measure suicidal ideation (SI; defined as self-reported thoughts of suicide-related behavior) and suicidal behaviors, including suicide attempts and NSSI. Suicides will also be tallied.

4 STUDY DESIGN

4.1 THE STUDY TEAMS(S)

Student participants: Students who meet all inclusion and no exclusion criteria and provide consent.

Counselor participants: CCC counselors who meet all inclusion and no exclusion criteria and provide consent.

Intake counselor: CCC counselor who meets all new students seeking mental health services.

Study liaison: Research staff, employed by the CCC, who are responsible for acting as a liaison between the CCC and study. Duties may include exporting study data form the electronic medical record, conducting consent visits, facilitating participant recruitment and treatment, and meeting with potential student participants and counselor participants.

Independent Evaluator (IE): Research staff responsible for conducting all baseline and longitudinal assessments.

Project Coordinator (PC): Site research staff responsible for day-to-day operations of the study.

4.2 OVERALL DESIGN

As shown in Figure 1 (on page 9), the proposed multisite SMART will involve randomization at two stages. At Stage 1, all student participants (N = 480) will be randomized to 4-6 weeks of CAMS or TAU. Beginning at session 4, the counselor will rate the student participant in terms of clinical response. Insufficient responders (e.g., non-responders) to Stage 1 will be re-randomized to one of two Stage 2 treatments for an additional 1-8 weeks: 1) CAMS (either continued or for the first time) or 2) CC-DBT.

Thus, four ATSs are possible:

- ATS-1: Start with CAMS, if responding, enter maintenance treatment; if not, continue with CAMS;
- ATS-2: Start with CAMS, if responding, enter maintenance treatment; if not, switch to CC-DBT;
- ATS-3: Start with TAU, if responding, enter maintenance treatment; if not, switch to CAMS;
- ATS-4: Start with TAU, if responding, enter maintenance treatment; if not, switch to CC-DBT.

Our pilot showed at Stage 1, 48% and 44% treatment response rates across CAMS and TAU, with 27% and 17% attrition rates, respectively—differences not statistically significant. Based on these findings, we assume an equal response rate of 50% across both Stage 1 treatments (CAMS and TAU), leaving N=240 participants eligible for Stage 2 treatments. Treatment responders at the end of Stage 1 will end study treatment and enter maintenance, which includes monthly monitoring and continued assessments with the IEs. All student participants will complete weekly measures as part of treatment. Research assessments by independent evaluators (IEs) will be conducted at baseline, mid-Stage 1 (Week 3), end of Stage 1 (Week 6), mid-Stage 2 (Week 10), end of Stage 2 (Week 14), and at 3-month follow-up (Week 26).

4.3 SCIENTIFIC RATIONALE FOR STUDY DESIGN

SMART designs provide a rigorous and principled approach to constructing decision rules that guide adaptive interventions, including type, dosage, sequence, and response to treatment.[17] ATSs are recommended when patients vary in response to treatment, the effectiveness of an intervention changes over time due to waxing and waning of symptoms, comorbidity renders

treatment more complex, there is a high probability of relapse, and adherence to interventions is difficult to achieve.[17] All of these conditions apply when treating SR at CCCs. Also, ATSs may help bridge the critical gap between research and practice,[17] as ATSs mirror more closely what happens in the real world (e.g., if one treatment does not work, try another). In addition, the lengths of treatment for our stages (4-6 weeks for Stage 1 and up to 8 weeks for Stage 2) were chosen in order to best match practices of CCCs (where average number of sessions is 5-6) and therefore are most likely to be implemented.

4.4 JUSTIFICATION FOR INTERVENTION

First Stage (Stage 1) of SMART Study (N=480): Randomization to TAU or CAMS (4-6 Weeks). After baseline, student participants will be randomly assigned to TAU (n= 240) or CAMS (n=240). Stage 1 treatment will last 4-6 weeks. We chose this treatment length because the average number of sessions at CCCs is 5.22 (with a median of 4 sessions),[21] 6-8 CAMS sessions were enough to resolve SR in college students in an earlier trial,[27] and in our CAMPUS feasibility study, average number of Stage 1 sessions was 6. Student participants who appear to be deteriorating (worsening SI on the Counselor CGI-I scale) or who maintain high levels of SI without improvement may be re-randomized to Stage 2 early after session 4.

Student participants randomly assigned to TAU will receive the customary treatment they would receive at that CCC—on average, weekly individual therapy, but it may also occasionally include group participation and/or medication referral. Counselors conducting TAU treatment will be informed to do counseling as usual for a period of 4-6 weeks, except that counselors will be asked not to utilize CAMS or DBT strategies. The book entitled "*Collaborative Assessment and Management of Suicidality: Managing Suicidal Risk: A Collaborative Approach (2nd edition)*"[7] will serve as the manual for CAMS treatment in Stage 1/Stage 2. CAMS individual sessions will be provided weekly for 50-60 minutes and will follow the Suicide Status Form.

Second Stage (Stage 2) of SMART Study (n≈240): Re-randomization to CC-DBT or CAMS (1-8 Weeks). The treatment length for Stage 2 was chosen based on previous studies with CAMS and DBT, ease of dissemination to CCCs later, and informed by data from the CAMPUS feasibility study. Based on previous CAMS studies,[27] our pilot study and CAMPUS feasibility study, we estimate that n≈240 of student participants will resolve their SR during Stage 1 and that n≈240 will be re-randomized to Stage 2.

DBT Individual Therapy. Participants will receive weekly individual teletherapy/in-person sessions with a CC-DBT-trained counselor for up to 8 weeks total. The DBT manual[29] guidelines such as orienting clients to the treatment model, using a diary card to monitor problematic behaviors, relying on a hierarchy of targets to guide treatment at each session, and conducting chain and solution analyses to determine and address controlling variables of problematic behavior will be followed.[145]

DBT Skills Training. The skills training sessions will follow the DBT Skills Training manual,[8,29,144] but adapted to fit within a standard academic term (6 weeks). The skills training sessions will be provided via teletherapy/in person and will include skills from all four modules of skills acquisition (mindfulness, emotion regulation, interpersonal effectiveness, and distress tolerance), but with the following modifications: greater focus on emotion regulation given past research with college students,[12,146] and fewer skills taught within each module. Depending on participant flow and time of the semester/quarter, skills training may be conducted individually or in group format.

Peer consultation team is an inherent part of DBT. Counselors will participate in weekly DBT consultation team meetings conducted remotely or in person.[29,147] Phone/text skills coaching is viewed as essential for the generalization of DBT skills to the environment.[29] Counselors will coach their own student participants but, adapting to this setting, they will be encouraged to observe their own limits and comply with local CCC policies/legal requirements, as warranted.

Hybrid Intervention Model

For the purposes of these studies, hybrid intervention model means that a student participant's course of treatment may be delivered completely via telehealth, completely in person, or via a combination of in-person and telehealth sessions. Decisions about what type of sessions to hold will be made by the counselor and based on several factors, including university and CCC policy, location/preference of the student participant, and location/preference of the counselor participant. We will be collecting data on the number of sessions conducted via each modality (captured via Titanium, the electronic medical record [EMR] utilized by all sites) as well as the number of participants who receive just teletherapy, just in-person sessions, and a combination. We recognize that allowing the modality of treatment delivery to vary between- and within-subjects may contribute to greater variability. We considered alternative treatment designs (e.g., constraining the treatment delivery to telehealth only) to reduce this variability. However, we decided to allow for flexibility in treatment delivery for several reasons. First, because this variability in delivery mode will occur across all arms, irrespective of treatment type, we do not expect it to bias the outcome analyses. Second, we do not believe constraining modality is reflective of the reality of practice in CCCs going forward (i.e., beyond the immediate response to Covid-19). Thus, we believe constraining the treatment modality in the study design would limit the external validity of the trial results. Third, relatedly, we believe a hybrid model has the greatest dissemination and implementation potential in the future across CCCs, where the expectation is that delivery of treatment will continue to vary within and across settings and will likely be some combination of in person and remote sessions. Thus, the resulting sequencing of care allows for this flexibility by design.

4.5 END-OF-STUDY DEFINITION

The end of the study for the CAMPUS Trial, is defined as completion of the Week 26 follow-up assessment shown in Table 1 Schedule of Activities (beginning on Page 16). Student participants

who terminate early will receive an end of study assessment identical to that required of participants who complete the entire protocol.

5 STUDY POPULATION

There are two study populations for these research projects (a) college students and (b) CCC counselors. The inclusion and exclusion criteria for each are described below.

5.1 INCLUSION CRITERIA

College Students. We will recruit N=480 male, female, and transgender/nonbinary college students across the participating sites for the CAMPUS trial. Inclusion criteria to participate in the study consists of:

(1) Enrolled at the university.
(2) Eligible to receive counseling services either in person or remotely at the campus CCC.
(3) 18 to 25 years of age.
(4) Moderate to severe SI over the last two weeks indicated by one or more of the following:
- A score of ≥2 on the Counseling Center Assessment of Psychological Symptoms (CCAPS) question, "I have thoughts of ending my life."
- Self-report during clinical interview at intake
- Other intake questionnaires given as standard clinical practice at CCCs (e.g., C-SSRS)

(5) Suicidality is a focus of treatment
(6) Agree to video recording of all therapy and assessment sessions.

CCC Counselors

We will recruit approximately N≈24 counselor participants across all participating sites. The number of counselor participants may increase or decrease throughout the project based on turnover, but we expect to maintain approximately 24 participating counselors at a time in each of the enrollment years.

Inclusion criteria to participate in the study consists of:

1. Currently or soon to be employed as a counselor or trainee at the CCC for at least the next year;
2. Willingness to work with suicidal college students;
3. Interested in learning to implement Collaborative Assessment and Management of Suicidality (CAMS) and Dialectical Behavioral Therapy for College Counseling settings (CC-DBT);
4. Willing to attend trainings in CAMS and CC-DBT;
5. Willing to have therapy sessions video-recorded and rated for adherence to the treatment model;
6. Interested in attending weekly consultation meetings to improve the quality and adherence of study treatments; and
7. Willing to complete measures about themselves and their student participants.

5.2 EXCLUSION CRITERIA

Exclusion Criteria for Student Participants and Rationale:

1. Students who are deemed clinically inappropriate to receive services at the CCC by an intake counselor because of imminent risk, severe psychosis, or inability to remain enrolled in school (e.g., academic failure);
2. Students being unable to remain enrolled in their university long enough to go through the minimum number of sessions for Stage 1 (4 sessions);
3. Students who have received services at the CCC within the last three months (i.e., ATSs must be based on a new treatment episode).

Exclusion Criteria for Counselor Participants:
Counselors will be excluded if they don't meet inclusion criteria or do not consent to study participation after recruitment.

5.3 SCREEN FAILURES

Due to the focus of the study, potential participants will have access to the CCC no matter if they are receiving treatment through participation in the study or not. Screen failures, and/or student participants who decide that they would no longer be able to participate in the study, will continue to have access to the CCC for services.

5.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment and Retention Strategies for Student Participants
Across participating sites, we will recruit a total of 480 student participants for the CAMPUS Trial. Recruitment will take place over 2 years.

Gender. In terms of gender, female students are more likely to seek treatment than male students. This is the case based on data collected at each of the participating sites and in terms of national data for treatment-seeking students.[2] Therefore, based on site and national data, we are predicting across sites that 60% of participants will be female, 38% will be male, and 2% will be transgender/non-binary. Two important caveats apply here: 1) Although, in general populations, females are more likely to report suicidal ideation than males, that discrepancy appears to not exist among treatment-seeking college students.[21] Therefore, the estimated gender breakdown will stay the same even among suicidal treatment-seeking college students and this matches our experience in other suicide-focused intervention studies. 2) Currently, approximately 1.6% of treatment-seeking college students nationwide self-identify as transgender or non-binary.[21] The NIH planned inclusion table does not allow these categories to be entered until the demographic data are in hand. So, it's not going to be reflected in the inclusion table, but it is an important demographic category given the known higher suicide rates for this segment of the population.[18] These data will be collected as part of this study, reflected in recruitment reports later, and gender identity (cisgender vs. transgender/non-binary) will be explored as a moderator of treatment response in this study.

Ethnicity/Race. Across all sites, Non-Hispanic White/Caucasian students are the most common category. One site, Rutgers Newark has a higher percentage of African American/Black students (25%). One site, Duke, has a higher percentage of Asian/Asian American students (28%), and two sites (UNR and Rutgers Newark) have a higher percentage of Latinos (18% and 25%, respectively). We have averaged these percentages, and across all sites, we are predicting the following: 12% African American/Black, 1% or less American Indian/Alaska Native, 15% Asian American/Asian, 15% Hispanic/Latino/a, 1% or less Native Hawaiian or Pacific Islander, 10% Multi-racial, and 47% White/Caucasian. For the study, data will be collected on both ethnicity (Latino vs. not) and race to facilitate recruitment reports.

Inclusion of Children. No children will be included in the study. This is justified based on the setting and scientifically. The target sample for this study is college students who are between 18 and 25 years old. We set 18 as an age minimum because a) 18 is suggested as the start of "emerging adulthood";[53] b) most college students are 18 and older, thus rendering our findings more generalizable; c) the proportion of college students under 18 is minimal (<5%); and d) students under 18 would need parental consent in most of the sites to participate which would impact recruitment procedures considerably as the study is currently designed.

Procedures to Monitor Enrollment and Track/Retain Participants. Recruitment and enrollment will be carefully monitored. The site PC will track participant flow through a REDCap database, from referral into the study (or not), date initial consent is scheduled, whether participant consented or not (if not, the reason(s) for refusing to participate will be documented), and dates of planned assessments, which will be shared with the IE locally, as well as the Duke Data Center (DDC). This database will be able to notify users via text or email of upcoming and over-due assessments to help facilitate participant retention.

To expedite referrals into the study for this high-risk population and minimize loss of participants, the intake counselor or study liaison will schedule an appointment with an IE directly within 24-48 hours. Participant tracking logs will be reviewed weekly locally by each site and by the cross-site SC to monitor recruitment and diversity of the sample. Files will be maintained by the DDC, with access granted to relevant individuals across sites.

Strategies to Ensure a Diverse, Representative Sample. As noted above, demographics will be tallied and tracked weekly with an eye towards ensuring that the study sample includes a representative sample of women and minorities (see Inclusion of Women and Minorities for more detail). Only students who are 18-25 years of age will participate (see Inclusion of Children). Inclusion of women (and men) and minorities was not a problem during the pilot and other studies conducted at the other sites. However, recruitment reports comparing the study sample to the population of other treatment-seeking students at that site will be discussed weekly during the cross-site SC call and reviewed every six months by the DSMB. If a significant discrepancy emerges, this will be discussed, investigated further, and corrective measures implemented, as advised.

Table 4. Assessment Reimbursement Amount by Visit for CAMPUS Trial						
	Assessment Point					
Type	Baseline	Mid Stage 1	End of Stage 1	Mid Stage 2	End of Stage 2	3-Month Follow Up
Visit Reimbursement	$40	$20	$40	$20	$50	$50

Participant Incentives. Participants will be reimbursed for completing study assessments at baseline ($40), mid-Stage 1 ($20), Stage 1 post ($40), mid-Stage 2 ($20), Stage 2 post ($50), and 3-month F/U ($50). Unless noted otherwise, the timeframe for assessments will fit the study design: "last month" for all assessment points, also "lifetime" and "last 6 months" at baseline, and "last 3 months" at F/U. The maximum total reimbursement for any student participant who completes all assessments as scheduled is $220 (see Table 4 above).

Recruitment and Retention Strategies for Counselor Participants

This study will recruit approximately 24 counselor participants across the participating sites. Additional counselors will be recruited during the second year of the study to replace counselors who left during the first year, if needed. Recruitment will take place at the beginning of the study, prior to student participant enrollment.

Gender/Race/Ethnicity. Counselor participants will be initially identified by the CCC Director and referred to the site investigators for possible study participation. The racial, ethnic, and gender breakdown of the counselor participants are expected to reflect the diversity of the overall CCC staff.

Procedures to Monitor Enrollment and Track/Retain Participants. We will conduct an annual check-in with all counselor participants to review their experiences with the study and to determine whether they will continue participating as a study counselor for an additional year. To ensure that we maintain an adequate number of counselor participants, we will ask all counselor participants to notify the study team at least four months in advance if they are considering ending their participation. This will allow adequate time to identify and train replacement counselors.

Strategies to Ensure a Diverse, Representative Sample. N/A

Participant Incentives. Counselor participants will receive ongoing consultation and as-needed individual supervision.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S)

6.1.1 PRE-SCREENING

Potential student participants will contact the college counseling center (CCC) to set up an initial appointment to access services (remote or in person dependent on local CCC policies). The student will be scheduled for an initial session with a counselor (for this first contact, the counselor will be referred to as "intake" and "intake counselor," respectively, henceforth).

6.1.2 SCREENING

Assessment of suicide risk (SR) and other safety issues are addressed by the intake counselor during the intake session across all participating sites. When the student meets for the intake session, as part of routine intake procedures, they will complete the Counseling Center Assessment of Psychological Symptoms (CCAPS-62). If the student selects a 2 or above on the question, "I have thoughts of ending my life," (range is 0 "not at all like me" to 4 "extremely like me") or endorses suicidality on other intake questionnaires or via self-report to the counselor the intake counselor will give the student a brief explanation of the study. Intake counselors will complete the Screening Data Form to assess basic inclusion and exclusion criteria. If a student meets all inclusion and no exclusion criteria and is interested in participating in the study, the PC will be notified, and an appointment will be scheduled with the research team for consenting (an e-consent process will be used) and a baseline assessment, which may be remote or in-person. If conducted remotely, the IE will reach out to the student ahead of the appointment with a link to a secure telehealth videoconferencing meeting. For students who decline to participate, the intake counselor will document reasons for declining participation.

6.1.3 BASELINE

The baseline assessment is conducted by the IE, either online or in person. The IE will first review the e-consent in detail with the student and answer any questions. The IE will confirm that the student agrees with: (1) being randomized to one of two treatments; (2) the possibility of proceeding in an "adaptive" manner—ending treatment/going into maintenance or being randomized to one of two treatments for up to 8 additional weeks; (3) possibly participating in a group (if assigned to DBT); (4) completing assessments even if no longer in treatment; (5) providing information to create a unique identifier; and (6) having their therapy sessions video-recorded. After consent is obtained, questionnaire/interview baseline assessments will be conducted by the IE (see Table 1). At the end of this assessment or within 1 business day, student participants will receive confirmation of who their counselor will be and the date of their first teletherapy/in-person appointment (typically within 7 days after the baseline visit, but clinical concerns will take precedence). Students who decline participation prior to giving consent, or who enroll but later choose to withdraw from the study, will have access to the usual care at the CCC (Note: all randomized student participants will be included in the ITT analyses).

6.1.4 RANDOMIZATION

Following the completion of the baseline assessment, the site PC will review the consent, document the randomization block variables (gender, medication, past suicide attempt), obtain randomization assignment from the Data Center at Duke University, and reveal randomization results to an already assigned counselor. Note that student participants will learn of their treatment assignment by the counselor at their first treatment visit (this procedure was used in the pilot project and received very favorably by students and counselors).

6.1.5 STUDY INTERVENTION DESCRIPTION

Study interventions include Treatment as Usual (TAU), the Collaborative Assessment and Management of Suicidality (CAMS), or CC-DBT.

TAU: Treatment as Usual consists of normal College Counseling Center (CCC) therapeutic procedures. TAU will allow counselors to determine level of care and therapeutic modality depending on the needs of the participant.

CAMS: CAMS is an evidence-based, suicide focused approach[61] that was first developed and studied in a CCC specifically for college students.[62] CAMS is a problem-focused treatment that targets client-defined suicidal "drivers" or issues that lead to SI.[7] Central to CAMS is the use of the Suicide Status Form (SSF), a multipurpose clinical assessment, treatment planning, tracking, and outcome tool.[7] The SSF serves as a clinical roadmap to guide collaboration as counselor and client sit next to each other exploring SR through quantitative/qualitative assessments and suicide-specific treatment planning. All CAMS sessions begin with a consideration of the "SSF Core Assessment." Sessions then focus on the CAMS Stabilization Plan (CSP) and the client's suicidal drivers. All sessions end by updating the CSP and problem-focused care targeting suicidal drivers. CAMS is theoretically agnostic; counselors use their own approach to treating client-identified suicidal drivers.

CC-DBT: DBT [8,29] is an empirically validated treatment for complex clinical presentations, including BPD, SI, and NSSI. DBT (which includes individual therapy, skills group, and peer consultation for counselors) produces gains for suicidal BPD clients across a variety of domains, including SI, BPD, SAs, NSSI, hospitalizations, and social functioning.[15,72] DBT is based on a skills deficit model that suggests that BPD is a disorder of emotion dysregulation stemming from important deficits in interpersonal, emotion regulation, and distress tolerance skills. Suicidal behavior is viewed as maladaptive problem-solving behavior reinforced by either an immediate reduction in emotional arousal and/or by the environment's response.[29] Thus, DBT focuses on teaching skills, particularly emotion regulation, and facilitating the replacement of maladaptive behaviors with skillful behavior. We will use an adaptation of DBT, CC-DBT, that is designed to disseminate within CCCs. Participants will receive up to 8 weeks of individual CC-DBT sessions as well as 6 weeks of DBT skills training. Counselor participants will attend weekly consultation team meetings. CC-DBT includes key DBT elements such as orienting clients to the treatment model, using a diary card to monitor problematic behaviors, relying on a hierarchy of targets to guide treatment at each session, and conducting chain and solution analyses to determine and address controlling variables of problematic behavior will be followed.[145]

Stage 1: Student participants will initially be randomized to TAU or CAMS. The duration of Stage 1 treatment will range from 4-6 weeks.

Stage 2: Non-responders to Stage 1 Treatments will be randomized into either CAMS or CC-DBT. The duration of Stage 2 treatment will range from 1-8 weeks.

6.1.6 ADMINISTRATION AND/OR DOSING

Treatment dosage for Stage 1 will consist of prescribed weekly sessions for up to 6 weeks for TAU or CAMS, followed by up to 8 weeks of CAMS or CC-DBT. It is assumed that weekly sessions align with typical CCCs. The counselor (interventionist) will be trained on CAMS and CC-DBT and will be evaluated for fidelity of implementation throughout the study. Length of time (e.g., student participant weeks in treatment) will be determined based on student participant responsiveness to their assigned treatment condition.

Except for the CC-DBT skills group and possibly other CCC therapy groups in the TAU condition, student participants will have no contact with other student participants, as this is an individualized treatment per each student participant.

Management of Student Participants in the Maintenance Phase. Student participants who are classified as responders during either stage 1 or stage 2 will end active study treatment and enter maintenance. Students may continue to receive CCC services during study maintenance. Students will continue to complete regularly scheduled IE assessments and remain in maintenance until the end of their study participation at 26 weeks. During the maintenance phase, the study team will contact students every four weeks. The four-week contact schedule will continue until their final assessment point. It is possible that students may experience a relapse in suicidality during the maintenance phase, which may be reported during the scheduled IE assessments, in response to a 4-week contact, or by the student spontaneously contacting a member of the CAMPUS trial clinical or research team. In these instances, students will be referred to their CCC for standard care. As noted elsewhere in this protocol (see section 6.5), treatments received outside of the study will be documented via the treatment history interview (THI).

Management of College Session Breaks. CAMS and CC-DBT individual sessions will be conducted either in-person or remotely via a HIPAA-compliant telehealth platform. Thus, management of treatment during short breaks will not be difficult. The end of an academic term often serves as a natural and longer-term break in treatment in CCCs. Given the nature of the academic calendar, participants may take a “break” from the study treatment while they are on academic breaks if they are unable or ineligible to receive CCC services (e.g., residing out of state for the summer), and then continue where they left off upon return. This is an essential adaptation to the setting, and it has been considered in terms of recruitment rates and will also

be considered in the analyses (e.g., dosage defined as number of sessions and not time since randomization per stage; number of additional treatment sessions received).

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Initial Suicide-Focused Treatments Training. During the training phase, the counselor participants will be asked to read manuals for CAMS[7] and DBT,[8,29] participate in a 3-hour online orientation to the study, and then 12-hours of CAMS remote training and 25-30-hours of DBT remote or in-person training, spread over multiple days. Each site will also have weekly DBT peer consultation team meetings. Remote consultation from DBT and CAMS experts will occur more frequently (e.g., weekly) when the trial begins and will occur less frequently as consultation teams grow in skill.

Counselor participants joining the study after the first study year will receive the same type and intensity of training (3-hour orientation to the study, 12-hours of remote CAMS training, and 25-30 hours of DBT training) as other counselor participants but the timing and delivery of the trainings will be dictated each year, based on the number of new counselor participants and their availability.

Certification Requirements. Participant counselors' first randomized case will be supervised more closely as a certification case. If a counselor does not receive satisfactory ratings on their certification case, an individualized adherence plan will be created with the therapist and DBT/CAMS experts. Any concerns about ongoing problems with counselors meeting adherence standards will be discussed with the QA committee. Under rare circumstances, counselors who consistently do not meet adherence standards may be asked to not provide a specific treatment or to leave the study.

Treatment Adherence to CAMS and DBT. All treatment sessions will be digitally recorded. During the counselor training phase, counselors will participate in weekly remote group consultation/supervision (CAMS or DBT), which will be supplemented with individual site-level remote supervision as needed. A Standardized Operating Procedure (SOP) will be developed for certifying that counselors are adherent to CAMS and DBT treatment protocols. Following the training phase, two sessions will be randomly selected to be rated for adherence per DBT student, one from the first two sessions and one from the remaining sessions. A random sample of 10% of DBT skills group sessions will be selected for rating. For CAMS sessions in Stage 1, the first session will be rated for adherence and one other session will be randomly selected from the other sessions for adherence rating. For CAMS sessions in Stage 2, the first session after re-randomization into CAMS will be selected for rating and then one other session will be randomly selected. Feedback will be provided to counselor participants (but not in real time) and tallied in terms of percent of time counselor participants met minimal (DBT) or satisfactory (CAMS) adherence.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Randomization

We will rely on an adaptive-biased coin design[109] to attempt to balance conditions at each stage based on gender, previous suicide attempt(s), and current psychotropic medications. At Stage 2, the PC will obtain information on the blocking variables, along with the tailoring variable, from counselors and the electronic medical record (EMR; Titanium for all sites) prior to randomization. The PC at each site will randomize subjects via the centralized database using a customized system tailored for the SMART design housed at the Duke Data Center.

All assessments of the main endpoints will be performed by the independent evaluators (IEs), who will remain blind to treatment status. It is always possible that student participants could tell the IE during their assessments about the type of therapy they have been receiving. To mitigate this risk, all student participants will be reminded about the importance of not telling the IEs which treatment they received. It is also possible that counselor participants could tell the IE which treatment condition a particular student participant is in; counselor participants will be frequently reminded not to do so. To evaluate how well blinding was maintained, the IEs will be asked to indicate what treatment group(s) they thought the student participant belonged to at the end of stage 1 and, if applicable, at the end of stage 2.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Student participant adherence will be tracked through EMR systems at each site including weekly therapeutic sessions.

6.5 CONCOMITANT THERAPY

If it is discovered during or after the study that a participant received a “crossover-treatment” on his/her own or received any other form of therapy, we will document these treatments in the clinical record and on the treatment history form that is completed by the student participant and the IE and develop procedures to minimize this threat as much as possible for use in the large-scale trial.

While clinical and research staff are expected to strongly discourage treatment outside the study, these student participants will continue to be treated within their assigned treatment arm. Stated differently, student participants receiving non-protocol treatments on their own accord are not automatically considered premature terminators. On the other hand, student participant-initiated crossover treatments should prompt consideration of a review of the student participant’s clinical status. An example of this would be the case of a student participant-initiated psychiatric hospitalization for worsening depression, which would automatically lead to premature termination.

Handling of Medications. Student participants will neither be asked to discontinue medications or to start medications as part of the study. Following regular CCC practice, student participants may be referred for a psychiatric consultation if needed. We will stratify on current use of psychotropic medication at both randomization points to equate medication use across

conditions. We will also assess for any mid-treatment use of medications via data collected on the treatment history interview. Approximately a quarter of students presenting to a CCC are already on a psychiatric medication.[42] This approach to medication reaches a good balance of allowing for medications while not including an active protocol on psychotropic management and it seems appropriate, given the limited evidence of pharmacotherapy-only treatment for SR.[148]

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Involvement in this study will be completely voluntary, and participants may withdraw from the study at any time. Withdrawal from the study will not prohibit student participants from continuing to receive counseling services from their college counseling center or counselor participants from continuing with their normal job duties at the CCC. If the potential student participant shows a lack of interest during intake and consent procedures, the intake counselor will drop the subject. Consent is an ongoing process, so as the study progresses, counselors will be instructed to contact the PC or the PI if the student participant expresses any concerns about continued participation and the PC or PI will be available to meet with the student participant and/or his/her counselor to discuss any concerns regarding continued student participation throughout the study.

Missing four consecutive “scheduled” treatment sessions without any contact with the research team or study counselor will constitute treatment dropout. (Note: attempts will be made to continue collecting outcome data on all student participants who are considered treatment dropouts.) Student participants who are contacted and inform the study team that they no longer wish to provide assessment data will be considered to have withdrawn consent and therefore meet the definition of a study dropout. For more detailed operational definitions, see section 7.2 below.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Death of participant.
- Participant withdraws from the school.
- Acute, chronic, or long-term physical or psychiatric illness in the participant leading to inpatient hospitalization during the study.
- Any clinical AE, onset of new medical condition or other situation that occurs such that continued participation in the study would not be in the best interest of the participant.

As with many other long-term studies, we will experience multiple scenarios of participant attrition. To develop procedures to appropriately manage these scenarios consistently across the sites, the various types of attrition have been defined below.

A. **Study Dropout** (aka Withdrawal of Consent). Study dropout refers to a student participant who withdraws from the assessment portion of the study. A student participant who drops out of the assessment component is not eligible to receive study treatment.

B. **Treatment Non-Compliance**. Treatment non-compliance pertains to a student participant who continues to participate in the treatment and assessment components of the study, but often fails to follow the study treatment procedures (e.g., refuses to appropriately engage in therapy or tends to miss treatment sessions, etc.). Such student participants have not withdrawn consent (those that do withdraw consent are classified as Study Dropouts) for either the treatment or assessment components, but simply have failed to fully participate in the assigned treatment arm.

C. **Treatment Dropout**. Treatment dropout pertains to a student participant who has withdrawn consent for the treatment component only. By definition, a treatment dropout is a student participant who is no longer willing to participate at all in his/her assigned treatment but is willing to participate in the assessment component.

D. **Premature Termination**. Premature termination refers to a student participant for whom the clinical team recommends additional treatment above what can be provided in the assigned treatment arm as randomized. The student participant, however, continues to participate in the assessment component and, insofar as possible, in the treatment component of the study.

   Premature termination occurs when the student participant deteriorates or develops an urgent clinical crisis that leads the clinical team to recommend the termination from the assigned study treatment as randomized. Such cases are equivalent to "investigator-initiated protocol violators." Premature termination from the assigned treatment arm simply means that the assigned treatment is no longer adequate to meet the clinical needs of the student participant. It does not necessarily mean that the intervention within the assigned treatment has been discontinued.

The reason for student participant study dropout, treatment dropout, and premature termination will be recorded. Consistent with intention-to-treat principles, student participants who sign informed consent and to whom randomization is revealed but do not receive the study intervention (e.g., choose to study drop before starting treatment) will not be replaced. Likewise, student participants who sign informed consent and are randomized and receive the study intervention but subsequently drop out of the study, or are prematurely terminated from the study, will not be replaced.

7.3 LOST TO FOLLOW-UP

A student participant will be considered lost to follow-up if he or she fails to complete scheduled assessments and study staff are unable to contact the participant after at least 3 attempts.

The following actions will be taken if a student participant fails to complete a scheduled assessment:

- The site IE will attempt to contact the student participant by telephone and email, reschedule the missed visit as soon as feasible, counsel the student participant on the importance of maintaining the assigned visit schedule and ascertain if the student participant wishes to and/or should continue in the study.
- The IE will ask the counselor if the student participant has changed phone number/email, is attending therapy, and/or has been in contact and may ask the counselor to prompt the student participant to contact study staff.
- Before a student participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the student participant (where possible, 3 telephone calls and, if necessary, a certified letter to the student participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the student participant's medical record or study file.
- Should the student participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

We have divided measures into demographics, primary and secondary dependent variables (DVs), mediators, moderators, and implementation/process variables. Measures were selected if they: 1) fit the study aims, 2) have adequate psychometrics, 3) are listed as Common Data Elements in NIH or have been used in previous SR studies, 4) have shown sensitivity to change, 5) have been used with college students, 6) map onto the RDoC categories (Negative Valence Systems, Positive Valence Systems, Cognitive Systems, Social Processes, and Arousal and Regulatory Systems),[79] 7) are directly relevant to the application of CAMS or DBT, and 8) allow for reduced burden to student participants—the latter in response to reviewers' concerns.

Demographic Variables.
With student participants' consent, age, marital status, family income, residence, GPA, race, year in school, major, ethnicity, sexual orientation, cultural identity, and gender identity will be obtained via EMR/the registrar or by completing the Demographic Information Form at baseline.

SMART Primary Tailoring Variable: Sufficient vs. Insufficient Response to Stage 1 Treatments.
Unique to SMARTs are tailoring variables or variables upon which subsequent randomizations are based.[59] For this trial, sufficient treatment response will be the primary tailoring variable and assessed by the Clinical Global Impressions (CGI),[103] adapted to SR. As noted in Preliminary

Studies, the CGI, adapted to SR, showed high inter-rater reliability and construct validity; this fits with other studies demonstrating that non-blinded trained counselors typically can offer CGI ratings commensurate to blinded IEs.[111]

In SMARTs, a tailoring variable is a tool for clinical decision-making, in this case deciding on response to treatment, and therefore it will be based on clinical assessments by providers (and not the IE).[59] Beginning at session 4 and following each subsequent session, the counselor will complete the 7-point Likert-style CGI developed in the CAMPUS feasibility study to rate overall improvement in SR since baseline from (1) "*Very much improved*" to (7) "*Very much worse.*" Sufficient response will be defined as an Improvement score of ≤ 2 ("*Much improved"* or "*Very much improved").*

A student participant in Stage 1 showing significant worsening may be re-randomized to Stage 2 conditions earlier. Similarly, students who begin the study with significant suicidality and show no improvement after 4 sessions may also be considered for early randomization to Stage 2.

Primary DV: Suicide-Related Behaviors – Relevant to Aims 1, 2, and 3.
Recognizing that measurement of suicide-related behaviors is fraught with challenges,[112] we are defining SR as "suicidal ideation, attitudes, behaviors and plans which take into account severity, intent, and ability to cope with ideation without engaging in suicidal behaviors, such as planning/rehearsal, NSSI, suicide attempts (SAs), and suicide." Our primary assessment measures for SR are two interviews to measure suicidal ideation (SI; defined as self-reported thoughts of suicide-related behavior) and suicidal behaviors, including suicide attempts and non-suicidal self-injury (NSSI). Suicides will also be tallied.

1) The Scale for Suicide Ideation—Current (SSI)[99,113] is a 19-question interview that assesses the student participant's highest SI in the past 2 weeks, including attitudes, behaviors, and plans. Each item is rated as 0,1, or 2 with a total scale of 0-38. The IEs will be trained and certified on the SSI.
2) The Self-Injurious Thoughts and Behaviors Interview (SITBI)[114] is a 3-15-minute interview containing modules that assess SI, suicide plans, suicide gestures, suicide attempts, and NSSI. The SITBI has been used with college students.[115,116] The IEs will be trained and certified on the SITBI.

Secondary DVs/Covariates: Functioning – Relevant to All Aims

1) The CCAPS-34[107] assesses key domains of college student mental health (Depression, Generalized Anxiety, Social Anxiety, Academic Distress, Eating Concerns, Substance Use, and Hostility/Anger) and an overall Distress Index score. Students respond to questions using a 5-point rating scale ("*not at all like me*" to "*extremely like me*"). The CCAPS-34 takes only 2-3 minutes to complete[107] and is widely used in CCCs.[221] The CCAPS will be assessed at all assessment points and at every session. The question on SI will screen prospective participants and the weekly administration can track SI fluctuations more frequently.

2) The CGI-I and CGI-S[103] are secondary DVs when completed by IEs, counselors, and student participants—allowing for differences among reporters to be evaluated. The pilot data provided support for the inter-rater reliability and construct validity of this measure.
3) Academic Functioning will be obtained via self-report by student participants. Academic functioning will include cumulative grade point average, enrollment status, and number of credits attempted vs. completed.

Mechanisms of Change/Mediators of Treatment – Relevant to Aim 4

1) The measures listed below include those found in prior studies (some by our team) to mediate outcome in DBT (#1-3) and CAMS (#4-5). The Difficulties in Emotion Regulation Scale (DERS)[117] includes 36 items rated on a 6-point scale to assess awareness and understanding of emotional experience, acceptance of emotions, ability to modulate emotional arousal, and effective action in the presence of intense emotions. See Preliminary Studies section.
2) The DBT-Ways of Coping Check List (DBT-WCCL)[104] is a 59-item self-report questionnaire measuring the use of DBT skills and dysfunctional, non-DBT coping strategies over the previous month. All items are rated from 0 to 3 (**"***never use***"** to **"***always use***").** The DBT-WCCL includes two subscales, one assessing coping via DBT skills and one assessing coping via dysfunctional means. See Preliminary Studies section.
3) The Acceptance and Action Questionnaire II (AAQ-II)[118] is a 7-item self-report measure of experiential avoidance rated on a 7-point scale ("*never true*" to "*always true*"). See Preliminary Studies.
4) The Suicide Cognitions Scale (SCS)[119] is an 18-item self-report measure based on the residual risk model with Unlovability, Unbearability, and Unsolvability subscales. It predicted SI after controlling for depression severity and hopelessness[120] and uniquely discriminated SR between control and CAMS care.[106]
5) The Optimism and Hope Scale (OHS)[102] is a 14-item self-report measure used to assess a combination of dispositional optimism and trait hopefulness.
6) PROMIS Self-Efficacy for Managing Emotions-Short Form 4a is a 4-item self-report measure which asks participants to rate, at that moment using a 1 (I am not at all confident) to 5 (I am very confident) scale, the following four items: (1) I can bounce back from disappointment, (2) I can avoid feeling discouraged, (3) I can find ways to manage stress, (4) I can handle negative feelings.

Moderators of Treatment—Relevant to Aim 5

Aim 5 pertains to the identification of predictors and moderators of treatment response, which could be incorporated as secondary tailoring variables in later studies or during dissemination. Potential predictors and moderators were gleaned from the suicidology literature and/or from DBT and CAMS specifically:

1) History of previous suicide attempts has been predictive of SR and moderated treatment response.[31]
2) Personality Assessment Inventory – Borderline Features Scale (PAI-BOR)[123] is commonly used to assess BPD features in college students.[124,125] The scale consists of 24 items, rated

on a 4-point scale, with a 0-72 range (38 is the cutoff for significant BPD features). BPD features has served as a proxy for chronicity.[32]

3) Optimism and Hope Scale (OHS)[102] See above. The OHS has been able to predict subsequent death by suicide.[126]
4) Global Assessment Scale (GAS)[127] is a measure of an individual's social, psychological, and work- related functioning ranging from 1 to 100 (higher is better) and will be completed by the IE.
5) Sexual orientation, gender identity, and cultural identity will be assessed as sexual and gender minorities (SGM)/LGBTQ+ individuals are at an increased risk for suicide, suicide attempts, NSSI, and SI.[18,19] Importantly, there are still large research gaps within this population (see[128]). Given the growing number of college students who identify as non-binary or transgender or with another culture, our large multisite study will add to the literature regarding this population.[129]
6) Alcohol Use Disorders Identification Test (AUDIT)[185] is a 10-item self-report measure of the severity of problematic alcohol use.
7) Drug Abuse Screening Test (DAST)[186] is a 10-item self-report measure of the severity of problematic substance use.

Implementation and Process Measures – Relevant to Aim 6

The implementation monitoring plan will be guided by 1) critical steps of the Quality Implementation Framework (QIF)[36]; 2) process evaluation and implementation monitoring outlined by Saunders[135]; and 3) implementation outcomes specified by Proctor.[35] The process evaluation will include both quantitative and qualitative assessments to monitor the implementation activities and address barriers that may arise during the study. The mixed methods will include feedback from the student participants, counseling staff, and directors.

1) Client Satisfaction Questionnaire (CSQ-8)[136] is an 8-item questionnaire that assesses clients' satisfaction with treatment and has been used in other CAMS studies.[66] See Preliminary Studies.
2) CSQ-8 (Therapist Version) and Reasons for Termination Checklist. Counselor participants' acceptability of and satisfaction with the interventions will be assessed at the end of Stage 1 and Stage 2 via the therapist version of the CSQ and Reasons for Termination Checklist. These measures were used in other CAMS[66] studies and our pilot.
3) Treatment Credibility Questionnaire. After session 1 of each stage, student participants will rate the therapy they are receiving on seven items adapted from Borkovec and Nau[137] that ask how logical, scientific, or potentially helpful the treatment appears to be.
4) Therapist Expectations. Two Likert-style questions regarding expectations about treatment utilized in prior studies[66] will be completed by counselor participants at the end of the first session in Stage 1 and Stage 2.
5) Treatment History Interview (THI)[138] is an interview to gather information about a client's psychiatric and medical treatment over a period of time, including psychotherapy, comprehensive treatment programs, case management, self-help groups, inpatient units, emergency treatment (e.g., emergency room visits, police wellness checks), medical treatment, as well as the use of psychotropic and other medications. The THI will be

collected at baseline, end of Stage 2, and follow-up. Data will be utilized descriptively and for cost analyses.

6) Telehealth Usability Questionnaire (TUQ)[187] is a 15-item questionnaire that assesses student participants' acceptability with using telehealth platforms for therapy.
7) TUQ-C (Counselor Version) is an adapted version of the TUQ questionnaire that assesses counselor participants' acceptability with using telehealth platforms for therapy. Counselors who provide DBT skills training via telehealth will also complete an adapted TUQ for DBT skills training.
8) Focused Interview. Counselor participants will each complete a focused interview at the end of their participation in the study. An independent party will conduct the focused interviews, which will center on each participant's experience of the study.
9) Counselor Session Telehealth Questionnaire (CSTQ). The CSTQ will be used to assess counselor perceptions of the technical adequacy of the virtual modality used during telehealth with their clients as part of the CAMPUS study. The CSTQ will also be used to evaluate counselor perceptions of comfort conducting therapy and risk assessment for heightened risk clients over a virtual format. The CSTQ is a 5-item measure and will be completed after every telehealth session.

Counselor Measures – Relevant to Aim 7

Aim 7 will explore aspects of counselor participants' experiences, including their beliefs about suicide, self-identified theoretical orientation and training experiences, expectations for and satisfaction with providing different types of therapy during the study, and general experiences of participating in the study.

1) CSQ-8 (Therapist Version) and Reasons for Termination Checklist. See above.
2) Therapist Expectations. See above.
3) Focused Interview. See above.
4) Zero Suicide Workforce Survey (Abbreviated). The Zero Suicide Workforce Survey (Abbreviated) assesses counselor participants' beliefs about suicide, techniques that counselor participants implement with suicidal clients, and confidence in their ability to treat suicidal clients.
5) Demographic Information Form. The Demographic Information Form will assess counselor participants' self-reported gender, race, ethnicity, sexual orientation, education level, years of clinical experience, years of experience working with suicidal clients, theoretical orientation, and experience with suicide, CAMS, and DBT.
6) TAU Questionnaire. The TAU Questionnaire will assess the interventions that counselor participants implemented during TAU. Counselor participants will complete this measure at the end of Stage 1 for each student participant they treat who was randomized to TAU.

8.2 SAFETY ASSESSMENTS

To monitor the safety of student participants, AEs and SAEs will be monitored at each treatment and assessment visit. For treatment visits, study counselors will document any new AEs/SAEs spontaneously reported during therapy sessions. Unsolicited events that meet the definition for AEs or SAEs (see sections 8.3.1 and 8.3.2) will prompt further inquiry by the

research team to ascertain onset, severity, relatedness to treatment, outcome, and measures taken to address AE or SAE, if any.

During each assessment visits, AEs and SAEs will also be assessed and monitored through general inquiry by the IEs. During remote assessments, IEs will first inquire as to where the participant is physically located. IEs will also implement the University of Washington Risk Assessment Protocol (UWRAP)[110] at each assessment to monitor suicide risk more closely.

The following specific steps will be taken:

1) The first step in managing risk during and following assessments with suicidal and other highly distressed or volatile student participants is to assess the participant's mood before the assessment starts. To this end, the IE administers the UWRAP pre-assessment questions at the beginning of each assessment session which assesses the student participant's level of stress and urges to suicide, self-harm, or use substances at the beginning of the assessment. The IE uses this information in structuring and pacing the assessment to the subject participant's tolerance.
2) At the first assessment meeting (and reviewed thereafter as needed), the IE begins the UWRAP Mood Improvement Protocol. Two items are used to determine strategies the student participant can use to manage any distress caused by the assessments.
3) At the end of each assessment session, the IE administers the UWRAP Debriefing Form, which asks about the student participant's mood, stress, and urges at that point. Thus, the IE can tell how the student participant's mood has changed during the session.
4) An Imminent Suicide Risk and Serious Self-Injury Form must be completed if the student participant rates suicidality higher than 4 on a 7-point scale or states that he/she is uncertain about being able to control suicidal impulses.
5) If suicide risk is moderate to high, the IE implements the necessary Suicide/Distress Intervention Protocol for Assessors. In these instances, IEs must also call the site PI (or his/her designee) to review the suicide risk assessment and intervention.
6) The Debriefing Form lists the strategies for responding to suicidal risk and those used should be checked off and described, if necessary.
7) At the end of the assessments, IEs offer and engage student participants in mood improvement activities according to the Mood Improvement Protocol. If there is not high risk, the IE then closes the assessment, works with the student participant to improve his/her mood, and sends the student participant home (if in person) or ends the videocall (if remote). The IE then makes a mood improvement rating for the student participant.
8) At the end of each assessment, IEs provide student participants with crisis resources and emergency phone numbers.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

An Adverse Event (AE) is any untoward medical occurrence in a study subject that does not necessarily have a causal relationship with this treatment.

An AE therefore can be any unfavorable and unintended sign (including laboratory finding), symptom or disease temporally associated with participation in an investigational study, whether or not considered intervention-related. In addition to new events, any increase in the severity or frequency of a pre-existing condition that occurs after the subject signs a consent form for participation is considered an AE. This includes any side effect, injury, toxicity, or sensitivity reaction.

Any condition, laboratory abnormality, or physical finding with an onset date prior to the subject signing consent for study participation is considered pre-existing in nature and part of the subject's medical history and will not be recorded as an AE.

In this study, we will classify the following as Adverse Events (AEs):

- Breach of confidentiality.
- Evidence of coercion to participate.
- Evidence of distress during assessments (as indicated by a score of >5 on item 2 of the UWRAP Debriefing Form *and* an increase of at least one point on this same item when compared to the UWRAP Pre-Assessment).
- Significant increase in suicidal ideation (as measured by a CGI-I score of 6 or 7, which is completed weekly by counselors following session 4 and at each assessment point by the IEs).

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

A Serious Adverse Event (SAE) is any adverse event occurring during the study or within 30 days of termination of the subject from the study that results in one or more of the following outcomes:

- Suicide death
- Non-suicide death
- Suicide attempt (not death) with non-zero intent to die
- Inpatient Hospitalization (specify below)
    - Suicidal ideation
    - Non-suicidal self-injury (NSSI)
    - Other mental health event (e.g., depression, homicidal ideation, anxiety)
    - Other non-mental health event (excludes scheduled hospitalizations for non-acute, unrelated cause such as an elective surgery)
- Emergency Department (ED) visit, not resulting in inpatient hospitalization (specify below)
    - Suicidal ideation
    - Non-suicidal self-injury (NSSI)
    - Other mental health event (e.g., depression, homicidal ideation, anxiety)

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere in participant's daily activities or functioning.
- **Moderate** – Events result in a low level of inconvenience and may result in some interference in participant's daily activities or functioning.
- **Severe** – Events interrupt a participant's usual daily activity or functioning and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by the student participant's treating counselor and/or IE based on the temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.
- **Possibly Related** – There is some evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.
- **Not related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).

8.3.3.3 EXPECTEDNESS

The study team will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

- Expected Adverse Event – an adverse event that may be reasonably anticipated to occur because of the study procedure(s) or the natural progression of the subject's underlying disease, disorder, or condition.

- Unexpected Adverse Event – an adverse event that is not anticipated to occur because of the study procedure(s) or one that is not part of the natural progression of the subject's underlying disease, disorder, or condition.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a participant presenting for care, or upon review by a study monitor.

As indicated in 8.4.1, AEs will be captured on the appropriate case report form (CRF). Information to be collected includes date and time the study team became aware of the event, event description, time of onset, study team's assessment of severity, relationship to study procedures, expectedness, time of resolution/stabilization of the event. AEs, as indicated in 8.4.1, occurring while on study will be documented appropriately regardless of relationship and will be followed until resolved or 7 days post-last intervention for all AEs or 30 days post-last intervention for all SAEs.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

The study team will record events with start dates occurring any time after informed consent is obtained until 7 days (for AEs) or 30 days (for SAEs) post-last treatment visit. At each treatment visit, study counselors will document unsolicited AE/SAEs since the last therapy session discussed during that therapy session. At each study assessment visit, IEs will inquire about and document the occurrence of AE/SAEs since the last assessment. Events will be followed for outcome information until resolution or stabilization.

8.3.5 EVENT REPORTING

Adverse events and serious adverse events that will be tracked for this study are described in 8.4.1. Considering the nature of the study, we expect most of these events will be considered unrelated to the study procedures, including serious adverse events, like suicide attempts. If AEs/SAEs occur, the following procedure will be activated:

The research staff member who observes or is notified of an adverse event (e.g., significant distress during the baseline assessment) will notify the Principal Investigator (or his/her designee) on the same business day. The PI (or his/her designee) will complete an Adverse Event Form for each event and will determine if the event is an SAE. If the AE is determined to be an SAE, the Serious Adverse Event Form will be completed.

All reports will be made in writing to the NIMH DSMB representative, NIMH Program Official (PO), and sIRB. These reports should indicate that the monitoring entities (i.e., the PI and IRB, and/or DSMB) and appropriate regulatory entities (e.g., OHRP, FDA) have been notified in accordance with the approved monitoring plan and federal regulations. Reports will be submitted to the monitoring entity (e.g., NIH-DSMB) at least annually or on a schedule determined by the monitoring entity's policy. Monitoring entities may require more frequent reporting.

To local IRB and Sponsor
Any AE is reportable to the sIRB and local IRB within 5 business days *when it meets the following definition*:

> Any harm experienced by a subject or other individual that, in the opinion of the investigator, is *unexpected* AND *at least probably related* to the research. (Note: A harm is *at least probably related* to the research if in the opinion of the investigator the research procedures more likely than not caused the harm.)

All AE/SAEs with an onset date after the subject signs consent for study participation will also be reported to the IRB at the time of annual renewal. Details of the event will include severity, relationship to study intervention, duration, action taken, and outcome. All AE/SAEs that are considered related to the study intervention will be followed to resolution, or stabilization if improvement is not expected. AE/SAEs that completely resolve and then recur will be recorded as a new AE/SAE. AE/SAEs that are considered related to the study intervention and continue at 30 days post-last intervention will have a comment in the source documents by the site PI that the event has stabilized or is not expected to improve.

To NIMH DSMB
All AEs and SAEs will be reported to the NIMH DSMB in data reports prepared three times annually. Details of the event will include the AE, severity, expectedness, relationship to study intervention, duration (start/stop date), action taken, and outcome.

In addition, SAEs will be reported to the NIH DSMB within 72 business hours of the site PI's awareness of the event.

All AE/SAEs that are considered **related** to study intervention must be followed to resolution or stabilization if improvement is not expected. AE/SAEs that completely resolve and then recur should be recorded as a new AE/SAE. AE/SAEs that are considered related to study intervention and continuing at 30 days post-last intervention should have a comment in the source documents by the PI that the event has stabilized or is not expected to improve. Other supporting documentation of the event may be requested by the DSMB/NIMH and should be provided as soon as possible.

DSMB/Regulatory reporting criteria for the PI are presented in Table 6.

Table 6. DSMB/Regulatory Reporting Criteria for Study PIs		
	Related to Intervention	**NOT Related** to Intervention
Expected Event	DSMB Tri-Annually	DSMB Tri-Annually
Unexpected Event	DSMB Immediately	DSMB Tri-Annually
Death	DSMB Immediately	DSMB Immediately
Note: DSMB Immediately = The AE/SAE should be reported as soon as possible to the NIMH DSMB, within **3 business days**. The SAE will also be included in the SAE section of the next DSMB Report.		

Table 7 defines the reporting requirements for a variety of study related events.

Table 7. Study Reporting Requirements.		
Reportable Event	When is Event Reported to the NIMH	Reported By
IRB or DSMB Suspensions or Terminations	Any suspension or termination of approval must include a statement of the reason(s) for the action and must be reported promptly to the NIMH PO within **3 business days of receipt.**	Regulatory or Monitoring Entity and Investigator
Deaths related to study participation	Deaths must be reported immediately (no later than within **3 business days)** of the principal investigator first learning of the death.	Investigator
Expected and Unexpected Serious Adverse Events related to study participation	Reported to the NIMH PO within **3 business days** of the study team becoming aware of the SAE.	Investigator
Unanticipated Problems Involving Risks to Participants or Others	Reported to the NIMH PO and NIMH-DSMB representative within **3 business days** of the investigator learning of the event.	Investigator
Serious or Continuing Noncompliance	Reported to the NIMH PO and NIMH-DSMB representative within **3 business days** of IRB determination.	Institution
Adverse Event	For all AEs that are deemed expected and/or unrelated to the study, a summary should be submitted to the NIMH PO with the **annual progress report**.	Investigator
Protocol Violations	With the **annual progress report**.	Investigator

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to

participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB), the NIMH DSMB, and to the Duke Data Center (DDC)/lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB, the NIMH DSMB, and to the DDC/study sponsor/funding agency within **3 business days** of the investigator becoming aware of the event
- Any other UP will be reported to the IRB, the NIMH DSMB, and to the DDC/study sponsor/funding agency within 5 business days of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 10 working days of the IRB's receipt of the report of the problem from the investigator

9 STATISTICAL CONSIDERATIONS

9.1 CAMPUS TRIAL STATISTICAL HYPOTHESES

The statistical hypotheses and endpoints have been previously summarized in Section 3 above.

9.2 CAMPUS TRIAL SAMPLE SIZE DETERMINATION

Power for Aim 1:
Sample size for the study is based primarily on Aim 1, although we also provide effect size (ES) estimates for the other aims given the proposed sample size. With respect to Aim 1, with a total sample of 480, the approach provided by Crivello and colleagues[178,179,180] guarantees that the adaptive intervention with the lowest estimated mean suicide risk (ideation + behaviors) at post-treatment is, in fact, the best adaptive intervention with 90% probability. This calculation assumes that the best two ATSs differ by d = 0.25 (or ≥2 points on the SSI), which corresponds to a small ES estimate.[181]

Power for Aim 2:
Aim 2 is a two-sample comparison (cells A+B+C vs. D+E+F). Using a two-side, two-sample t-test based on Type-I error rate of 2.5%, a sample of 240 randomized to each Stage 1 treatment arm (N=480 total), we will have 85% power to detect a small, standardized ES of d = 0.30 in the between groups difference in change on the primary outcomes. Based on prior studies and our pilot data with SD=7 for SSI,[113] this ES corresponds to a clinically meaningful difference of 2 in the SSI. Note that this is a conservative estimate of power: in the repeated measures LMM, power increases in proportion to the within person correlation in baseline to 26-week SSI which can be as high as 0.40 ($p<.01$, based on pilot data). At 3-month follow-up (assuming a baseline to 48-week within correlation of 0.3) we will have 94% power to detect the same moderate ES.

Power for Aim 3:
Assuming about 50% response (N=240) and about 50% insufficient response rate [N=240, which is chosen to be slightly higher for a value divisible by the four possible treatment paths from Stage 1 to Stage 2 (CAMS-CAMS, CAMS-DBT, TAU-CAMS, and TAU-DBT) (based on pilot data)] to Stage 1 treatments corresponding to N=60 potential student participants to be randomized to each of the 4 Stage 2 arms among the non-responders as illustrated in the Schema Figure in section 1.2. We anticipate an at most Stage 1 attrition rate of about 25% among those with an insufficient response leaving N=180 total student participants to be randomized in Stage 2 (approximately 45 student participants per ATS). Estimates of attrition are chosen as equal across each treatment path but are in essence worst case scenarios, where we may see less attrition for specific treatment paths compared to others; therefore, all power estimates are conservative, with more power achievable with more available student participants for different treatment combinations. Based on the method outlined by Oetting and colleagues[182] and a within-person correlation of 0.60, 2.5% Type-I error, we will have over 80% power to detect a difference of ≥3.4 (d = 0.34) in change in SSI between DBT vs. CAMS.

Power for Aims 4 and 5:
Best practices for power calculations for mediation and moderation models within SMART designs are still debated. For mediation, we will use the work of Fritz and MacKinnon,[183] who document sample size requirements to guarantee 80% power under the sequential regression framework[166] and the formulas of Vittinghoff et al.[184] Under the assumption of a medium effect for intervention on the mediator and a medium effect for intervention on outcome covarying

the mediator, and an alpha=0.025, the total sample size is calculated as N=166. Therefore, our design consisting of a sample size of 480 within Stage 1 and at least 90 subjects per two Stage 2 arms (CAMS vs CC-DBT) (N=180 total), is sufficiently powered to detect mediation within Stage 2. For moderation, we use Cohen's[181] power tables, our sample size of 480 at the start of Stage 1 and at least 90 subjects per arm at Stage 2 is more than sufficient to detect a medium-to-large ES for a moderator.

Table 8. The 4 Adaptive treatment strategies embedded in the proposed SMART

Adaptive Treatment Strategy	Stage 1 Treatment	Status at End of Stage 1	Stage 2 Treatment	Cells Involved in Comparisons	
1	CAMS	Responder	Maintenance/ Monitoring	A	A + B
		Insufficient Responder	Continue CAMS	B	
2	CAMS	Responder	Maintenance/ Monitoring	A	A + C
		Insufficient Responder	Switch to CC-DBT	C	
3	TAU	Responder	Maintenance/ Monitoring	D	D + E
		Insufficient Responder	Switch to CAMS	E	
4	TAU	Responder	Maintenance/ Monitoring	D	D + F
		Insufficient Responder	Switch to CC-DBT	F	

9.3 CAMPUS TRIAL STATISTICAL ANALYSES

9.3.1 GENERAL APPROACH

Overview and Intent-to-Treat. The proposed trial design of adaptive treatment strategies (ATSs) is like a factorial design;[156,157,158,159] different analytic subgroups (see Table 8) are combined to answer different questions. Aim 1 is the trial's primary aim; Aims 2-5 are secondary aims and Aim 6 as an implementation aim. All student participants, once randomized, will be included in the intent-to-treat sample, and every effort will be made to collect all primary and secondary outcomes even if a student participant does not engage in randomly assigned treatments. The primary outcome of interest is suicidal risk, which includes suicidal ideation as well as suicide-related behaviors, such as non-suicidal self-injury (NSSI) and suicide attempts (SAs); however suicidal ideation is the primary DV due to relatively low rates of suicidal behaviors post-baseline with college students. Suicides will be tallied as well. All analyses allow for the inclusion of covariates listed as demographics and covariates in Section 8.1. Covariates will enter the model based in clinical importance (gender, age, current alcohol use, current substance use, etc.) and retained on a case-by-case basis based on statistical significance.

9.3.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Aim 1 analyses (Primary Aim) will compare and contrast the 4 pre-specified ATSs embedded in the SMART design to determine whether one is clearly better or worse than the others with respect to mean suicidal ideation (SI) and suicide-related behaviors (NSSI and suicide attempts), which are the primary outcomes, at the end of 14 weeks of treatment. The data analysis method of Robins and colleagues[160,161] will be used to contrast the 4 ATSs based on reducing

suicide-related risk behaviors (SI, NSSI, and suicide attempts) to determine whether any of the interventions appear to be clearly better or worse than others. As part of the design, a student participant will contribute differentially to one or more of the 4 strategies (depending on the treatments to which he or she is randomized and whether he or she is a treatment responder), requiring a weighted comparison. Specifically, this analysis involves a weighted comparison of the cells A+B vs. A+C vs. D+E vs. D+F (see Table 8); the method by Robins and colleagues[160,161] weights each student participant using the known randomization probabilities. Linear contrasts among the components of the ATSs will be performed to further understand impact on efficacy. Similar analyses will compare the 4 strategies on the follow-up and secondary outcomes outlined above. Additionally, in response to reviewers' input, a composite outcome including suicidal ideation, suicide attempts, and NSSI will be derived. Death by suicide will be tallied but not included in the composite score. Song and colleagues[162] provide a thorough discussion of the best ways to create composite scores, especially when dealing with a mixture of continuous and count outcomes. The analysis team will determine the best approach in the formation/derivation of the composite using the steps discussed by Song et al[162]. Similar analyses will compare the 4 strategies on the derived composite as outlined above.

Aim 2 analyses will contrast ATSs beginning with CAMS vs. interventions beginning with TAU (i.e., to evaluate the main effect of initial treatment) on change (decrease) in suicide-related risk behaviors (SI, NSSI, and suicide attempts—the primary outcomes) from baseline to the end of Stage 2 (the primary contrast). This is a comparison of cells A+B+C vs. D+E+F (see Figure 2 and Table 8). Note that the primary continuous longitudinal outcome is assessed at baseline, mid-Stage 1 (3 weeks), post Stage 1 (6 weeks), mid-Stage 2 (10 weeks), post-Stage 2 (14 weeks) (end of acute treatment) and then again at 3-month follow-up (26 weeks), for a total of 6 measurement occasions. Linear mixed models[163] (LMM, also known as random effects or growth curve models), fit with SAS PROC MIXED will be used to analyze the longitudinal data. LMMs use all available measurements, allowing student participants to have an unequal number of observations and producing unbiased parameter estimates as long as unobserved values are missing at random. The analysis will fit a LMM with fixed effects for the intercept, time, group, and a group-by-time interaction term, where group is an indicator of phase-one treatment (CAMS vs. TAU as referent). The LMM will also include random effects for the intercept and time and an unstructured within-person correlation structure for the residual errors and will adjust for the following measures collected at baseline (pre-randomization): site, age, race, and clinical severity. Model diagnostics will be used to determine suitability of more parsimonious (e.g., autoregressive) correlation structures, and nonlinear (e.g., quadratic) effects for time. We do not expect the intervention effects to be attenuated due to counselor participants who are cross classified between the interventions. Nonetheless, we will assess the potential attenuation by assessing the counselor x intervention interaction. If significant, we will examine if the attenuation effect is limited to a select few counselors and eliminate as needed to remove potential counselor contamination of intervention effects. Counselor will be treated as a random effect which models potential correlation between student participants within a common counselor. If there is not sufficient variance, indicated by the reliability estimate of the random effect falling below 0.02 (a slighter lower threshold compared to

Raudenbush and Bryk[164] (p.125), we will treat counselor as a fixed effect. The primary contrast is between groups' difference in change from baseline to month 6 (end of acute treatment through Stage 1 and Stage 2 active treatment). The follow-up contrast at week 26 (12 weeks post-acute treatment) will also be examined in this and in all subsequent analyses. LMMs like the above for the primary outcome will be run for the secondary longitudinal outcomes: CAMS vs. TAU on CCAPS subscales (Depression, Anxiety, Academic Distress, Overall Distress), CGI-I and CGI-S (measured by IE), and cumulative GPA.

AIM 3 analyses will examine the relative effectiveness of switching to a more comprehensive suicide-focused treatment approach (e.g., CC-DBT) among those who do not respond sufficiently to Stage 1 treatments vs. a less intensive suicide-focused approach (e.g., CAMS). This analysis is a comparison of cells C+F (switch to CC-DBT) vs. B+E (switch or continue with CAMS) in Table 8. Both primary and secondary longitudinal outcomes outlined above will be examined using an LMM like that described above, but (a) including only the subset of responders to Phase 1 treatment, (b) defining group as switching to CC-DBT (cells C+F) vs. continuing or switching to CAMS (cells B+E), and (c) using monthly longitudinal outcomes from week 4 to week 24 (7 measurement occasions).

9.3.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

AIMS 1-3 analyses are the same as the preceding subsection 9.4.2.

AIM 4 analyses focus on treatment-specific mediation in both CAMS and CC-DBT. The potential mediators (for CC-DBT: DERS, DBT-WCCL, and AAQ; for CAMS: SCS, OHS; Self-Efficacy,) are assessed at baseline, midpoints, and endpoints. To maintain the temporal sequence order of the mediator per Kraemer and colleagues,[165] mediation occurs when, after partialling out the change in the mediator (baseline through midpoints), the relationship between intervention condition and the change in outcome from midpoint(s) through endpoint, when controlling for early change in the outcome (baseline to midpoint), is significantly reduced (in full mediation the relationship is zero). Standard mediation analyses[166] assume sequential ignorability. We will implement causal mediation approaches,[167,168] as described by MacKinnon and colleagues,[169] which provide an adjustment due to potential unmeasured confounding and the violation of the assumption of sequential ignorability. The analysis team has experience implementing these models.[170,171] VanderWeele's research team[172] recently described the above mediation technique specifically suited for LMM framed under a generalized mixed effects structure, which we will incorporate. We will fit separate causal mediation models for Stage 1 and Stage 2. Exploratory analyses will focus on multiple mediation and moderated mediation within the causal mediation framework.

AIM 5 analyses focus on moderation within Stage 1 and Stage 2 (gender identity, sexual orientation, minority culture, number of prior suicide attempts, AUDIT, DAST, PAI-BOR, OHS, GAS). A moderator is a baseline characteristic that has a differential effect on outcome across intervention condition[165] and, in the context of a SMART, could be used to further individualize treatment to a particular student participant. Note that a predictor is a non-specific

moderator—namely, it does not vary by treatment condition. Assessment of moderation will be made by augmenting our outcome analyses described above to include the interaction of the effect of intervention with the potential moderator. Predictor analyses will be conducted in the absence of moderation by removing the interaction term. Additionally, analyses will focus on developing a personalized advantage index (PAI). The PAI was discussed by DeRubeis et al.[173] as a set of algorithms that can be used to select the optimal treatment for a given patient. Kessler et al.[174] used machine learning methods to develop his selection algorithm. We will do the same with the SAS software procedure PROC QLEARN,[175] which uses the Q-Learning technique described in Nahum-Shani et al.[159]

9.3.4 BASELINE DESCRIPTIVE STATISTICS

We will compare Stage 1 treatment conditions on baseline measures to evaluate group equivalency using inferential statistics.

9.3.5 PLANNED INTERIM ANALYSES

N/A

9.3.6 SUB-GROUP ANALYSES

We plan to conduct sub-group analyses for the moderation analyses in Aim 5 described previously in Section 3.

9.3.7 EXPLORATORY ANALYSES

Aim 6 analyses focus on the implementation of ATSs within CCC settings. Descriptive statistics with confidence intervals will be derived for the implementation outcomes within Stage 1 and Stage 2 separately. For student participant level measures nested within counselor, we will implement HLM to account for the clustering attributable to student participants within counselor. A benchmarking procedure will be used to compare various treatment combinations.[176] Stakeholder interviews and the quarterly CCIAB meetings will be audio-recorded for subsequent transcription. Thematic content analysis techniques will be used to analyze the transcript text. Data management and data reduction will be accomplished using the ATLAS-ti text-analysis software. To examine the efficiency of alternative intervention strategies, we will estimate the service costs for each of the four ATSs. Our cost analyses consider both the payer perspective, focusing on service costs, as well as the patient perspective, focusing on cost-effectiveness, which considers health outcomes in addition to service costs. Psychological service utilization will be measured primarily through EMRs from the CCCs and through health care visits at the student health centers. To capture services outside of the universities, the Treatment History Interview (THI) will be administered at follow-up. Service utilization will be converted to monetary costs using average reimbursement rates for the corresponding category of services in the national Medical Expenditure Panel Survey (MEPS). We will also query each site about any local reimbursement rates, to examine comparability with the MEPS data and to gain a sense of potential variability across regions. In addition to service costs, implementation costs such as participation in trainings and

supervision corresponding to the intervention will be tracked using logs of personnel time (and multiplied by corresponding wage and facility overhead rates). To make cost-effectiveness comparisons, incremental cost-effective ratios (ICERs) will be calculated as the incremental cost divided by the incremental clinical benefits (e.g., remission rate of suicide risk) for each pairwise comparison of intervention strategies. Uncertainty surrounding these estimates will be calculated as cost-effectiveness acceptability curves and confidence intervals, using bootstrapping with Monte Carlo simulations. In addition, we will conduct an exploratory analysis of the "hidden costs" to college campuses associated with not providing adequate treatment for students experiencing suicidal ideation and behaviors (e.g., crises on campus, NSSI in residence halls).

Aim 7 analyses focus on the experience of counselors in the study. Given the relatively small sample size, the fact that the same counselors will be administering all treatments, and no *a priori* hypotheses, we regard these analyses as exploratory. Counselors will be divided into clinically relevant groups based on cut-points on key demographic variables (e.g., age, gender, years of overall experience, years of *experience* treating suicidal students, etc.). Analyses of variance will be used to examine differences in continuous outcomes; logistic regression analyses and contingency table analyses will be used to analyze differences in dichotomous outcomes. we will also use effect size benchmarks and descriptive statistics to gauge potentially meaningful effects (e.g., eta-square > .06; odd ratios > 2.0).

Aim 8 analyses focus on statistical contrast of the two randomized arms within Stage 1 and the two randomized arms within Stage 2. For Stage 1 comparisons, linear mixed models[163] (LMM, also known as random effects or growth curve models), fit with SAS PROC MIXED will be used to analyze the longitudinal data. LMMs use all available measurements, allowing student participants to have an unequal number of observations and producing unbiased parameter estimates if unobserved values are missing at random. The analysis will fit a LMM with fixed effects for the intercept, time, group, and a group-by-time interaction term, where group is an indicator of stage-one treatment (CAMS vs. TAU as referent). The LMM will also include random effects for the intercept and time and an unstructured within-person correlation structure for the residual errors and will adjust for the following measures collected at baseline (pre-randomization): site, age, race, and clinical severity. Model diagnostics will be used to determine suitability of more parsimonious (e.g., autoregressive) correlation structures, and nonlinear (e.g., quadratic) effects for time. Complexity of the model may be constrained by the available repeated measures. Counselor will be treated as a random effect which models potential correlation between student participants within a common counselor. If there is not sufficient variance, indicated by the reliability estimate of the random effect falling below 0.02 (a slighter lower threshold compared to Raudenbush and Bryk[164] (p.125), we will treat counselor as a fixed effect. The primary contrast is between groups' difference in change from baseline to end of Stage 1. Comparison of these findings will be to the results from the linear contrasts of the components of the ATS as described in Aim 1.

Stage 2 analyses within Aim 8 focus on statistical contrast of the two randomized arms within Stage 2. Patients are the non-responders from Stage 1. Linear mixed models[163] (LMM, also known as random effects or growth curve models), fit with SAS PROC MIXED will be used to analyze the longitudinal data. LMMs use all available measurements, allowing student participants to have an unequal number of observations and producing unbiased parameter estimates if unobserved values are missing at random. The analysis will fit a LMM with fixed effects for the intercept, time, group, and a group-by-time interaction term, where group is an indicator of stage-one treatment (CC-DBT vs. CAMS as referent). The LMM will also include random effects for the intercept and time and an unstructured within-person correlation structure for the residual errors and will adjust for the following measures collected at baseline (pre-randomization): site, age, race, and clinical severity. Model diagnostics will be used to determine suitability of more parsimonious (e.g., autoregressive) correlation structures, and nonlinear (e.g., quadratic) effects for time. Complexity of the model and variance/covariance structures may be constrained by the available repeated measures. Counselor will be treated as a random effect which models potential correlation between student participants within a common counselor. If there is not sufficient variance, indicated by the reliability estimate of the random effect falling below 0.02 (a slighter lower threshold compared to Raudenbush and Bryk[164] (p.125), we will treat counselor as a fixed effect. The primary contrast is between groups' difference in change from Stage 2 randomization to end of Stage 2. Comparison of these findings will be to the results from the linear contrasts of the components of the ATS as described in Aim 1.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

Prior to starting any study procedures all participants (both student participants and counselor participants) will complete their respective informed consent document and be provided with the opportunity to ask any questions or concerns they might have about the project.

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consents describing in detail the study intervention, study procedures, and risks will be given to the participant and documentation of informed consent will be completed prior to starting the study intervention. Given the remote nature of the study, all consents, even those completed in person, will be read and signed using an eConsent process. eConsent is available via REDCap (managed and stored on Duke Secure Servers). This functionality provides the ability to consent remote participants or participants in clinic via laptop, tablet or other touchscreen device. Participants will have the capability to sign electronically with a stylus, mouse, or finger. Once the consent form is submitted, participants will receive an email that includes a PDF attachment with a copy of the signed consent form. Written versions of the e-consents for both student participants and counselor participants are submitted with this protocol.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Each site IRB and the sIRB will have approved the consent forms and protocol prior to study initiation. Students presenting for treatment at one of the CCCs who meet inclusion criteria will be informed about the study by the clinic intake counselor (including features such as randomization(s) to treatment, variable length and approach to treatment, hybrid delivery of treatments, potential participation in a group, and study elements such as completion of assessments). Intake counselors, who will have just met the prospective student participant for the first time, either via teletherapy or in-person, will be trained on how to present the study in a way that is clinically sensitive, gives enough crucial information to the student to be able to indicate an interest or not, and allows students to decline easily. Intake counselors routinely follow up on suicidality to ascertain level of risk and this will allow them to gauge if this is an area the student would need/want to address in treatment. Intake counselors will be trained to only approach students who seem open to the idea of participating in a study; if the student seems quite distressed and unable to focus, this discussion may be delayed until a future time; or if the student shows lack of interest, the intake counselor will drop the subject. If the student shows interest in participating after learning about the study in some detail, he/she will be scheduled with a member of the local research team.

Research staff will then meet, either online or in-person, depending on campus operations and research staff/participant preferences, with the student to go over the consent form in detail, prompt for and answer any questions, and obtain consent. The consent form will be detailed and will include information such as procedures and randomization(s), the collection of GUID, potential type/length of intervention, potential risks and benefits, limits to confidentiality, video-recording of sessions and assessments, compensation for assessments, and the ability to withdraw from the study without penalty. Both the intake counselor and the research staff will inform prospective student participants that declining to participate in the study will not affect their usual care at the CCC in any way. Students who decline participation at this stage (or who enroll but later choose to withdraw from the study) will have access to the usual care at the CCC. Consent is an ongoing process, so as the study progresses, counselors will be instructed to contact the Project Coordinator (PC) or the PI if the student participant expresses any concerns about continued participation and the PC or PI will be available to meet with the student participant and/or his/her counselor to discuss any concerns regarding continued student participation throughout the study

Counselor participants will also be consented for participation in the study by research staff who do not oversee the counselor participants' work at the CCC. They will be given the opportunity to read the consent, ask questions, and talk with counselors who participated in the pilot and/or feasibility studies. The consent form will be detailed and will include information such as overall study goals and procedures, randomization processes, the collection of GUID, type/length of interventions, potential risks and benefits, limits to confidentiality, video-recording of sessions, and the ability to withdraw from the study without penalty.

For both groups, potential participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A pdf copy of the signed informed consent document will be sent via email to all participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participants undergo any study procedures. The rights and welfare of the potential participants will be protected by emphasizing to them that the quality of their medical care/employment will not be adversely affected if they decline to participate in this study.

Note: The main study consent forms also include opt-in/opt-out sections pertaining to inclusion of data in the NDA database, use of recorded video for training purposes, and willingness to be contacted in the future about additional research uses of their data. Subject responses to these opt-in/opt-out provisions will be tracked and stored within the REDCap database associated with each individual consent. These responses will be consulted and followed, prior to any of these optional data uses occurring.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform study participants, the IRB, and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Participants will be contacted, as applicable, and be informed of changes to the study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

Please see 2.3.2, minimizing risk due to a breach of confidentiality.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

All data collected via completion of questionnaires or participation in clinical interviews will be kept in each participant's research record for at least seven (7) years after the study is completed. At that time, either the research information not already in the participant's medical record will be destroyed or information identifying the participants will be removed from the database. Any research information entered into the participant's medical record will be kept indefinitely.

All research data will be kept in the REDCap database that is managed by the Duke Data Center (DDC) at Duke University Medical Center (DUMC). The servers hosting the REDCap data repositories are connected to the Duke internal network and protected by the Duke Health Enterprise firewall. Access to the repositories is permitted only through properly authenticated web application programming interfaces. REDCap data are encrypted both at rest and in transit. The DUMC database-hosting infrastructure has been audited by the Duke Information Security Office for compliance with HIPAA and Duke Health data security policies.

The digital recordings of session data will also be kept at locally at sites or at DUMC with QA reviewers being granted view-only access to conduct ratings for adherence to the treatment model. Digital recordings will also be preserved for seven years, as this is mandated by some of the sites. Once these ratings have been completed and at least seven years have passed, the video data will be immediately erased. Those student and counselor participants who provide consent allowing the use of edited segments of digital recordings for educational/training purposes will be kept indefinitely.

With the participant's approval, de-identified data from this study will also be submitted to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH) and stored indefinitely. Digital-based data will not be submitted to the NDA at NIH. During the conduct of the study, an individual participant can choose to withdraw consent to have his or her data stored at NIH.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Organizational and administrative structure of the multisite study team

To ensure scientific integration of research procedures, overall managerial and administrative responsibilities will rest with the Steering Committee (SC), which will be comprised of the PIs and Co-Is from each site, the Principal Statistician, the NIMH PO, and NIMH DSMB Liaison. As relevant, additional team members, including PCs, will participate in SC meetings. The SC will be responsible for all decisions concerning the overall research program, including plans for data analysis and publications. The SC will hold weekly video conference calls to monitor the overall course of the study including recruitment, retention, and any out-of-protocol deviations. In case of disagreements, each site will have one vote and the statistician will break a tie. Various subcommittees (e.g., Quality Assurance, Treatment, Assessment) will be formed across investigators and consultants and these subcommittees will present potential challenges/solutions to the SC.

To facilitate the efficiency of the SC, an Executive Committee (EC) will be constructed which will hold weekly calls to manage and facilitate study operations and set the agenda for the SC conference calls. The EC will be comprised of the Coordinating Center PI (Dr. Compton), one other site PI (which will rotate among the remaining PIs annually), and a Co-I at the Duke site (currently Dr. Blalock). The EC will be responsible for suggesting that various subcommittees (See Table 9 below) convene to address relevant issues, as needed. These subcommittees will problem-solve issues and present potential solutions to the SC for approval (these actions will be documented via minutes).

There will also be two boards: (1) a Scientific Advisory Board (SAB) composed of a suicidologist with expertise in multisite trials, a psychiatrist, and a college student expert (for names, see Table 9) and (2) a College Counseling Implementation Advisory Board (CCIAB), composed of the site CCC Directors (for names, see Table 7), four counselors across sites (TBD), and other key stakeholders (TBD).

Scott Compton, the PI at Duke University, will serve as the primary liaison with NIMH. The PIs/Co-Is/PCs will attend an annual study meeting and also meet at professional conferences throughout the year.

Table 9. Administrative and Advisory Organization

Site 1 University of Nevada-Reno	Site 2 Duke University	Site 3 University of Oregon	Site 4 Rutgers University
Jacqueline Pistorello, Lead PI, Director of Counseling Services, Research Faculty; Francesca Kassing, Co-I Research Faculty David Jobes, Co-I, Professor, Catholic University; Robert Gallop, Consultant, Professor, West Chester University	Scott Compton, PI, Associate Professor Kyla Blalock, Co-I, Assistant Professor	John Seeley, PI, Professor; Alisia Caban, Co-I, Clinical Director; Daniel Eisenberg, Co-I, Associate Professor, University of California, Los Angeles	Shireen Rizvi, PI, Professor Linda Oshin, Co-I, Assistant Professor

Steering Committee: Scott Compton (Co-chair), John Seeley (Co-chair), Jacqueline Pistorello, Shireen Rizvi, David Jobes, and Robert Gallop, Mary Rooney (NIMH PO), and Lorie Shora (NIMH DSMB Liaison)

Executive Committee: Scott Compton, Kyla Blalock, rotating site PI

Statistical Committee: Robert Gallop, Scott Compton, John Seeley

Assessment Committee: John Seeley, Kyla Blalock, & Scott Compton

Treatment Committee: David Jobes, Shireen Rizvi, Jacqueline Pistorello

CAMS Training Committee: David Jobes, Jacqueline Pistorello

DBT Training Committee: Shireen Rizvi, Jacqueline Pistorello, Kathryn Korslund

Implementation Science Committee: John Seeley, Daniel Eisenberg, Jacqueline Pistorello

Quality Assurance Committee: Scott Compton, John Seeley, Robert Gallop

Scientific Advisory Board (SAB): Dr. King (Chair and multisite/suicidology expert; U of Michigan), Dr. Walkup (Member and psychiatric expert; Northwestern U), Dr. Almirall (statistical and methods expert; U of Michigan), and Dr. Meilman (Member and CCC expert; Georgetown U). Goal: To provide scientific guidance to the SC.

College Counseling Implementation Advisory Board (CCIAB): Directors of the participating CCCs and Dr. Pistorello (Lead PI). Additional members to be named later. Goal: To provide guidance on study procedures and subsequent CCC implementation to the SC.

10.1.6 SAFETY OVERSIGHT

10.1.7 CLINICAL MONITORING

Clinical site monitoring is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is compliant with currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s). The main features are below.

- Monitoring for this study will be performed by NIMH Clinical Trials Operations and Biostatistics Branch (CTOBB) monitors.
  - Monitoring will be conducted on-site, throughout the study, and involve targeted data verification of key data variables
  - The site PI will be provided copies of monitoring reports within 10 days of each visit and will be provided to the NIMH DSMB liaison within 30 days of the visit.
  - Details of clinical site monitoring are documented in the CMP. The CMP describes who will conduct the monitoring, at what frequency monitoring will be done, at what level of detail monitoring will be performed, and the distribution of monitoring reports.
  - The site will perform internal quality management of study conduct, data collection, documentation and completion. An individualized quality management plan will be developed to describe the site's quality management.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

We will closely monitor participant recruitment to the study, retention status, withdrawal, and adverse events. These data will be entered into REDCap at each site. The DDC will then generate reports to be reviewed by relevant entities. The frequency of planned data review for this study differs according to the type of data and can be summarized in the following in Table 10:

Table 10. Frequency of Data Review

Data Type	Frequency of Review	Who Will Review It
Subject recruitment (adherence to protocol regarding demographics, inclusion/exclusion)	Weekly at the beginning of the study and after each recruitment cycle thereafter (semester/ quarter)	At each site, local team for local recruitment; PCs and PIs across all sites; all Boards (DSMB, CCIAB, and SAB)

Adverse event rates	As they occur	At each site, local team for internal events; PIs across all sites; DSMB/Single IRB. In certain instances, NIMH and Local IRBs
Out of range assessment data	Quarterly	PIs across all sites. Sub-Committee on Quality Assurance composed of Dr. Compton (PI at Data Management Site), Dr. Gallop (Statistician), and Dr. Pistorello (PI at Coordinating Site). See Overall Structure of Study Team
Stopping rules report regarding statistical power implications of drop-outs and missing data	Yearly	PIs across all sites. Sub-Committee on Quality Assurance (see above)

Quality Assurance (QA) Measures

QA processes will be overseen by the site PIs, in collaboration with PCs and RAs, and will include creating and training on study-wide Standard Operating Procedures (SOPs), approving and tracking SOP deviations, and ensuring Good Clinical Practice (GCP) and human subjects research training. The Duke Data Center (DDC) will provide the PIs with information regarding timeliness of data submission from the projects, protocol deviations and missing data. This information will help identify areas of deficiency, aspects of GCP that need reinforcement, or additional training that may be required. If these steps do not correct deficits or GCP concerns, steps may be taken to discipline, relocate, or replace staff members or modify study procedures. The DDC will generate the data for NIH data submissions, under the auspices of the Quality Assurance Sub-Committee (see above).

In coordination with the other trial sites, the Duke site in its coordinating capacity, will oversee monitoring of all study sites for quality assurance (QA) purposes. Some components of monitoring may be delegated to on-site managers, but will still be reviewed on the following basis by the central Duke team QA reviewer. For each site, at least every 6 months, 3 subject charts will be selected by the QA reviewer. The QA reviewer will randomly select charts to review across the entire enrollment period (old and newly enrolled), prioritizing those that have not been previously reviewed. Additionally, any site-specific regulatory documentation will be reviewed at the same time. The QA reviewer will also have access to the study REDCap database to allow comparison between original documents and REDCap entry.

<u>Components of QA review will include the following</u>:

1. Regulatory documentation verification
    a. Protocol – all approved versions.
    b. Research summary – all Institutional Review Board (IRB)-approved versions.
    c. Informed consents – all IRB-approved versions.

d. IRB submissions and approvals (initial, amendments, changes to study status, SAEs, correspondence, review/approval notices).
e. Delegation of authority/signature log for all key personnel, maintained by site.
f. Documentation of training required to perform assigned study activities
g. FDA 1571/1572; Curriculum vitae (CV), medical license and financial disclosure forms for personnel listed on 1572.
h. Data collected and stored as described in the Research Data Security Plan (RDSP) (e.g., in REDCap versus in a spreadsheet).
i. Required agreements that have been executed and available (e.g., DTA, MTA).

2. Participant study record
    a. Participant consented per policy.
    b. Screening/treatment/intervention conducted per protocol.
    c. Serious adverse events / adverse events (SAEs/AE) reported per Human Research Participants Protections (HRPP) policy.
    d. Participant compensation documented (if applicable).

<u>Reporting and Corrective Action</u>

1. The reviewer records findings and required corrective actions in the QA Review Report Form in REDCap. The reviewer routes findings to the designated recipient (e.g., PI, lead CRC) via a survey link e-mailed from REDCap. Reviewer findings that can be clarified during the review or that do not require additional corrective action are not included in the form.
2. The PI/Study team resolves deficiencies in a timely manner and provides corrective action plans via the Study Team Response Form linked in the REDCap e-mail. PI/Study team notifies the reviewer when the form has been completed and submitted.
3. HIPAA deficiencies including, but not limited to, lost or misplaced PHI must be promptly reported by the reviewer to the Privacy Officer in the Duke Office of Audit, Risk and Compliance (OARC). There is a 60-day time frame for federal reporting if the missing item is a disclosure that is determined to be a reportable breach under HIPAA/HITECH. A formal breach analysis must be completed by OARC to make this determination. The 60-day clock begins at the time of first discovery of the breach, not at the time of reporting to OARC.
4. If the reviewer has additional concerns after the initial review of participant and study records, the designated reviewer may select additional participants for a follow-up review.
5. Deficiencies that may warrant escalation include but are not limited to:
    a. Expired IRB approvals or delayed submissions
    b. Reportable SAEs that were not reported within the required time frame
    c. Participants enrolled on non-IRB approved protocols
    d. Protocol-specific procedures or treatment occurring prior to consent
    e. Missing original consent in study files
    f. Ineligible participants enrolled in the study
    g. Protocol deviations putting a participant at increased risk of harm
    h. Treatment dosing and/or administration deviations determined to be UPIRTSO
    i. Confidentiality or privacy violations

j. Forged documents or signatures
k. Large number of deficiencies or other findings

Reviews and findings from monitoring conducted by the NIMH monitoring team may count towards these requirements and also be used to inform future areas of focused monitoring by the Duke QA reviewer(s).

Quality Control (QC) Measures
The Duke Data Center (DDC) will work closely with the PIs and will oversee consistent application of scientific standards and methodological rigor for data collection, processing, entry, cleaning, and analytics. The DDC will be responsible for QC for all questionnaire data collected online and interview data to be entered locally into REDCap at each site by IEs/RAs. This will be accomplished by intensive training of all study staff, the development of well-defined study specific procedures (SSPs), and Manuals of Procedures (MOPs) with detailed instructions for procedures involved in data acquisition, processing, and upload to the REDCap platform. Fidelity to research procedures will be accomplished by the development of well-defined protocols and internal audits. Protocol-specific training will be based on the delegated roles of investigators and staff as defined in delegation of responsibility logs. IEs will be trained in the administration of interviews by experts in those particular interviews by reading/observing an administration and then being observed and finally certified by members of the assessment committee. Intensive reliability training, continuing interrater reliability ratings being performed by IEs across sites and regular cross-site conference calls to avoid drift will be QC measures for interview assessments.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Accountability in Data Management
The project will have internal QC procedures for generation of high-quality data, including project-specific MOPs, standardized controls and site data review prior to upload. Any data collected on paper forms will be double entered by site study staff and then directly uploaded into the REDCap database using specific electronic case report forms (eCRFs) developed by the DDC for the study. The data management and statistical team will then download data for analysis. Many data validation rules (e.g., blank but required entries, out-of-range values, skip patterns) will be enforced by the electronic data capture (EDC) system during data entry. Other, more complex error conditions will be checked using custom error-check programs. Inconsistencies in data patterns across forms will be used to identify complex errors or confirm the validity of data. The DDC will continually monitor data quality as data are entered using built-in range-checking values, which we have successfully deployed in other studies. Any inconsistencies or possible errors must be resolved by site study staff and approved and documented by the DDC. Using the REDCap auditing system, each error will be annotated and marked as either resolved by a data update, approved as an extreme value, or unrecoverable. Such error checking will be run daily, providing the trial the opportunity to address data issues

early when the probability of resolution is highest. We will resolve individual and recurring problems with the data entry system during DDC weekly staff meetings. These meetings will be used to discuss and resolve issues and answer operational concerns, such as data entry questions, use of technologies, and EDC. Dr. Compton will manage the data resolution process and host training sessions as needed. Procedures regarding QC will be performed to address inconsistencies that emerge following data validation processes. The DDC will also work with study staff to address data quality issues and to refine data collection and reporting processes. In addition, the DDC will prepare monthly reports for all site PIs and PCs and oversee data QC, providing timely reports on quality and submission of data and protocol deviations to the PIs.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for 7 years after the close of the study. Video-recordings of therapy sessions will be maintained for seven years.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonization Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the PIs to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation, or within 10 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents, reported to the NIMH Program Official and the DDC. Protocol deviations will be sent to the reviewing sIRB per their policies. The PIs will be responsible for knowing and adhering to the reviewing sIRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information and FDA Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in

peer-reviewed journals. Data from this study may be requested from other researchers 3 years after the completion of the primary endpoint by contacting the PIs.

In addition, this study will comply with the NIH Data Sharing Policy and Implementation Guidance, and any other relevant policies.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIMH has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ABBREVIATIONS AND SPECIAL TERMS

AAQ	Acceptance and Action Questionnaire
AE	Adverse Event
ATE	Average Treatment Effect
ATS	Adaptive Treatment Strategies
BPD	Borderline Personality Disorder
DBT	Dialectical Behavior Therapy
CAMS	Collaborative Assessment and Management of Suicidality
CCAPS	Counseling Center Assessment of Psychological Symptoms
CCC	College Counseling Center
CCIAB	College Counseling Implementation Advisory Board
CFR	Code of Federal Regulations
CGI-I	Clinical Global Impression – Improvement
CGI-S	Clinical Global Impression – Severity
CMP	Clinical Monitoring Plan
Co-I	Co-Investigator
CRF	Case Report Form
CRC	Clinical Research Coordinator
CSP	CAMS Stabilization Plan
CSQ	Client Satisfaction Questionnaire
CTEQ	Counselor Treatment Expectations Questionnaire
CTOBB	Clinical Trials Operations and Biostatistics Branch
CTSQ	Counselor Session Telehealth Questionnaire
CV	Curriculum Vitae
DBT	Dialectical Behavior Therapy
DDC	Duke Data Center
DERS	Difficulties in Emotion Regulation Scale
DHHS	Department of Health and Human Services
DIF	Demographic Information Form
DSMB	Data Safety Monitoring Board
DTA	Data Transfer Agreement
DUMC	Duke University Medical Center
DV	Dependent Variable
EC	Ethics Committee
EDC	Electronic Data Capture
eCRF	Electronic Case Report Forms
EMR	Electronic Medical Record
ES	Effect Size
FDA	Food and Drug Administration
F/U	Follow-Up
GAS	Global Assessment Scale
GCP	Good Clinical Practice
GPA	Grade Point Average
GUID	Global Unique Identifier
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
HRPP	Human Research Participants Protections
THE	Heterogeneity of Treatment Effect

IB	Investigator's Brochure
ICERs	Incremental Cost-Effective Ratios
ICH	International Council on Harmonization
ICMJE	International Committee of Medical Journal Editors
IE	Independent Evaluator
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ISO	Information Security Office
ITT	Intention-To-Treat
LMM	Linear Mixed Model
LSC-R	Life Stressor Checklist-Revised
MEPS	Medical Expenditure Panel Survey
MOP	Manual of Procedures
MTA	Material Transfer Agreement
NCT	National Clinical Trial
NDA	National Institute of Mental Health Database
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NSSI	Non-Suicidal Self-Injury
OARC	Office of Audit, Risk and Compliance
OHRP	Office for Human Research Protections
PAI-BOR	Personality Assessment Inventory – Borderline Features Scale
PC	Project Coordinator
PI	Principal Investigator
PII	Personally Identifiable Information
PO	Program Officer
QA	Quality Assurance
QC	Quality Control
QIF	Quality Implementation Framework
RA	Research Assistant
RDoC	Research Domain Criteria
RDSP	Research Data Security Plan
REDCap	Research Electronic Data Capture
RCT	Randomized Controlled Trial
SA	Suicide Attempt
SAB	Scientific Advisory Board
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SC	Steering Committee
SCS	Suicide Cognitions Scale
SD	Standard Deviation
SGM	Sexual and Gender Minorities
SI	Suicidal Ideation
SITBI	Self-Injurious Thoughts and Behaviors Interview
SMART	Sequential Multiple-Assignment Randomized Trial
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOP	Standard Operating Procedure
SR	Suicidal Risk
SSF	Suicide Status Form

SSI	Scale for Suicidal Ideation
SSL	Secure Sockets Layer
STCQ	Student Treatment Credibility Questionnaire
STEQ	Student Treatment Expectations Questionnaire
TAU	Treatment as Usual
THI	Treatment History Interview
UP	Unanticipated Problem
UPIRTSO	Unanticipated Problems Involving Risk to Subjects or Others
US	United States
UWRAP	University of Washington Risk Assessment Protocol
WCCL	Ways of Coping Checklist
ZSWS	Zero Suicide Workforce Survey - Abbreviated

10.3 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Ver	Date	Source	Description of Change	Brief Rationale
1.0	4/21/20	Protocol	Added two questionnaires to assess comorbid substance and alcohol abuse; Changes to the protocol made in Table 1 (on page 8), Table 2 (on page 24), Section 8.1 (on page 43) and Section 9.3.3 (on page 55-56). References were also added.	Recommendation made by the NIMH DSMB.
1.0	4/21/20	Protocol	Added a questionnaire that assesses cultural identity; Changes to the protocol made in Section 8.1 (on page 43) and Section 9.3.3 (on page 55). Reference was also added.	Recommendation made by the NIMH DSMB.
1.0	4/21/20	Protocol	Modified statistical analysis plan (SAP) in Section 9.3.2 on page 54 to include the following statement: "Linear contrasts among the components of the ATSs will be performed to further understand impact on efficacy."	Recommendation made by the NIMH DSMB.
1.0	4/21/20	Protocol	Added the following wording to Section 8.4.2 on page 51 to the first and second paragraph: "the NIMH DSMB."	Recommendation made by the NIMH DSMB.
1.1	7/13/20	Protocol	Added Aim 8 and Aim 9 within Tables of Aims (Table 4) under Exploratory Analyses consisting of the contrast within Stages of the randomized treatments (pages 38-39).	Recommendation made by the NIMH DSMB.
1.1	7/13/20	Protocol	In Section 9.6.7 (Exploratory Analyses), added description of Aim 8 (Comparison of CAMS vs. TAU within Stage 1) (pages 77-78).	Recommendation made by the NIMH DSMB.
1.1	7/13/20	Protocol	In Section 9.6.7 (Exploratory Analyses), added description of Aim 9 (Comparison of DBT vs Continued CAMS within Stage 2) (page 79).	Recommendation made by the NIMH DSMB.
2.0	9/14/20	Protocol	Changed title to reflect what we are now calling the project in all protocols, communications, and correspondence (Page i).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated protocol number to ver 2.0 (page i) and updated date of submission to 14 September 2020 (page i).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated Table of Contents (pages ii-iii).	Necessary change due to COVID-19 pandemic.

Ver	Date	Source	Description of Change	Brief Rationale
2.0	9/14/20	Protocol	In Section 1 (Protocol Summary), updated study synopsis to reflect new title, rational for revising study protocol, the addition of the Feasibility Study to the protocol (Overall Feasibility Study description, objectives, endpoints, population, and experimental manipulation), and a statement indicating changes to a hybrid delivery format to original larger trial design (pages 5-11).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 1.2 (Schema), added a figure providing a graphical overview of the study design for the feasibility study (page 12).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 1.3 (Schedule of Activities), added a schedule of activities table for the Feasibility Study (Table 1) (pages 14-15).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.1 (Study Rationales), provided a rationale for why the Feasibility Study is needed (pages 19-20).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.2 (Background), added a statement that the current design, which evaluates treatments delivered remotely or in person, will better reflect current and future practices within CCCs (page 21).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.2 (Background), added a more general statement that the current design also better reflects current and future mental health practices more broadly (page 23).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.2 (Background), added a statement about the proposed methodology being novel as no studies have undertaken an evaluation of a hybrid online/in-person format (pages 24-25).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.3.1 (Known Potential Risks), added a statement about the unknown risks associated with teletherapy (page 26).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.3.1 (Known Potential Risks), added a statement about the potential risk that private communications are vulnerable to hacking which, if done, may compromise confidentiality (page 26).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.3.2 (Known Potential Benefits), added a statement about the potential benefit of current design to address gaps in the current literature. Specifically, the need to gather data about the potential benefits/effectiveness of	Necessary change due to COVID-19 pandemic.

Ver	Date	Source	Description of Change	Brief Rationale
			online training for clinicians and online treatment of college students (pages 27-28).	
2.0	9/14/20	Protocol	In Section 2.3.3 (Assessment of Potential Risks and Benefits), included information about the change from in person to hybrid format, for training as well, when discussing strategies to minimize risk of worsening symptoms. Added the requirement of knowing the student's current location and emergency contact numbers for third party involvement. Finally, highlighted our plan of developing robust plans for reconnecting with students during the provision of care if there are technical issues (pages 28-29).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.3.3 (Assessment of Potential Risks and Benefits), added information relevant to minimizing Risk 2: minimizing confidentiality and privacy of participants. Noted the use of fully HIPPA compliant platform, steps that clinicians will be taken to ensure that therapy is provided in a secure and private location, and the use of unique links for completing all assessments (pages 29-31).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.3.3 (Assessment of Potential Risks and Benefits), added the following statements in the section on steps taken to minimize Risk 3 (emotional distress resulting from assessments): collecting additional contact information to manage suicide risk when evaluated remotely, indicating the time required to complete all Feasibility Study assessments (Page 31).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 2.3.3 (Assessment of Potential Risks and Benefits), given the remote nature of the therapy, added a statement in Minimizing Risk 4 strategies that a third party (family member, relative, or friend) may be used to help coordinate voluntary and/or involuntary hospitalizations, if needed. Procedures will be developed to identify potential people willing to help as a third party during the first treatment session (page 32).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 3 (Objectives and Endpoints), added summary of the objectives, endpoints, and justification for the	Necessary change due to COVID-19 pandemic.

Ver	Date	Source	Description of Change	Brief Rationale
			endpoints for the Feasibility Study in Table 3 (pages 33-35).	
2.0	9/14/20	Protocol	In Section 4.2 (Overall Designs), added an overall summary of the Feasibility Study design (page 39).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 4.3 (Scientific Rational for Study Designs), added scientific rationale for Feasibility Study design (pages 40-41).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 4.4 (Justification for Intervention), added justification for Feasibility Study interventions (pages 41-42).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 4.4 (Justification for Intervention), added a description of the hybrid model and the reasons why we decided to allow for flexibility in the modality of treatment delivery (page 43).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 4.5 (End-of-Study Definition), added end-of-study definition for Feasibility Study (pages 43-44).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 5.1 (Inclusion Criteria), added the sample size needed for the Feasibility Study and updated eligibility criteria to include both in person or remote treatment (page 44).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 5.4 (Strategies for Recruitment and Retention), updated recruitment and retention strategies section (5.4) to reflect recruitment needed for Feasibility Study (page 45).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In Section 5.4 (Strategies for Recruitment and Retention), added Table 4 and related paragraph that summarizes/reviews assessment schedule and participant reimbursement amounts (page 47).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated Section 6.1.1 (Pre-screening) to include option for intake session to be remote or in person (page 48).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated Section 6.1.2 (Screening) to include the online e-consenting process (page 48).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated Section 6.1.3 (Baseline) to include baseline assessment details for the Feasibility Study (pages 48-49).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated section 6.1.4 (Randomization) to include details specific to the Feasibility Study (page 49).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	Updated section 6.1.6 (Administration and/or Dosing) to include treatment dose in weeks allowed during the Feasibility	Necessary change due to COVID-19 pandemic.

Ver	Date	Source	Description of Change	Brief Rationale
			Study and the use of a HIPAA-complaint platform for telehealth sessions (pages 50-51).	
2.0	9/14/20	Protocol	Updated section 6.2.1 (Interventionist Training and Tracking) to include online training, certification, and details about treatment adherence, including the number, frequency, duration of trainings, and QA processes for both CAMS and DBT (pages 51-52).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 6.3 (Measures to minimize bias: randomization and blinding), randomization details specific to the Feasibility Study are included (page 52).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 8.1 (Endpoint and other non-safety assessments), outcomes specific to the Feasibility Study are listed (pages 55-56, 60).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 8.2 (Safety Assessments), details about how safety assessments will be conducted during remote assessments are included (pages 61-62).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 9.1 (Statistical Hypotheses), details about the aims and hypotheses for the Feasibility Study are added. There are six (6) Feasibility Study hypotheses (pages 68-69).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 9.2 (Feasibility Study Sample Size Determination), a paragraph about the rationale for the sample size of the Feasibility Study is added (page 69).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 9.3 (Feasibility Study Statistical Analysis), details about the Feasibility Study statistical analyses are provided, this includes cut points for a benchmark analysis associated with each hypothesis and a description of mitigation strategies (pages 69-73).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 10.1.1.1 (Consents and Other Informational Documents Provided To Participants), included statement about our use of an e-consent during both feasibility and main study (pages 79-80).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 10.1.1.2, modified description of consent process to include e-consenting procedures as implemented in REDCap (page 80).	Necessary change due to COVID-19 pandemic.
2.0	9/14/20	Protocol	In section 10.1.5 (Key Roles and Study Governance), updated membership of the Steering Committee and Executive	Necessary change due to COVID-19 pandemic.

Ver	Date	Source	Description of Change	Brief Rationale
			Committee to reflect staff changes and Duke as Coordinating Center for the study, rather than UNR (pages 83-84).	
1.0	9/14/20	Feasibility Subject Consent (Multi-site Template)	New Document – Feasibility Subject Consent was drafted based on same general language used in Main Consents, updating study purpose and visit structure, etc., accordingly.	Necessary due to addition of Feasibility study portion.
1.0	9/14/20	Feasibility Counselor Consent (Multi-site Template)	New Document – Feasibility Counselor Consent was drafted based on same general language used in Main Consents, updating study purpose and visit structure, etc., accordingly.	Necessary due to addition of Feasibility study portion.
2.0	9/14/20	Main Counselor Consent	**Page 1: Inserted** The therapy sessions may be online, in person, or a combination of both.	Added reference to possibility of remote treatment sessions.
2.0	9/14/20	Main Counselor Consent	**Page 2: Moved** This study is paid for by a grant from the National Institute of Mental Health (NIMH). This grant will help pay for part of Dr. **<Last name of PI>** and **<His/her>** research team's salaries.	Moved from bottom of previous section to better match consent structure.
2.0	9/14/20	Main Counselor Consent	**Page 2: Deleted** individual	Clarifying language as some consultation supervision may be via group as well as individual.
2.0	9/14/20	Main Counselor Consent	**Page 3: Inserted** (online, in person, or both)	Added reference to possibility of remote treatment sessions.
2.0	9/14/20	Main Counselor Consent	**Page 3: Deleted** 2	Specific number deleted to allow more leeway as regards number of questions asked. Likely number will be 3, but it also could vary slightly from session to session.
2.0	9/14/20	Main Counselor Consent	**Page 3: Inserted** Treatment visits may be conducted in person at **<Name of CCC (abbreviation)>** or online via a HIPAA compliant telehealth platform. Decisions about whether treatment will occur in person or online will depend on the current policies at **<Name of CCC (abbreviation)>**, your preferences, and your client's preferences. Study staff can answer any questions you have about this process.	Added reference to possibility of remote treatment sessions, including that relevant Counseling Center policies will be followed in determining location/manner of treatment.

Ver	Date	Source	Description of Change	Brief Rationale
2.0	9/14/20	Main Counselor Consent	**Page 5: Inserted** It may also feel more challenging to provide treatment to suicidal clients via telehealth.	Added reference to possibility of remote treatment sessions.
2.0	9/14/20	Main Counselor Consent	**Page 5: Deleted** individual	Added reference to possibility of remote treatment sessions.
2.0	9/14/20	Main Counselor Consent	**Page 6: Inserted** The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this certificate, unless you have given your permission, the researchers may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless: • There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings); • You have consented to the disclosure, including for your medical treatment; or • The research information is used for other scientific research, as allowed by federal regulations protecting research subjects. You should understand that a Confidentiality Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you must also actively protect your own privacy. Finally, you should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.	Added language pertaining to Certificate of Confidentiality based upon CAMPUS team discussions that this should be included in the Counselor consents.

Ver	Date	Source	Description of Change	Brief Rationale
2.0	9/14/20	Main Counselor Consent	**Page 7: Inserted** (or alternate remote, secure means)	Added reference to possibility of remote treatment sessions.
2.0	9/14/20	Main Counselor Consent	**Page 8: Deleted** individual	Clarifying language as some consultation supervision may be via group as well as individual.
2.0	9/14/20	Main Counselor Consent	**Page 8: Deleted** a free CAMS webinar and	Unnecessary language given the mention of free comprehensive CAMS training above.
2.0	9/14/20	Main Counselor Consent	**Page 10: Deleted** XXX **Page 10: Inserted** **XXXX**	Minor typographical fix.
2.0	9/14/20	Main Student Consent	**Page 1: Inserted** Your therapy sessions may be	Added note to Concise Summary that therapy may be online and/or in person.
2.0	9/14/20	Main Student Consent	**Page 1: Inserted** online, in person, or both.	Added reference to possibility of telehealth.
2.0	9/14/20	Main Student Consent	**Page 2: Inserted** and how to adapt these treatments to work well via telehealth, when needed.	Added reference to possibility of telehealth.
2.0	9/14/20	Main Student Consent	**Page 2: Inserted** that will occur online via a HIPAA-compliant telehealth platform such as Zoom, or in person.	Added reference to possibility of telehealth.
2.0	9/14/20	Main Student Consent	**Page 3: Inserted** Treatment visits may be conducted in person at **<Name of CCC (abbreviation)>**, or online via a HIPAA-compliant telehealth platform such as Zoom. Decisions about whether treatment will occur in person or online will depend on the current policies at **<Name of CCC (abbreviation)>**, your preferences, and your counselor's preferences. Study staff can answer any questions you have about this process.	Added language about possibility of treatment involving a mix of in person and telehealth, and that the decision about format will be based on relevant Counseling Center policy.
2.0	9/14/20	Main Student Consent	**Page 4: Inserted** You will be interviewed, fill out online questionnaires (via a secure internet website), and complete an activity online during these visits.	Added language about potential online completion of some questionnaires.
2.0	9/14/20	Main Student Consent	**Page 4: Deleted** via a secure webcam **Page 4: Inserted** via HIPAA compliant telehealth platform, such as Zoom. If you are completing assessment visits online, study staff will work with you to ensure that you have	Added reference to possibility of telehealth.

Ver	Date	Source	Description of Change	Brief Rationale
			access to a private, confidential setting to complete the visit.	
2.0	9/14/20	Main Student Consent	**Page 4: Inserted** *Access to Records* In order to gauge the impact of treatment, if any, on your campus life, we will ask your approval to obtain access to your **<Name of University>** school records (GPA, enrollment status, demographics, etc.) as well as your usage of services elsewhere on campus (e.g., Health Center, other Student Services offices, such as Accessible Education Center) for a period of 12 months after the consent signing date. No specific information about the type of research you are participating in will be provided to the university personnel, except for the fact that you are a study participant who has given us permission to collect their institutional data. Once we receive the academic and health care use information, we will merge the information into a file with only a Global Universal Identifier (GUID) number and no names (GUID is further explained below, in the Confidentiality section). {Please initial your selection below, then sign} I agree to grant researchers access to my **<Name of University>** school records, as noted above, for the purposes of this study, for a period of 12 months from the date of signature below: _____ Yes _____ No _____ ___ _____ Student Signature Date signed	Added a section to address FERPA permission for student educational records.
2.0	9/14/20	Main Student Consent	**Page 6: Inserted** Privacy and internet connection issues can also be problematic when receiving treatment online.	Noted additional study risk of privacy and internet connection issues, if telehealth is used.
2.0	9/14/20	Main Student Consent	**Page 6: Inserted** , including how to provide this treatment online.	Noted that telehealth effectiveness findings are an added potential benefit to research body of knowledge.

Ver	Date	Source	Description of Change	Brief Rationale
2.0	9/14/20	Main Student Consent	**Page 8: Inserted** (or alternate remote secure means)	Added mention of possible remote GUID generation method.
2.0	9/14/20	Main Student Consent	**Page 8: Inserted** *Risks Associated with Telehealth* Generally speaking, the risks and benefits of telehealth are similar to those of in-person sessions. There are additional risks, however. First, although we will use secure platforms (e.g., Zoom for Healthcare) with industry-standard encryption and security, there is no way to guarantee that this software is completely failure-proof. As with any technology, there is a chance of a security breach that would affect the privacy of personal and/or medical information. Second, since you will be completing sessions in your own home, we cannot guarantee the same level of privacy that you have when you are in our clinic. This means that you are responsible for making sure that you are in a private area where disruptions (e.g., others coming into the room or hearing what you say in another room) are minimized as much as possible. Third, in the event of group sessions conducted via video, it is possible that your confidentiality could be breached if others in the group are not in a confidential setting. In order to reduce risks to confidentiality, we suggest that all video or telephone sessions occur in a private room with no one else present and that you wear headphones to limit the possibility of other people overhearing confidential information.	Added a section addressing possible risks associated with Telehealth.
2.0	9/14/20	Main Student Consent	**Page 10: Inserted** Any additional treatment required, outside of that provided by the counseling center, will need to be covered by your insurance, you, and/or your family, as with your regular medical care.	Added language noting that any additional non-Counseling Center treatment that subjects may require is not covered by the study.
2.0	9/14/20	Main Student Consent	**Page 11: Inserted** your insurance,	Added language noting that insurance may also aid with payment, if any non-covered costs were incurred.

Ver	Date	Source	Description of Change	Brief Rationale
2.0	9/14/20	Main Student Consent	**Page 12: Deleted** XXX **Page 12: Inserted** **XXXX**	Minor typographical fix.
2.0	9/14/20	Main Student Consent	**Page 12: Inserted** {Intentionally Left Blank}	Due to new page formatting, note that there is some blank page here, prior to Statement of Consent and signature section of ICF.
2.1	10/27/20	Protocol	Added a question to the Feasibility Study rationale section (2.1.1) about the need to assess the feasibility of IEs collecting outcome assessments remotely (page 20).	Recommendation made by the NIMH DSMB.
2.1	10/27/20	Protocol	Added hypothesis about feasibility of collecting outcome assessments to Table 3 (page 34).	Recommendation made by the NIMH DSMB.
2.1	10/27/20	Protocol	In Table 4, combined Aims 8 and 9 into one aim, now Aim 8 (page 39).	Recommendation made by the NIMH DSMB.
2.1	10/27/20	Protocol	In section 8.1, Feasibility Study Outcomes, added evaluating feasibility of collecting study outcomes as one of the study outcomes (page 57).	Recommendation made by the NIMH DSMB.
2.1	10/27/20	Protocol	In section 9.1, added Aim 4 to the Feasibility Study hypotheses list (Hypothesis 4) (page 69).	Recommendation made by the NIMH DSMB.
2.1	10/27/20	Protocol	In section 9.3 (Statistical Analyses), described general approach to evaluating the feasibility of collecting outcomes remotely (page 71).	Recommendation made by the NIMH DSMB.
2.1	10/27/20	Protocol	In the Statistical Analysis Section, Exploratory Analysis subsection (9.6.7), combined statistical methods for old Aims 8 and 9 into one new aim, now Aim 8 (pages 79-80).	Recommendation made by the NIMH DSMB.
2.1	3/12/2021	Feasibility Student ICF	In Concise Summary, removed ",depending on your response to treatment"	Phrase is incorrect if randomized to DBT.
2.1	3/12/2021	Feasibility Student ICF	Starting on page 3, updated language to: "All of these treatments have helped students feel less distressed. For all of these treatments, you will be asked to complete several brief questionnaires, throughout treatment. If you were assigned TAU or CAMS in Stage 1, your counselor will be assessing how you are doing at each treatment visit and treatment will proceed or end depending on sufficient progress. If you show	Improved clarity for subjects regarding how Stage 1 and Stage 2 work if assigned to DBT.

Ver	Date	Source	Description of Change	Brief Rationale
			sufficient progress in Stage 1, your study treatment could end after 4-8 sessions. If not, you will move into Stage 2 of the study. If you were initially assigned to DBT you will complete 8 weeks in Stage 1, then you will continue DBT in Stage 2 for an additional 8 weeks. <u>*Stage 2*</u> If you were assigned TAU or CAMS in Stage 1 and do not show enough improvement after Stage 1, you will be randomly assigned (like flipping a coin) to either CAMS or DBT for Stage 2 for an additional 8 weeks."	
2.1	3/12/2021	Feasibility Student ICF	Starting on page 4, in *Access to Records* section, updated language to: "In order to gauge the impact of treatment, if any, on your campus life, we will ask your approval to obtain access to your **<Name of University>** school records (GPA, enrollment status, demographics, semester and cumulative grade point average or GPA, credits attempted, credits completed, and enrollment status) as well as your usage of health services on campus (<**list Student Health Center and Counseling Center**>) for a period of 12 months after the consent signing date. This information will help us to assess how your treatment has impacted your educational and general functioning on campus, over a period of a year. No specific information about the type of research you are participating in will be provided to the university personnel, except for the fact that you are a study participant who has given us permission to collect their institutional data. This may involve asking you to sign separate document(s), specifically requesting that the {**Campus Registrar's Office and Campus health entities**} grant us access to only data and information noted above, and only over the 12 month timeframe. Once we receive the academic and health care use information, as part of maintaining your confidentiality, we will	Wording changes to better characterize the educational and health data being sought, partly in consult with University Counsel for their preferred FERPA-related language.

Ver	Date	Source	Description of Change	Brief Rationale
			merge the information into a file with only a Global Universal Identifier (GUID) number and no names (GUID is further explained below, in the Confidentiality section)."	
2.1	3/12/2021	Feasibility Student ICF	On page 5, updated language to: "clinical and research team (and clinical supervisors of your therapist(s), if applicable) with the following exceptions: (1) transcripts, suitably modified to protect your identity, may be used in writings by Dr. **<Last Name of PI>** as illustrations to enhance the understanding of persons with psychological difficulties similar to your own and their treatment and (2) edited sections of the recordings may be listened to or viewed by those providing training to the therapist(s) who provide these treatments."	Improved clarity for subjects regarding how clinical supervisors/trainers of therapists may have access to securely review session videos for training/supervisory purposes.
2.1	3/12/2021	Feasibility Student ICF	At top of page 6, changed "group therapy" to "DBT skills training".	Non-DBT subjects will not get group treatment, so providing clearer and more correct language for subjects.
2.1	3/12/2021	Feasibility Student ICF	At bottom of page 10, updated compensation plan to $30 at Baseline, Week 8, and Week 16 from $10/$20/$40 respectively (with possible $20 bonus). Total compensation remains $90.	Study team decision that simpler plan was better for subject understanding as well as disbursement management.
2.2	9/9/21	Protocol	Changed protocol number from 2.1 to 2.2	Update protocol version.
2.2	9/9/21	Protocol	Updated Feasibility study sample sizes for counselor participants and student participants through document. New sample size is ~24 for counselor participants, ~6 per site. And new sample size for student participants is N=62, with CAMS n=21, TAU n=20, and DBT n=21. This change has been made on the following pages: 6, 7, 19, 33, 40, 42, 45, 51, 70, 71	Change needed to address efficacy of updated training protocols.
2.2	9/9/21	Protocol	Corrected a found inconsistency in prior version of the protocol regarding the number of Stage 2 sessions. Several places said between 4-16, correct number is between 1-16 and varies by treatment condition. This change has been made on the following pages: 7, 8, 10, 13, 23, 42	Corrected inconsistency within prior protocol.
2.2	9/9/21	Protocol	Added a statement about total duration of student participation not including	Corrected oversight in prior protocol.

Ver	Date	Source	Description of Change	Brief Rationale
			holidays or extended breaks. (pages 11, 52)	
2.2	9/9/21	Protocol	Updated Figure 1 to reflect new sample sizes. (page 12)	Change needed to address efficacy of updated training protocols.
2.2	9/9/21	Protocol	Deleted line in Assessment Table 1 that indicated students would complete an AE form at each treatment visit. (page 14)	Corrected inconsistency within prior protocol.
2.2	9/9/21	Protocol	Replaced Beck Hopelessness Scale with Optimism Hope Scale. (pages 14, 16, 37, 38, 60)	OHS measures similar construct, is open source and shown to be sensitive to change.
2.2	9/9/21	Protocol	Removed the completion of the Treatment History Interview (THI) at the week 8 assessment point. (pages 15, 17, 59)	Corrected oversight in prior protocol.
2.2	9/9/21	Protocol	Expanded the academic years in which the feasibility study will take place to include the 2021-2022 academic year.	Change needed to address efficacy of updated training protocols and to complete enrollment targets for feasibility study.
2.2	9/9/21	Protocol	Added Study Liaison as a study team member. (page 39)	Corrected oversight in prior protocol.
2.2	9/9/21	Protocol	Added a statement in the protocol allowing for students who maintain high levels of SI without improvement to be eligible for re-randomization to Stage 2 earlier than week 8. (pages 43, 58)	Corrected oversight in prior protocol.
2.2	9/9/21	Protocol	Expanding study inclusion criteria to include those students who endorse SI (1) on the CCAPS, (2) during the intake clinical interview, or (3) on other measures given as part of standard practice at the CCC. Specifically, the inclusion criteria for SI will now state the following (which changes in bold font): Moderate to severe suicide ideation over last two weeks as indicated by **one or more of the following**: (1) a score of >=2 on CCAPS question "I have thoughts of ending my life"; **(2) self-report during clinical interview; or (3) other intake questionnaires given as standard practice at CCCs (e.g., C-SSRS).** (page 45)	Correcting potential problem with inclusion criteria to ensure that all appropriate students are given opportunity to participate in the trial.
2.2	9/9/21	Protocol	Changed reimbursement schedule to be $30 per assessment completed rather than an escalating payment schedule. Please note that the total reimbursement amount does not change. (page 47)	To enhance data collection.

Ver	Date	Source	Description of Change	Brief Rationale
2.2	9/9/21	Protocol	Removal of Stage 1 randomization for CAMS and TAU. This is necessary to implement the revised training protocols. (pages 50, 53)	Change needed to address efficacy of updated training protocols for CAMS and DBT.
2.2	9/9/21	Protocol	During the feasibility study, we identified the need to accommodate potential gaps in treatment due to the academic calendar (scheduled breaks such as summer vacation). Given our goal to create an intervention approach that fits with the CCC environment, our intervention and assessment schedule must be able to handle gaps in care. Therefore, for students whose treatment will be disrupted due to a scheduled break in the academic calendar, we are seeking approval to add additional assessment points before/after scheduled breaks lasting longer than 6 weeks to capture their clinical status prior to leaving campus and upon their return. These additional assessments will only be completed by those students who experience a gap in treatment and will only include the primary outcomes. (Page 52)	Corrected oversight in prior protocol.
2.2	9/9/21	Student ICF	Changed total sample size from N=44 to N=62 and each site sample size to approximately n=17. Replaced updated Figure 1. Feasibility Study Design. Changes were made to the sample size in each group in Stage 1: CAMS (old n=16, new n=21), TAU (old n=16, new n=20), DBT (old n=12, new n=21). Sample size for Stage 2 treatments were also updated: CAMS (old n=8, new n=10) and DBT (old n=8, new n=10). Finally, the number of weeks listed for Stage 2 CAMS treatment was changed to reflect the options more accurately. For CAMS, old number of weeks = 8, new = "up to 8".	To make consistent with protocol.
2.2	9/9/21	Student ICF	Removed references to accessing student's usage of campus health services in Section "Access to Records" starting on Page 4. This was entered in error as this information will be collected during the Treatment History Interview (THI).	To make consistent with protocol.
2.2	9/9/21	Student ICF	Changed reimbursement amount to match protocol, namely $30 for each assessment.	To make consistent with protocol.

Ver	Date	Source	Description of Change	Brief Rationale
			Note that the total amount reimbursed remains the same.	
2.2	9/9/21	Student ICF	Clarified language about length of study participation being dependent upon which treatment they are randomly assigned. Section "HOW LONG WILL I BE IN THIS STUDY" starting on Page 6.	To make consistent with protocol.
2.2	9/9/21	Student ICF	In Section "**HOW LONG WILL I BE IN THIS STUDY**" starting on Page 6, we clarified how study participation will be managed during academic breaks (e.g., winter break and summer break).	To make consistent with protocol.
2.2	9/9/21	Student ICF	In Section "WILL MY INFORMATION BE KEPT CONFIDENTIAL?" starting on Page 7, we added a sentence about sharing information gathered during study assessments to their treating counselor to prevent harm to self or others and to coordinate care.	To correct an oversight in last version of ICF
2.2	9/9/21	Counselor ICF	Clarified that counselor's weekly time commitment for study will depend on study caseload and changed overall time commitment for study participation from 12 months to one 'academic year'.	To make consistent with request protocol changes
2.2	9/9/21	Counselor ICF	Clarified language regarding study expectations for caseload and duration of each treatment group.	To make consistent with request protocol changes
2.2	9/9/21	Counselor ICF	Made minor wording changes with the goal of improving readability and clarity. For all of these changes, the intended content remained the same. Please see "tracked changes" version of the ICF for examples.	For clarification.
2.2	9/9/21	Counselor ICF	Removed language about randomization treatments.	To make consistent with request protocol changes
2.2	9/9/21	Counselor ICF	Updated Figure 1 to reflect new sample sizes	To make consistent with request protocol changes
2.2	9/9/21	Counselor ICF	In section "WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY" starting on page 9, added additional details about the process for counselors who wish to leave the study.	Improve processes around counselors who decide to withdraw consent for participation.
2.3	1/6/22	Protocol	Changed total sample size for the feasibility study from N=62 to N=85 and site sample size from n»12 to n»21. This change was made on pages 6, 8, 19, 40, 42, 45, 46	To ensure that each counselor treats one student in CAMS and DBT post-certification in the respective treatment protocol.

Ver	Date	Source	Description of Change	Brief Rationale
2.3	1/6/22	Protocol	Removed tracking of non-mental health ED visits as a SAE. Will continue to track and report as a standard AE. This was removed from the list of SAEs on page 64.	Clarify what needs to be tracked as SAE.
2.3	1/6/22	Protocol	Updated sample size estimates in "Figure 1. Feasibility Study Design" on page 12.	To ensure that each counselor treats one student in CAMS and DBT post-certification in the respective treatment protocol.
2.3	1/6/22	Protocol	Added Counselor Session Telehealth Questionnaire (CTSQ) as a measure to be completed after each telehealth therapy session by counselors and by QA raters for an assessment of reliability. This change was made on pages 17, 61, 91	To document telehealth best practices
2.3	1/6/22	Protocol	In Table 3 (starting on page 32), we note that to achieve the aims of the feasibility study, only N=76 students are needed. The sample size requested of N=85 is included in case therapists need to treat additional certification cases because they did not pass on the first case or their first case withdrew prior to completing treatment. This point is also noted in the "Statistical Considerations" section on page 70.	To ensure that each counselor can treat an additional training case if they fail to pass on the first one.
2.3	1/6/22	Student ICF	Changed sample size of study from N=62 to N=85 and updated Figure 1	To make consistent with protocol.
2.4	4/29/22	Protocol	Changed protocol to allow for training of counselor participants to be either online or in-person. Decisions about which format to use will be based upon counselor preferences, research team preferences, and CDC and institutional guidelines surrounding large in-person meetings at the time. Changes to the protocol that reflect this modification are on page 28.	To allow flexibility due to changing guidelines surrounding COVID-19.
2.4	4/29/22	Protocol	Clarified AE reporting. Non-suicidal Self-Injuring (NSSI) will now be tracked and reported as an SAE rather than an AE. In prior version of the protocol, NSSI was listed as an AE and SAE. Changes to the protocol that reflect this modification are on page 64.	For clarification.
2.5	7/14/22	Protocol	Removed all references to CAMPUS Feasibility protocol.	No longer needed as feasibility study has been completed.
2.5	7/14/22	Protocol	Changed Total sample size to 480	Updated sample size to match new protocol design

Ver	Date	Source	Description of Change	Brief Rationale
2.5	7/14/22	Protocol	Changed treatment length to 14 weeks and total treatment duration to 26 weeks.	Updated treatment duration to match new protocol design.
2.5	7/14/22	Protocol	Changed follow-up period to 12 weeks	Updated follow-up period to match new protocol design.
2.5	7/14/22	Protocol	Updated Figure 1 and added Figure 2	Updated to match new protocol design and added Figure 2 for clarification.
2.5	7/14/22	Protocol	Updated Table 1 (Assessment Schedule)	Updated to match new protocol.
2.5	7/14/22	Protocol	Updated description of DBT.	Updated to match new protocol.
2.5	7/14/22	Protocol	Updated participant reimbursement schedule.	Updated to match new protocol.
2.5	7/14/22	Protocol	Added monthly monitoring of students who enter the maintenance phase of the ATS and during follow-up period.	Updated to improve risk management of students.
2.5	7/14/22	Protocol	Changed requirement of 3 consecutive sessions of "response" before deciding on next treatment phase.	Old rule was too rigid. New rule improves clinical flexibility and enhances participant retention.
2.5	7/14/22	Protocol	Changed academic outcomes to self-report	Necessary as follow-up period is now too short.
2.5	7/14/22	Protocol	Removed Life-Death Implicit Association Test	Too difficult to administer in remote environment; too burdensome for participants.
2.5	7/14/22	Protocol	Removed Copenhagen Burnout Instrument	To reduce burden on counselors
2.5	7/14/22	Protocol	Updated power section to reflect new sample size.	Updated to match new protocol.
2.6	12/30/22	Protocol	Minor change to how DBT sessions are randomly selected for adherence rating. Change is reflected in protocol on page 40 of this protocol.	Help to ensure that every student's adherence to DBT is accurately evaluated, regardless of the number of sessions they receive
2.7	04/08/2023	Protocol	In order to enhance clarity, a few minor wording changes were made to Inclusion Criteria 4 for student participants. The goal was to include the phrase "one or more of the following:" to improve clarity and reduce ambiguity. It's worth noting that this change was approved in Version 2.2 of the Protocol, but the updated wording was not implemented at that time.	To ensure consistency with the approved Protocol version 2.2, and for the purpose of clarification.

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