Comprehensive Adaptive Multisite Prevention of University student Suicide (CAMPUS) with Duke as a Site, and Duke as Single IRB of Record (DUHS IRB - sIRB)

Duke Student ICF

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Duke University Health System

Consent to Participate in a Research Study
ADULT - Duke Site
Adapting Treatments for Suicidal College Students: A Multisite Trial

CONCISE SUMMARY

Suicidal thoughts affect many college students, and we still don't know the best ways to offer help. We are doing this study to learn more about 4 different treatment strategies for college students with suicidal thoughts.

If you join the study, you will:

- Be randomly assigned (like flipping a coin) to at least one treatment and possibly two.
- Receive study treatment(s) for 4-14 weeks; how much treatment you receive depends on how well you are doing.
- Stay in touch with the study team for 3 months after the 14-week treatment period ends.

The treatment you receive during this study will focus primarily on reducing your suicidal thoughts. Treatment sessions may be online, in person, or both. There is initial evidence that the treatments being evaluated and their sequences are helpful for people who struggle with suicidal thoughts, but we cannot guarantee that the treatments provided during this study will help you. It is possible that talking about your feelings will be upsetting. If so, study clinicians and research staff will help you manage this situation if this happens.

If you are interested in this study, please continue reading below.

We are asking you to join this research study because you are a Duke University student seeking treatment at the Duke Counseling and Psychological Services (CAPS) and having suicidal thoughts.

Please read this consent form carefully. Take your time to decide. Feel free to talk with your family and friends before you decide. Research studies are voluntary and include only people who choose to join. If you do not clearly understand any words or information in this form, please ask a study team member to explain them to you.

What happens in this study, possible benefits and risks, and other important information are described on the following pages.

WHO IS THE PRINCIPAL INVESTIGATOR ON THIS STUDY?

Dr. David Goldston is the Principal Investigator at Duke University. His contact information is included below if you have any questions or concerns about the study throughout your participation. If you decide to participate in this study, Dr. Goldston will be in touch with your counselor while you are in the study and afterward, if needed.

Duke University Health System

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This study is paid for by a grant from the National Institute of Mental Health (NIMH) and funding from this grant pays for part of Dr. Goldston and the clinical and research team's salaries.

WHY IS THIS STUDY BEING DONE?

The main goal of this study is to learn how to better help college students who struggle with suicidal thoughts. Prior research has shown that several talk therapies are helpful for people with suicidal thoughts and we hope that the results from current study will help inform counselors at college counseling centers which treatment or sequences of treatment is best for individual students.

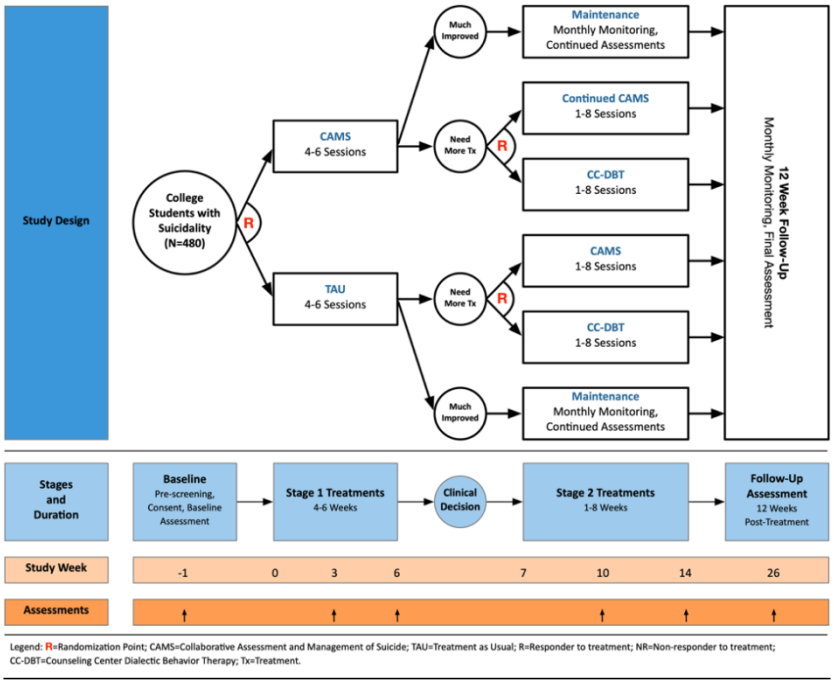
HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 480 students will participate in this study at several different colleges the US. About 120 students at Duke will join this study.

WHAT IS INVOLVED IN THE STUDY?

Figure 1 provides a visual overview of the study design, its stages, and the sequences of treatment that will be offered to students who participate.

Figure 1. CAMPUS Trial Study Design
(Comprehensive Adaptive Multisite Prevention of University student Suicide)



Baseline Assessment

If you agree to participate in this study, we will schedule a baseline (pre-treatment) assessment visit. This visit will be conducted either in-person or remotely via a HIPAA-compliant telehealth platform such as Zoom. During this assessment you will complete a clinical interview and several online questionnaires that will ask you about your emotions, thoughts, behaviors, relationships, life experiences, school performance, and mental health history.

Stage 1

After the baseline assessment, you will be assigned to one of the counselors at **CAPS** who is also participating in this trial as a study therapist. The treatment you will receive by your study counselor will be randomly assigned (like flipping a coin). Your counselor will let you know which treatment you will receive at your first treatment visit.

Please note that if you decide to participate in this study, you cannot choose which treatment you will receive.

Treatment visits will be conducted in person at CAPS or online via a HIPAA-compliant telehealth platform such as Zoom. Decisions about whether your treatment will be provided in person or online will depend on current policies at CAPS, your preferences, as well as your study counselor's preferences.

At Stage 1 there are two treatment possibilities. One treatment is called "Treatment as Usual" or TAU. TAU is essentially the standard care currently offered to students being treated at CAPS with suicidal thoughts.

The other treatment is called "Collaborative Assessment and Management of Suicidality" or CAMS. CAMS is a therapeutic framework for suicide-specific assessment and treatment. It's a flexible approach that actively encourages your participation with your study counselor in the development of your treatment plan.

Both treatments have helped students with suicidal thoughts feel less distressed.

Regardless of which treatment you receive, you will be offered between 4-6 weekly individual treatment sessions during Stage 1. The treatment sessions must be completed within the 6-week Stage 1 study period. Please note that all students will be offered at least 4 treatment sessions. The total number of study treatment sessions you receive during Stage 1 will depend upon how much improvement you have experienced since joining the study (baseline). You will only receive the number of treatment sessions you need.

Stage 2

If you show sufficient improvement by the end of Stage 1—namely, suicidality no longer needs to be the focus of treatment—your study treatment will end and you will move into the maintenance phase of the

trial which involves brief monthly check-ins with a member of the study team. Please note that although your study treatment may end at this time, you may continue to receive treatment from your CAPS counselor for other mental health concerns.

If you do not show sufficient improvement by the end of Stage 1—namely, suicidality is still a focus of treatment—you will be randomly assigned (like flipping a coin) to one of two possible Stage 2 treatments for up to an additional 8 weeks. Like Stage 1, the number of Stage 2 treatment sessions offered will depend on how much improvement you experience. You will only receive the number of treatment sessions you need.

One of the Stage 2 treatments is CAMS. The CAMS treatment offered in Stage 2 is the same CAMS treatment offered Stage 1. If you received TAU during Stage 1, you will switch to CAMS in Stage 2. However, if you received CAMS in Stage 1, you may continue CAMS treatment during Stage 2.

The other treatment offered in Stage 2 is "Dialectical Behavior Therapy" that has been modified to better fit the needs of students and counseling centers. This treatment is called "Counseling Center Dialectical Behavior Therapy" or CC-DBT.

CC-DBT will involve weekly individual counseling sessions with your CAPS study counselor and participation in weekly CC-DBT skills training. The CC-DBT skills training will focus on helping you learn new strategies to better manage emotions and distress, and the training may occur in either a group or individual format.

The total number of Stage 2 study treatment sessions you will be offered will range from 1-8. However, all study treatment must be completed within the 8-week Stage 2 study period. The total number of study treatment sessions you receive during Stage 2 will depend upon how much improvement you have experienced since joining the study (baseline). You will only receive the number of treatment sessions you need.

Assessment Visits

In addition to receiving study treatments, you will also be asked to complete 6 assessment visits with research staff. These assessments are necessary so that we can document how much improvement you have experienced since starting the study. Each assessment visit will involve a clinical interview with a member of the research staff and several online questionnaires. The assessment visits will be conducted either in-person at CAPS or remotely using a HIPAA-compliant telehealth platform such as Zoom.

The assessments will be completed at baseline, week 3 (halfway through Stage 1), week 6 (end of Stage 1), week 10 (halfway through Stage 2) and week 14 (end of Stage 2). To evaluate the durability of your treatment response we will also ask you to complete a 3-month follow-up assessment at week 26. We will also collect information from your medical record at the counseling center.

You will be asked to complete these assessments whether you are actively in treatment or are in the

maintenance phase of the study.

Video and Audio-Recordings of Your Treatment and Assessment Sessions

Each treatment session will be recorded using a digital video recorder. These recordings will be used so we can (1) evaluate whether your study counselor is providing treatment consistent with the treatment protocol and (2) at the end of the study, evaluate whether specific content or processes observed during therapy might be related to treatment outcomes.

Each assessment session will also be recorded using a digital video recorder. These sessions will also be reviewed by research staff to ensure that the person conducting the assessment session was also following assessment protocols.

All digital video recordings will be stored on secure servers and remain confidential to members of Dr. Goldston's clinical and research team. Identifiers other than your image and voice (e.g., name, address, date of birth, social security number) will not be linked to these recordings. A separate ID number will be assigned to your recordings.

Please note that agreeing to have your treatment and assessment sessions digitally recorded is a requirement of the study. That is, you cannot participate in the current study if you do not agree to allow your treatment and assessment sessions to be digitally recorded.

We are also seeking your permission to possibly use this data for professional purposes, such as printing edited transcripts of treatment sessions in future publications or showing digital snippets of a therapy session that illustrate the application of a specific therapeutic technique during a professional training. These purposes are optional and will not influence your ability to participate in the current study. If a segment of one of your digital recordings is selected for professional purposes, and you have agreed (see below) to allow us to do so, it will be suitably modified to protect your identity.

Please initial below if you are willing to allow us to use your digital video recordings for these professional purposes.

Choose the options you prefer below and initial each one.

Yes ☐ No ☐	I consent to use of sections of transcripts of my treatment sessions in writings for educational purposes. _____
Yes ☐ No ☐	I consent to use of edited sections of my video/audio recordings for professional training purposes. _____

HOW LONG WILL I BE IN THIS STUDY?

The total duration of study participation is 26 weeks. This includes up to 14 treatment sessions over 14

weeks and the final assessment at the 3-month follow-up period. See Table 1 below for an overview of the treatment and assessment schedule.

Please note that the individual treatment sessions will last about one hour each, skills training sessions will last about two hours each, and each assessment visit will take between one to three hours to complete, with the baseline assessment taking the longest to complete.

Table 1. Study Visit and Assessment Schedule

		Stage 1						Stage 2								Post
Study Week	**Baseline Visit**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**26**
Private Treatment Visits* (1 hour)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Skills Training** (2 hours)									X	X	X	X	X	X		
Assessment Visits (1-2 hours)	X			X			X				X				X	X

*Your progress will be monitored by your counselor weekly; you will continue to have weekly visits if you still need them. Your treatment participation could end as early as week 4. If you enter Stage 2 your progress will be monitored by your counselor weekly and you will continue to have weekly visits if you need them.

**You will participate in 6 skills training sessions if you are randomized to receive CC-DBT. These sessions may occur individually or in a group format.

WHAT ARE THE RISKS OF THE STUDY?

It is possible that talking about your thoughts and feelings will be upsetting. Discussing painful details about yourself and your life can be difficult and stressful for some people. We will help you manage this distress if this happens. Privacy and internet connection issues can also be problematic when receiving treatment online.

There might be unknown or unexpected risks to joining the study. That's why keeping in touch with the research team will be so important during and after the study.

It is possible that the study team might decide to end your participation. If this happens, we will remain in contact with you and your care providers. The reasons why this might happen are described later in this form.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You will be treated for your suicidal thoughts during this study. There is evidence that the treatments and treatment strategies provided may help, but we cannot guarantee that being in this study will benefit you. In general, getting treatment is more helpful than trying to cope on your own suicidal thoughts.

We hope this study will help us create guidelines on how to best treat college students who have suicidal thoughts, including how to provide this treatment via telehealth or using a hybrid telehealth/in-person model.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

This study is for research purposes only and you do not have to join the study. If you do not join the study, you will receive the same care and treatment you would otherwise receive from CAPS.

This treatment might include:

- Talk therapy and counseling
- Support groups
- Referrals to other local caregivers for medication and/or counseling

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Being in a research study involves some loss of privacy. We will collect personal information like your name, date of birth, address, and health related information. We understand that your information is personal, and we are committed to protecting your privacy but we cannot guarantee total confidentiality.

The personal information we collect will be seen by research staff at Duke University, and may be seen by others, including research staff at other sites, staff members at the Duke University Institutional Review Board (IRB), staff members at NIMH, and possibly other people in state and federal agencies, as appropriate. If any of these groups review your research data, they may also need to review your medical record.

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:

1. There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. You have consented to the disclosure, including for your medical treatment; or
3. 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 research team is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The research team may share information gathered during your assessments with your study counselor at CAPS to prevent harm to yourself or others and to help coordinate your care. Members of the research team may also reach out to you directly to gather information about your symptoms and any care you may receive at CAPS or elsewhere.

We will keep your study information in a research record for 7 years after the study is finished. When that time has passed, any information in the research record that identifies you will be removed. The study record might also be destroyed. Research information that is entered into your medical record will stay there forever.

Information we collect during this study might be shared at meetings, or it might be published in a report. If this happens, none of your personal information will be included.

Because email and texting are not completely secure and confidential, please call us if you want to guarantee privacy.

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.

Risks Associated with Audio-Recording or Video-Recording

Risks from audio- or video-recording therapy and assessment sessions include possible loss of privacy if the recordings are hacked or made available to non-study personnel. We will store and encrypt digital video recordings of your therapy sessions and assessments.

Encrypted video files will be shared with study staff at other institutions on HIPAA-compliant cloud servers. We label all recordings with your study ID number (not your name) and only study staff, both clinicians and researchers, will have access to them. We will not allow any further use of the recordings without your written permission.

We will keep video and audio data in your research record for seven (7) years after the study is completed. At that time, either the research information may be destroyed or information identifying you will be removed.

NIMH Data Sharing

Data from this study will be sent to the NIMH Database (NDA) at the National Institutes of Health (NIH). NDA is a large database of de-identified study data from many NIMH studies. De-identified study data means that all personal information about you (like name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your de-identified study data helps researchers learn new and important things about mental health and substance use more quickly.

During and after the study, the researchers will send de-identified study data to the NDA. Other researchers across the world can then request your de-identified study data for their research. Every researcher (and institutions to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity.

Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with the NDA. The study data provided to the NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will never be contacted directly about the study data you contributed to the NDA.

How Will My Information be De-identified?

For our data sharing with the NDA, a unique identification number (Global Unique Identifier, or GUID) will be created for you. The GUID is in addition to your study ID and this number will be used to connect (link) your research information from this study to other research studies that you may participate in that also use the GUID system. To receive this number, study staff member will utilize a secure internet website on a computer at the research clinic (or alternate remote, secure means) and enter information about you: your first, middle and last names at birth, any suffixes (Jr., III, etc.), your date of birth, name of the city where you were born, and your country of birth. Once the GUID is created, your personal information will be deleted from the NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be sent to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today.

If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell the NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about the NDA, visit http://nda.nih.gov.

Choose the option you prefer below and initial each one.

Yes ☐ No ☐ I consent to allow my study data to be sent to the NDA. _____

It is required by law to post this clinical trial on the website https://clinicaltrials.gov/. This post might include a summary of the study's results. There will be no information that can identify you. You can search this website at any time.

WHAT ARE THE COSTS TO YOU?

There is no additional cost to be in this study. The normal services you receive at CAPS are covered by the counseling fee you pay every semester and summer. As long as you are eligible to receive CAPS services, you may participate in the study. 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.

WHAT ABOUT COMPENSATION?

You will be paid for completing assessments at the following times:

- Baseline ($40)
- Mid Stage 1 ($20)
- End of Stage 1 ($40)
- Mid Stage 2 ($20)
- End of Stage 2 ($50)
- 3-month Follow-Up ($50)

- Therefore, the maximum total reimbursement if you complete all study assessment visits is $220.

Table 2. Assessment Payments by Visit

	Assessment Point					
Type	**Baseline**	**Mid Stage 1**	**End Stage 1**	**Mid Stage 2**	**End Stage 2**	**3 Month Follow Up**
Visit Reimbursement	$40	$20	$40	$20	$50	$50

To process your payment, we may need to collect your social security number. This information will be kept in a separate location from you research data and will be destroyed once your reimbursements have been processed.

WHAT ABOUT RESEARCH RELATED INJURIES?

If you are injured because of being in this study, immediate necessary medical care is available at Duke University Health System. However, there is no commitment by Duke University Health System, study researchers, or the study sponsor to provide financial compensation or free medical care in the event of a study-related injury.

If the researcher believes you need a higher level of care (like hospitalization or ambulance rides), the costs for that care will be the responsibility of your insurance, you, and/or your family as regular medical care.

For questions about the study or research-related injury, contact Dr. David Goldston at (919) 678-0074 during regular business hours and at 919-619-5710 after hours and on weekends and holidays.

In addition, if you experience an adverse event or serious adverse event while you are a participant in the study, you may be contacted by a research staff to gather additional information and details about the event.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to join the study. If you do join the study, you may choose to leave the study at any time, for any reason. If you choose to leave the study, it will not affect your job status if you are a Duke University employee and/or your grades if you are a Duke University student.

If you do not sign this form, you will continue to receive care, but not as a part of this study. It is normal for CAPS to refer students to other providers if their problems are severe or complex. It is possible that CAPS may refer you to other providers for this reason. If this happens, it is not a penalty for choosing not to join the study.

If you choose to leave the study early, no new information about you will be collected unless there is an adverse event (a bad effect) related to the study. If an adverse event happens, we may need to review

your medical record. Any information we collect about an adverse event related to the study will be sent to the study sponsor (NIMH).

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke University. If you withdraw, we ask that you contact David Goldston in writing and let him know that you are withdrawing from the study. His email address is: david.goldston@duke.edu. Please note that if you leave the study, we will ask if you are willing to complete all future assessments. However, you may also withdraw from both treatments and assessments.

We will tell you about new information we learn during the course of this study that might affect your health, welfare, or willingness to stay in this study.

Involuntary Termination from Treatment

If you miss 4 appointments in a row and the study team and counseling center do not hear from you during this time frame, we will assume you are dropping out of the treatment component of the study. Dr. Goldston or the study's review board may also remove you from the study if they find it necessary for your safety or well-being. Regular ups and downs are normal for people who have suicidal thoughts. However, if you appear to be getting much worse during the study, we must try a different treatment. If this happens, Dr. Goldston and your counselor will explain your removal and discuss other treatment options with you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Goldston at (919) 678-0074 during regular business hours and at (919) 619-5710 after hours and on weekends and holidays.

Please contact the Duke University Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have questions about your rights as a research participant.
- You want to discuss problems, concerns, or suggestions related to this study.
- You want to obtain information or offer input about this study.

STATEMENT OF CONSENT

"The study team has explained the purpose of this study, the things that will happen, and the risks and benefits. I have been given the time to ask questions and the study team has answered them in full.

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I know who to contact if I have any questions, comments, concerns, or suggestions or if I want to discuss any problems related to the study.

I have read this consent form and agree to be in this study, knowing that I can withdraw at any time. The study team will give me a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time