Official title:	Improving Glycemia & Reducing Diabetes Distress in Adolescents & Young Adults With T1D: Healthy And Positive Pathways for Young People With Type 1 Diabetes (HAPPY T1D)
NCT number:	NCT05413239
Document:	Informed consent and assent form
Document date:	01/30/2023

Joslin Diabetes Center	Key Information for Study Participation			
	CHS Protocol Number	STUDY00000154	*Version Date*	01/30/2023

Principal Investigator	**Lori Laffel, MD, MPH**
Study Title	**Improving Glycemia and Reducing Diabetes Distress in Adolescents and Young Adults with Type 1 Diabetes: *Healthy And Positive Pathways for Young People with Type 1 Diabetes (HAPPY T1D)***

We are asking you (for adults) or your child (for parents/guardians of children under age 18) to participate in this research study. *"You" or "your" refers to the person who has been asked to participate.*

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the study at any time. Your decision will not impact the clinical care you receive at the Joslin Diabetes Center.

We are doing this study to find out if monthly 1-on-1 sessions can help increase percent time-in-range (70-180 mg/dL) and reduce diabetes distress in teens and young adults with type 1 diabetes.

Summary of Procedures

This study will last for 2 years. It has 3 parts:

- **In-clinic study visit at Joslin every 6 months (5 visits total)**
  - Each visit will be about 30 minutes.
  - Each visit will involve the following procedures: questions about medical information and diabetes treatment, fingerstick for A1c, surveys.
- **CGM data collection every 3 months (9 times)**
  - If you are already using CGM, you will wear your own CGM system during the study.
  - If you are not currently using CGM, you will wear the FDA-approved Dexcom CGM system for 14 days every 3 months.
- **Monthly one-on-one sessions with a member of the study team (12 sessions total)**
  - At the first study visit, you will be randomly assigned (like flipping a coin) to 1 of 2 groups.
    - If you are in Group 1, you will have the monthly sessions during the 1st year of the study.
    - If you are in Group 2, you will have the monthly sessions during the 2nd year of the study.
  - Each session will be about 30 minutes.
  - During each session, you will meet with a member of the study team (in-person or remotely) to discuss strategies for improving glycemic control and reducing diabetes distress.

For more information about study procedures, see the "Study Details/Procedures" section of the Research Consent & Authorization Form.

Risks

Likely	Mild to moderate	• Bleeding and/or pain from fingersticks and CGM use
Unlikely	Moderate	• Significant skin redness and/or swelling from CGM use • Discomfort during monthly sessions
	Serious	• Infection from fingersticks and CGM use • Loss of confidentiality (information collected during study obtained by others)

For more information about risks, see the "Study Risks/Discomforts" section of the Research Consent & Authorization Form.

Benefits

Potential benefits include improved glycemic control and decreased diabetes distress. Of course, because individuals respond differently to treatment, no one can know in advance if participating in the study will be helpful for you in particular.

Alternative Treatments

You do not have to participate in this study to receive treatment for your condition. You may continue with your usual diabetes care.

Subject's Name	
Principal Investigator	**Lori Laffel, MD, MPH**
Study Title	**Improving Glycemia and Reducing Diabetes Distress in Adolescents and Young Adults with Type 1 Diabetes: *Healthy And Positive Pathways for Young People with Type 1 Diabetes (HAPPY T1D)***

Introduction

"You" or "your" refers to the person who has been asked to participate in this study – either you (for adult participants) or your child (for parents/guardians of children under 18 years of age).

This is a long and important document. This document describes a research study and explains how your medical information will be used and/or disclosed for the purposes of this research study, if you choose to participate.

You should take the time to read this document carefully. If you choose, you may take a copy of this document to discuss with your physician, legal counsel, family member or anyone else you would like before signing it.

This document may contain information or words that are difficult to understand. It is very important that you ask the study investigator or a member of the study staff to explain any words or information that you do not understand.

Your participation in this research study is completely voluntary. If you agree to participate in this study, you will be asked to sign this form to show your consent to participate and your authorization for the use and/or disclosure of your medical information.

Do not sign this document unless you are comfortable with your decisions regarding both your consent to participate in this research study and your authorization for the use and/or disclosure of your medical information for this research study.

Study Purpose

The purpose of this study is to find out if working with a coach, who is trained in diabetes and the associated stress that often comes with managing diabetes, will help increase the amount of time during the day and night that glucose levels are in range (70-180 mg/dL) and reduce diabetes distress in teens and young adults with type 1 diabetes.

Study Participants

You are being asked to participate in this study because you are 14-25 years old and have type 1 diabetes.

This study is being conducted at the Joslin Diabetes Center (by Dr. Lori Laffel and her research team) and at Stanford University (by Dr. Korey Hood and his research team).

About 90 people will take part in this study at the Joslin Diabetes Center. A total of 180 people will take part in this study at both study sites.

Study Sponsor / Funding

This study is funded by the National Institutes of Health (NIH)/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Study Details / Procedures

This study will last for 2 years. It has 3 parts:

- In-clinic study visit with surveys and A1c every 6 months
- CGM data collection every 3 months
- Monthly one-on-one sessions with a member of the study team (during either the 1st or 2nd year of the study)

During the study, you will keep seeing your regular diabetes health care team for clinic appointments.

During the study, we will call, text, or email you reminders about your study visits and assessments.

IN-CLINIC STUDY VISITS

🗓 Every 6 months, you will come to Joslin for an in-clinic study visit (5 visits total). (If you cannot come to clinic, you may complete the visits remotely.)

🕒 Each visit will last about 30 minutes.

📋 The following procedures will occur at these visits:

- You will answer some questions about: demographic information, medical history, and diabetes treatment.
- You will have a fingerstick blood sample to measure A1c
- You will complete surveys related to diabetes management, diabetes distress/burden, eating behaviors, treatment satisfaction, diabetes technologies, hypoglycemia, diabetes acceptance, and quality of life. You will complete the surveys on a tablet computer. They will take about 20 minutes to complete.
- After the visit, we will collect demographic information, medical history, and diabetes treatment information from your medical record.

CGM WEAR

🗓 CGM data will be collected every 3 months.

- If you are already using CGM, you will wear your own CGM system during the study. We will ask you to provide the study with access to your personal CGM account (e.g., Clarity) for the time that you are in the study so that we can download your CGM data.
- If you are not currently using CGM, you will wear the FDA-approved Dexcom CGM system for 14 days every 3 months. Dexcom is providing the CGM systems to Joslin and Stanford at no cost for the purposes of the study. Dexcom has no other involvement in this study. At the first study visit, we will teach you how to use the CGM system. For each CGM wear period, we will mail the supplies to you or give them to you in the clinic.

- If your downloaded CGM data has <10 days, we will ask you to wear the CGM for additional days.

MONTHLY SESSIONS

At the first study visit, you will be randomly assigned (like flipping a coin) to 1 of 2 groups. You cannot choose what group to be in. The study team cannot choose what group you will be in. You will have an equal chance of being in either group.

- If you are in Group 1, you will have the monthly sessions during the 1st year of the study. During the 2nd year, someone from the study team will contact you each month (by phone, email, or text) for a brief check in about the study.
- If you are in Group 2, you will have the monthly sessions during the 2nd year of the study. During the 1st year, someone from the study team will contact you each month (by phone, email, or text) for a brief check in about the study.

Monthly sessions:

- There are 12 monthly sessions.
- During each session, you will meet with a member of the study team (in-person or remotely) to discuss strategies for improving glycemic control and reducing diabetes distress.
- Remote sessions will be conducted using a secure web-based platform.
- Each session will last about 30 minutes.
- We will record and review the study sessions to make sure that we are doing a good job. We will destroy all recordings at the end of the study.

Study Risks / Discomforts

Participating in research studies often involves some risks, possible risks and/or discomforts.

- ***Confidentiality.*** There is a low risk that information about you collected during the study may be obtained by others outside of the study. This risk will be minimized by training of study staff and secure storage and transmission of study data. Study data sent between the study teams at Joslin and Stanford will be identified by study ID numbers, not participant names, and sent using a secure encrypted system. Secure HIPAA-compliant systems will be used for remote study sessions and online data collection.
- ***Discomfort during monthly sessions.*** One of the goals of the monthly sessions is to help reduce negative feelings about diabetes. Therefore, some of the discussions may make you uncomfortable. If you are feeling uncomfortable at any time, you can ask to stop the session discussion and we will move on to another topic.
- ***Continuous glucose monitoring (CGM).*** The risks associated with CGM use during the study are no greater than usual diabetes care. These risks include skin irritation (redness or rash), itching, bruising, discomfort, pain, and bleeding. There is also a low risk of infection at the insertion site. Infection or excessive bleeding occurs less than 8% of the time sensors are worn. There is a very low risk (about 2 in 10,000 sensor uses) of the sensor tip breaking off and remaining under the skin. If this occurs, you should contact the study team. If the CGM system malfunctions, this may cause hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar).

- ***Fingersticks for A1c.*** You may feel some pain from the fingersticks to measure A1c. In about 1 in 10 cases, a small bruise may develop. The risk of infection is less than 1 in 1000. These risks are no greater than usual diabetes care.

In addition to the risks, possible risks and/or discomforts listed above, there may be risks/discomforts involved in this study that are not known at this time.

New Information and Questions

If any new information about the study becomes known that could affect you or might change your decision to participate in this research study, you will be contacted by the study investigator.

If you have any questions at any time about this study, you may contact the study investigator, Dr. Lori Laffel, at 617-732-2603.

Alternative Procedures/Treatments

You do not have to participate in this study to receive treatment for your condition. You may continue with your usual diabetes care.

Information for Women of Childbearing Potential

If you are a woman who is pregnant or wanting to become pregnant during the next 2 years, you may not participate in this study. If you suspect that you have become pregnant at any time, you must notify the study investigator or study staff. If you become pregnant, you will not be allowed to continue your participation in this research study.

Sharing of Results

Information from this study that is clinically relevant to your diabetes treatment will be documented in your medical record at Joslin for safety purposes.

Removal from Study

Your participation in this research study may be discontinued before you complete the study if circumstances arise which make this necessary. Your participation may be discontinued for any of the following reasons:

- Failure to follow the study protocol;
- Change in your medical condition;
- Discontinuation of the study for any reason by the sponsor, investigator, Joslin Diabetes Center, or government agencies; or
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by research participants in this study.

If you are discontinued from the study for any reason, this will have no effect on your current or future relationship with the Joslin Diabetes Center. You will not be penalized or lose any other benefits to which you are otherwise entitled.

Adverse Events or Injuries

If an adverse event or study-related injury occurs as a direct result of taking part in this study, you should immediately contact the study investigator, Dr. Lori Laffel, at 617-732-2603. On evenings, weekends, and holidays, you should call the on-call Joslin doctor at 617-309-2400.

In the event of an adverse event or study-related injury, you or your insurance company may be responsible for some or all of your medical costs for any necessary medical treatment, which will be arranged by Dr. Lori Laffel and the Joslin Diabetes Center.

It is not the policy of the Joslin Diabetes Center to provide free medical treatment or financial compensation for such things as lost wages, disability, and/or discomfort as a result of an adverse event or study-related injury.

Anticipated Benefits

Based on their previous research, the Investigators believe that the monthly sessions may be of benefit to teens and young adults with type 1 diabetes. The potential benefits include improved glycemic control and decreased diabetes distress. Of course, because individuals respond differently to treatment, no one can know in advance if it will be helpful in your particular case.

Remuneration/Reimbursement

You will receive the following compensation for your time and effort:

- $75 for each 6-month survey/A1c collection (you must complete BOTH the surveys AND A1c)
- $75 for each 3-month CGM data collection

If you complete all surveys/A1cs and CGM data collections, you will receive a total of $1050. You will also receive a parking voucher for each in-clinic study visit.

Since you will be receiving compensation for your participation in this study, Joslin's Fiscal Office requires your name, address and social security number in order to issue the check(s) for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). A Form 1099 will be sent to you by Joslin's Fiscal Office if your total payments for study participation are $600.00 or more in a calendar year.

If this study should result in the development of any marketable product, it is not the policy of the Joslin Diabetes Center to share any profits with participants in the research study.

Future Use of Data/Samples

Identifiable private information collected from you during this study may be used for future diabetes-related studies or shared with other researchers for future diabetes-related research. If the research investigator distributes your information to other researchers or institutions, your information will be labeled with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your information.

Responsibility for Costs

All study-related procedures will be provided to you at no cost. Your or your insurance company will not be billed for the costs of study-related procedures.

The study will not pay for your standard diabetes care (medical appointments, medicines, etc.). These costs will still be billed to you or your insurance company.

There may be extra costs to you (unpaid time off from work, child care costs, etc.) if you participate in this study. The study will not pay for these costs.

Right to Withhold or Withdraw Consent, or Refuse Procedures

Your consent to participate in this research study is completely voluntary. You do not have to give your consent, but you will not be allowed to participate in this research study without providing such consent.

At any time you may withdraw this consent and/or refuse a procedure.

If you withdraw your consent or refuse a procedure, you will not be allowed to continue your participation in this research study. To formally withdraw your consent to participate in this research study, you must provide a written and dated notice of this withdrawal to the study's investigator, Dr. Lori Laffel, at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

If you refuse a procedure, the Investigator will determine if you may continue in the study without completing that procedure or if you must stop participating in the study.

Whether or not you provide your consent to participate in this research study, withdraw your consent, or refuse a procedure will have no effect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with the Joslin Diabetes Center. You will not be penalized or lose any other benefits to which you are otherwise entitled.

Privacy & Confidentiality – HIPAA Authorization

A federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, you must provide written authorization for the use and/or disclosure of your medical information in connection with research involving your treatment or medical records.

This section gives more specific information about the privacy and confidentiality of your medical information. It explains what medical information will be collected during this research study and who may use, disclose or receive your medical information. It also describes how you can revoke this authorization after you sign this document and your right to inspect your medical information.

We will only collect medical information that is needed for this research study. Your medical information will only be used and/or disclosed as explained in this document or as permitted by law.

The results of this research study may be published in scientific journals and/or presented at medical meetings. If the results of this study are published and/or presented, your identity will be kept confidential.

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.

In addition to this document, you will receive the Joslin Diabetes Center's Notice of Privacy Practices, which provides more information on how the Joslin Diabetes Center can use and/or disclose your medical information. If you have not received the Joslin Diabetes Center's Notice of Privacy Practices, please ask the study investigator or a member of the study staff.

Medical Information Involved in this Study

This study may involve the use and/or disclosure of medical information already in your medical record here at Joslin and/or in another health care provider's records. The information that will be used will be limited to information concerning:

- Basic demographic information (for example, date of birth)
- Vital signs, height, weight
- Medical history and new medical information during the study
- Other medical conditions
- Medications
- Diabetes treatment
- Lab data in the medical record (for example, glycemic control [A1c, CGM], lipids, celiac disease, thyroid function)
- Health service utilization (for example, hospitalizations, ER visits, psychological services)

This medical information will be used and/or disclosed only for the purpose of this research study.

Additionally, this research study may generate new medical information that will be placed in your research record and kept at Joslin Diabetes Center. The nature of the medical information resulting from your participation in this research study that will be placed in your research record includes:

- Survey responses
- Interview responses
- CGM data
- A1c results
- Information from monthly sessions

This medical information will be used and/or disclosed only for the purpose of this research study.

Access to Medical Information Involved in this Study

In addition to the study investigators listed on the first page of this document and their study staff, the following individuals may have access to your medical information involved in this study:

- Authorized representatives of the Joslin Diabetes Center Audit and Compliance Office;
- Authorized representatives of the Joslin Diabetes Center Committee on Human Studies;
- Other medical centers/institutions/study investigators outside the Joslin Diabetes Center participating in this research study;

- Governmental entities that have the right to see and/or review research and/or your medical information, such as the Office of Human Research Protections and the Food and Drug Administration;
- Hospital and other accrediting agencies;
- A data safety monitoring board;
- Clinical staff not involved in this study who may become involved in your care, if the medical information is potentially relevant to treatment;

All reasonable efforts will be used to protect the privacy and confidentiality of your medical information. However there is a risk of a breach of confidentiality that cannot be totally eliminated. To minimize this risk, study records will be kept in restricted areas at the Joslin Diabetes Center and computer access will be restricted by a password known only to the authorized members of the staff at the Joslin Diabetes Center. Information that could identify you, such as your name, will be maintained in a file separated from all study information. In spite of these efforts to protect the privacy and confidentiality of information about you, there is a risk that sensitive information may be obtained by others or discovered or inferred by members of your family. For example, a court of law may order Joslin to release confidential information about you.

Additionally, all reasonable efforts will be used to protect the privacy and confidentiality of your medical information when the Joslin Diabetes Center is authorized to disclose such information to others. However, if your medical information is disclosed to a party not required by law to keep it confidential, then that information may no longer be protected, and may subsequently be used and/or disclosed without your permission.

Right to Withhold or Withdraw Authorization

Your authorization to use and/or disclose your medical information for the purpose of this research study is completely voluntary. You do not have to give your authorization, but you will not be allowed to participate in this research study without providing such authorization. At any time you may withdraw this authorization, but you will not be allowed to continue your participation in this research study.

If you withdraw your authorization, no new medical information about you will be obtained. However, medical information obtained for, or resulting from, your participation in this research study prior to the date you formally withdrew your authorization may continue to be used and/or disclosed for the purpose of this research study.

To formally withdraw your authorization to use and/or disclose your medical information for the purpose of this research study, you must provide a written and dated notice of this withdrawal to the study's Principal Investigator, Dr. Lori Laffel, at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

Whether or not you provide or withdraw your authorization for the use and/or disclosure of your medical information for the purpose of this research study will have no effect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with the Joslin Diabetes Center. Additionally, whether or not you provide or withdraw your authorization will have no effect on your current or future relationship with a healthcare insurance provider.

Continuation of Authorization

Your authorization to use and/or disclose your medical information will continue until you withdraw your authorization. Your medical information may continue to be used and/or disclosed for this research study for an indefinite period of time. This is because information and data that is collected for this study will continue to be analyzed for many years and it is not possible to determine when such analysis will be complete.

Access to Medical Information

Except for certain legal limitations, you are permitted access to any medical information obtained for, or resulting from, your participation in this research study. However, you may access this information only after the study is completed.

VOLUNTARY CONSENT & AUTHORIZATION

I understand that no one has contacted my primary care physician or any other doctor from whom I may be receiving care regarding my involvement in this research study. I understand that I should consult with any such doctor, and have been encouraged to do such, prior to participating in this study to discuss whether there is any reason he/she is aware of why I should not participate in this study.

I have been informed of and understand the purpose of the research study entitled **"Improving Glycemia and Reducing Diabetes Distress in Adolescents and Young Adults with Type 1 Diabetes: Healthy And Positive Pathways for Young People with Type 1 Diabetes (HAPPY T1D)"** and the study's procedures. I have been informed of and understand the foreseeable risks, potential risks, discomforts, and benefits associated with this study. I have been advised of and understand that unforeseen complications may occur. I understand that I may or may not be entitled to free medical care or compensation in the event that I am injured as a result of my participation in this study. I understand that if this research study should result in the development of any marketable product, it is not expected that any profits would be shared with me.

I have been informed of and understand that my medical information may be used and/or disclosed for the purpose of this research study. I understand that the study investigators, study staff, and the Joslin Diabetes Center will make all reasonable efforts to protect my privacy and confidentiality. I have been advised of and understand that there is a risk that my medical information may be obtained by others. I have been advised of and understand that if others obtain my medical information, my medical information may no longer be protected, and may be subsequently used and/or disclosed without my permission. I have been informed of and understand that this study may be published or otherwise shared for scientific purposes. I understand that my name will not be published and that every reasonable effort will be made to protect my confidentiality.

I have been informed of and understand that my participation in this study is completely voluntary. I may refuse to consent to my participation in this study. Once enrolled in this study, I may withdraw my consent or refuse a procedure at any time. I may refuse to authorize the use and/or disclosure of my medical information for the purpose of this study. Once enrolled in this study, I may withdraw my authorization at any time. I have been informed of and understand that I will not be allowed to participate in this study, or continue my participation in this study, without both my consent and authorization.

I have read this document and been provided with the opportunity to discuss any questions and/or concerns regarding the research study and/or this document with the study investigator or a member of the study staff. I have received the Joslin Diabetes Center's Notice of Privacy Practices.

I have been informed of and understand that I may contact the Joslin Diabetes Center's Committee on Human Studies if I have questions regarding my rights as a research participant in this study. I may contact either:

- **Leigh A. Read, CIP**, Research Compliance & Programs Director at **(617) 309-2543**
- **Robert C. Stanton, M.D.**, CHS Chairperson, at **(617) 309-2477**

I have been informed of and understand that I may contact the Joslin Diabetes Center's Chief Audit and Compliance Office if I have questions regarding my rights associated with the use and/or disclosure of my medical information. I may contact:

- Joslin Diabetes Center's Compliance Officer, at **(617) 309-2400**

This is a legal document that may affect my legal rights, my rights to privacy and my medical conditions and information. I understand that I have had the opportunity to consult with legal counsel, and my own physician about this study before signing this form.

I will be given a copy of this form in case I want to read it again.

CONSENT *(FOR SUBJECTS 18 YEARS OR OLDER OR PARENT/LEGAL GUARDIAN)*

I, _____, hereby provide my consent for me or my child, _____, to participate in this study and authorize the use and/or disclosure of my/my child's medical information for this research study, as described in this document.

_____ _____

Signature (Adult Participant or Participant's Representative) *Date*

_____ _____

Print your name (Adult Participant or Participant's Representative) *Relationship to Participant*

PLEASE NOTE

I do not have to provide my authorization for the use and/or disclosure of my or my child's medical information for this research study, as described in this document. If I do not want to provide my authorization, I must check the box below and initial this statement. If I do not provide my authorization, I may not be able to participate in this study.

☐ I **do not** authorize the use and/or disclosure of my medical information for this research study, as described in this document. _____ Participant's Initials

ASSENT *(FOR SUBJECTS AGES 13-17)*

I, _____, hereby assent to participate in this study and authorize the use and/or disclosure of my medical information for this research study, as described in this document.

_____ _____

Signature (Participant under age 18) *Date*

_____

Print your name (Participant under age 18)

VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled **"Improving Glycemia and Reducing Diabetes Distress in Adolescents and Young Adults with Type 1 Diabetes: Healthy And Positive Pathways for Young People with Type 1 Diabetes (HAPPY T1D)"**, the nature of the study procedures, and such foreseeable risks, potential risks, discomforts, and benefits that may result from their participation in this study. This explanation was made in appropriate language. I have advised the above-named participant to contact their primary care doctor regarding his/her participation in this study, if such contact has not been previously made. I have asked the above-named participant if they have any questions and/or concerns regarding this research study or any of the study's procedures, and I have answered his/her questions to the best of my ability.

I hereby certify that I have explained to the above-named participant the nature and purpose of the use and/or disclosure of his/her medical information, including the possibility that his/her medical information may be obtained by others. This explanation was made in appropriate language. I have asked the above-named participant if they have any questions and/or concerns regarding the use and/or disclosure of his/her medical information for the purpose of this research study, and I have answered his/her questions to the best of my ability.

I hereby certify that I have informed the above-named participant that his/her participation in this research study is completely voluntary. To the best of my knowledge, the decisions made by the above-named participant regarding his/her consent and authorization are accurate reflections of his/her personal choices. To the best of my knowledge, the above-named participant has not been coerced or induced into his/her participation in this research study.

_____ _____

Signature of Investigator or Investigator's Representative *Date*

_____

Investigator or Investigator's Representative (Print Name)