# KEY INFORMATION FORM FOR TELE-CBT-DD

We are asking you to choose whether or not to volunteer for a research study about a diabetes research study called Cognitive Behavioral Therapy to Treat Diabetes Distress in Young Adults with type 1 diabetes (CBT-DD). We are working to test a new care program created for young adults with T1D that we hope will decrease diabetes related stress, increase the emotional well-being, and improve blood sugar control. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

## WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The 12 month diabetes program consists of one-on-one sessions with a licensed psychologist to discuss diabetes management, problem-solving therapy, relaxation and stress management, along with continuous glucose monitor weekly review and feedback as part of the process. We will supply you with all of the CGM products for the duration of the study. Cognitive behavioral therapy has been shown to help other people with diabetes reduce diabetes distress and improve blood sugar control, but has not been tailored to young adults with type 1 diabetes before, even though there is an urgent need, and has never been paired with CGM feedback which might make more positive effects last longer.

By doing this study, we hope to learn about and improve diabetes distress (DDS) in young adults with Type 1 diabetes, using Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD).

Your participation in this research will last about 12 months.

## WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We are asking you to join this study because your doctor identified you as someone eligible to participate based on your age, type 1 diabetes diagnosis, and risk for diabetes stress. For a complete description of benefits, refer to the Consent Document below. The possible benefits of taking part in this study include reduction of diabetes stress and increase of emotional well-being, as well as improved blood sugar control.

## WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

We do not think there are any physical risks related to participating in this research study.You may be uncomfortable answering some questions. You do not have to answer all the questions and you may stop at any time. We will do our best to keep your information safe by using a special code in research records. However, a risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. *For a complete description of risks, refer to the Consent Document below.*
For a complete description of alternate treatment/procedures, refer to the Consent Document below.

## DO YOU HAVE TO TAKE PART IN THE STUDY?

You do not have to participate. It is your choice. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

## WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Shivani Agarwal and Dr. Jeffrey Gonzalez. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 646-592-4506. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einsteinmed.org.

**ALBERT EINSTEIN COLLEGE OF MEDICINE**
**MONTEFIORE MEDICAL CENTER**

**DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION**

## Introduction

You are being asked to participate in a research study called ***Telemedicine-Delivered Cognitive Behavioral Therapy to Reduce Stress in Young Adults with Type 1 Diabetes (Tele-CBT DD)***. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Their names are Dr. Shivani Agarwal & Dr. Jeffery Gonzalez. You can reach Drs. Agarwal & Gonzalez at:

**Office Address: 1180 Morris Park Ave**
**Bronx, NY, 10461**
**Telephone #: 646-592-4506**
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by the Juvenile Diabetes Research Foundation and DexCom Inc.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.org , or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

## Why is this study being done?

The goal of this study is to assess and to improve diabetes distress (DDS) in young adults with Type 1 diabetes, using Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD). Young adulthood (ages 18-30 years) is a developmentally challenging period of life accompanied by profound changes in geographic, vocational/educational, financial, and social situations. Concurrently, many young adults (YA) with chronic disease undergo a healthcare transition from pediatric to adult care. For YA with T1D, these changes, along with newfound independence, compete with disease self-management and attainment of optimal glycemic control. YA have some of the highest HbA1c levels of all age groups with T1D. While recent behavioral interventions in YA with T1D show improvement in glycemic control and engagement in clinical care, these high-touch interventions usually required skilled multidisciplinary teams that are not readily available (MD, OT) and do not offer commercially available strategies, thus limiting implementation and dissemination. Moreover, they do not target diabetes distress specifically, which leaves gaps in our understanding of whether targeting a specific psychological issue that is highly prevalent in YA with T1D will improve glycemic control.

**Why am I being asked to participate?**

You are being asked to participate in this study because your doctor identified you as someone eligible to participate based on your age, type 1 diabetes diagnosis, and risk for diabetes stress. You also meet the study inclusion criteria of (1) T1D duration ≥6 months; (2) 18-30 years old; (3) HbA1c ≥8.5-14%; (4) English- or Spanish-speaking (5) At least moderate DD (score of ≥2 on T1D-Diabetes Distress Scale19); (6) Stable insulin treatment regimen (insulin prescription, use of pump, etc.) for at least 3 months prior to study enrollment. We plan to enroll 150 young adults with type 1 diabetes from the Supporting Emerging Adults with Diabetes (SEAD) program at the Fleischer Institute at Einstein (Bronx, NY), the Diabetes Center at Children's Hospital at Montefiore (Bronx, NY), the T1D Exchange National Registry (Boston, MA), and public sources using T1D organizations, influencers, and blogs.

**What will happen if I participate in the study?**

If you say yes, you will first undergo a diagnostic interview by a licensed psychologist to determine if you have underlying clinical depression, anxiety, eating disorders, or other psychiatric disorders which might not be best suited for the therapy provided in this project, and thus exclude you from participating. If you are deemed to have a psychological condition that you were unaware of or need help finding treatment for that qualifies for exclusion from this study, we will do our best to supply you with local mental health resources for you to get adequate care for your condition.

After you screen eligible for the study, you will have a virtual study visit for all explanations of procedures and setup of study supplies. Please refer to the Figure for the following explanation of the timeline of the study procedures. For the first 2 weeks of the study, you will be asked to wear a CGM that we supply to you, in addition to whatever CGM you may also have, and answer cell-phone survey questions daily. The cell phone surveys will be delivered to you via a smartphone app that we will help you set up at the first virtual study visit. Questions asked on the cell phone will pertain to distress related to having and managing diabetes, how you manage your diabetes, physical activity, diet, and sleep. We will not be able to see your data at this time.

After this initial 2-week period, you will be randomly assigned to participate in either the diabetes program (Tele-CBT DD) virtual video sessions or CGM only where written educational materials on diabetes distress will be provided. The core part of the diabetes intervention program, if you are assigned to the treatment, will consist of 8-10 weekly sessions over 3 months with a licensed psychologist, all delivered by video visit or in person if desired and close to the Bronx, where the study site is. To review, the CBT one-on-one sessions will be tailored to your specific requests and needs to discuss diabetes management, problem-solving therapy, relaxation and stress management, as well as CGM weekly review and feedback as part of the process. During the 3 months of CBT or CGM only, you will be assigned weekly cell-phone surveys to complete before CBT sessions.

After the 3 months of either CBT sessions or CGM only, you will enter a 2-week post-intervention period where you will continue to wear the CGM and answer cell phone surveys daily again. This first phase of the project is 3 months. After the 3 months are over, you will have a virtual study visit where you will be asked to stop the cell phone surveys, and mail any study supplies back. You will be asked to wear the CGM for another 3 months past the intervention,

for a total of 6 months. At 12 months from the start, you will have a final study visit to end the study.

At the beginning of the study (baseline), 3 months, 6 months, 9 months, and 12 months, you will be asked to fill out surveys sent to your phone or email address. In addition, at each of these time points, you will be asked to check your HbA1c level with a mailed test kit to your residence. We will instruct you how to use the kit and how to mail in the package back to the laboratory for processing, which you must do immediately, both so that the test does not expire and we can have your results, but also because mailing everything in a timely fashion is linked to your compensation for participation in the study. If you do not have a working smart phone, we can loan you a study phone that you can use during the entirety of the study, but you must return the phone back to us at the end of the study. All cell phone plans will be automatically turned off and phones reported as stolen if study phones not returned to us within a timely fashion after the study has ended.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S.law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As part of this study we will review your medical records and put the information we collect in our research records.

**How many people will take part in the research study?**

You will be one of about 150 people who will be participating in this study. The study will be conducted at approximately 2 locations outside of Montefiore Medical Center/Albert Einstein College of Medicine/North Bronx Health Network.]

**Will there be audio and/or video recording?**

Participants' CBT one-on-one sessions will be recorded with video and sound via video conference. Participants face's will be recorded, however; no identifying characteristics of individuals will be published or presented. These recordings will only be used for tabulation of specific criteria by the research team, including our licensed psychologists, to assess and review CBT sessions and intervention fidelity checks throughout the 12 month period. The confidentiality of data will be maintained by using research identification numbers that uniquely identify each individual. Safeguards will be established to ensure the security and privacy of participants 'study recordings. All recordings will be destroyed after study analysis for intervention fidelity.

**Information Banking (Future Use and Storage)**

No Data is Stored

Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

**Will I be paid for being in this research study?**

You will receive a total of $575 for study visits over the 12 month period. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

**Will it cost me anything to participate in this study?**

There will be no cost to you to participate in the study.

**Confidentiality**

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

## Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details. Per FDA guidance, there is a low risk for developing a local skin infection at the site of the FDA-approved commercially used CGM sensor needle placement. Pruritis, redness, bleeding, and bruising at the insertion site may occur as well as local tape allergies. Participants will be given both the written instruction manual and visual/verbal instructions on the baseline visit call, that are FDA-approved for commercial use. In addition, a minimal amount of blood (<1 cc blood) will be used for test results. Participants will be able to contact study staff for any issues with HbA1c testing, which are minimal risk. The intervention does not convey more than minimal risk and there is no reason to suspect that any serious adverse events will be attributable to it.

**Questionnaire**
You may be uncomfortable answering some questions. Participants will complete smartphone-delivered questionnaires, which include questions about their unique experiences, private attitudes, feelings and behavior related to diabetes. It is possible that some people may find these questionnaires to be mildly upsetting. Similar questionnaires have been used in previous research and these types of reactions have been uncommon. Subjects may choose to not answer questions. Given that most participants will be familiar with smartphones prior to this study, it is unlikely that there will be discomfort in using these devices. You do not have to answer all the questions and you may stop at any time. We will do our best to keep your information safe by using a special code in research records.

**New Findings**
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

## Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include reduction of diabetes stress and increase of emotional well-being, as well as improved blood sugar control.

## Alternative Proposals

The alternative is for potential subject to not participate in the study. If potential participants decline to enroll in the study but express interest in accessing care, we will inform them of the procedures to do so.

## Are there any consequences to me if I decide to stop participating in this study?

If you decide to take part in the study, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at your facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she/he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

**Can the study end my participation early?**

We will not let you participate in the study any more if during the screening diagnostic interview and over the course of the CBT sessions, licensed psychologists/CBT protocol therapists assess intent to harm oneself or others. Licensed clinical psychologists are trained on how to appropriately respond to expression of intent to harm self or others, and will maintain a Manual of Procedures (MOP), which includes state law requirements and local emergency phone numbers. If developed over the course of the study and identified, that participant will be withdrawn from the study but their data accruing until the point of withdrawal may be used.
In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

## CONSENT TO PARTICIPATE

Do you have any questions?

Do you voluntarily consent to participate in this research? (Record potential subject's response)
[ ] Yes [ ] No

| | | |
|---|---|---|
| _____ | | _____ |
| Printed name of participant | | Date |
| _____ | _____ | _____ |
| Printed name of the person conducting the consent process | Signature | Date |