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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)***

I. Objectives

The primary objective is to implement and assess the impact of an intervention to reduce diabetes distress and improve glycemic outcomes in adolescents and young adults with type 1 diabetes (T1D). Within a 2-year randomized clinical trial, participants will be randomly assigned to either the usual care control condition or the intervention group. The intervention consists of one-on-one monthly intervention sessions aimed at improving glycemic outcomes (4 sessions) and diabetes distress outcomes (8 sessions). To ensure adequate recruitment and retention, the control group will receive a delayed intervention and participate in the monthly sessions during the second year of the study. Both groups will provide continuous glucose monitoring (CGM) data every 3 months and complete surveys every 6 months. A1c will be measured centrally every 6 months. We will compare the two groups on the primary outcome of percent time-in-range (TIR) of 70-180 mg/dL assessed by CGM and on the secondary outcomes of diabetes distress and A1c from baseline to 1 year. We hypothesize that the intervention group will demonstrate an improvement in percent TIR, diabetes distress, and A1c compared with the usual care control group.

II. Background

Adolescents and young adults with T1D are especially at risk for missed diabetes visits and suboptimal self-care behaviors, as evidenced by their poor glycemic control with very high A1c levels. Even with intensive T1D management and the use of advanced diabetes technologies, such as insulin pumps, continuous glucose monitors (CGM), and some automated insulin delivery systems, many struggle to meet treatment targets for time-in-range (TIR) target glucose of 70-180 mg/dL and A1c <7%, often due to competing life demands and self-care burdens associated with diabetes therapies. As a group, adolescents and young adults with T1D represent the subpopulation of all persons with T1D across the lifespan that has the poorest glycemic control, reaching a peak mean A1c value >9% at age ~19 [1].

In addition, diabetes distress is common in adolescents and young adults with T1D and contributes to their suboptimal self-care behaviors and outcomes. Diabetes distress is driven by the burden and worries associated with daily management. Symptoms may appear similar to depressive symptoms – frustrations, anger, mood changes, and change in behaviors – but they are the result of the complex and demanding nature of diabetes management. Multiple studies and clinical observations show that diabetes distress is associated with poorer diabetes self-care and higher hemoglobin A1c values [2-5].

The American Diabetes Association (ADA) recommends routine screening for diabetes distress using validated surveys and, when identified, referral for diabetes education or mental health treatment [6]. Persons experiencing diabetes distress are at increased risk for missed medical appointments and deficient diabetes self-management. This is concerning because, without intervention, diabetes distress does not remit and either remains stable or intensifies over time. Further, adolescents and young adults may not adequately access or use advanced diabetes technologies due to perceptions of possible increases in self-care burden and diabetes distress when, in fact, such technologies could aid in their efforts to enhance self-care and improve glycemic control.

To improve glycemic outcomes and reduce diabetes distress in this high risk age group, our study will test a new, theoretically-grounded intervention that is rooted in evidence-based components. Specifically, the components are from

Drs. Laffel and Hood's collective studies aimed at improving these outcomes in this age group. Dr. Korey Hood is Professor of Pediatrics, Psychiatry & Behavioral Sciences at Stanford University and a former fellow and Research Associate at Joslin. Drs. Laffel and Hood have collaborated for nearly 20 years. Clinic-based research conducted by Dr. Laffel has been shown to lower A1c and improve psychosocial outcomes [7-10]. In fact, in a meta-analysis of programs that improve A1c, the Joslin Care Ambassador program was 1 of just 3 to demonstrate efficacy [11]. A recent study conducted by Dr. Hood that was aimed at depression prevention in adolescents with T1D showed distress reduction as far out as 3 years post-intervention [12]. However, A1c was only stabilized in this study and not improved, albeit more favorable than the alternative of an increase. Thus, this study will combine the evidence-based components from these programs in order to improve both glycemic and distress outcomes in adolescents and young adults aged 14-25 years in suboptimal glycemic control with A1c values 7-13%.

III. Study Design

a. Recruitment Methods

Potential participants will be recruited from the Joslin and Stanford pediatric and adult diabetes clinics. Participants will be recruited by referrals from clinicians, flyers, postings on the clinic/institution websites, and from study listings in clinic/institution publications (e.g., newsletters, clinicaltrials.gov). Other potential participants who contact the 2 clinical sites will also be considered for enrollment. All recruitment materials will be approved by the CHS prior to use.

Study staff will request a partial waiver of authorization for recruitment to obtain PHI from medical records in order to identify and contact potential study participants.

If recruitment is slower than expected, additional participants will be recruited from outside of the Joslin and Stanford diabetes clinics using CHS-approved recruitment materials (e.g., flyers, online postings) that have been approved for this purpose.

b. Inclusion and Exclusion Criteria

Eligibility will be assessed by a combination of self/parent-report, medical record review, and investigator assessment.

Inclusion criteria:

- Age 14-25 years
- Diagnosis of type 1 diabetes (according to ADA criteria)
- Type 1 diabetes duration ≥12 months
- A1c 7-13%
- Smartphone or regular access to wifi via computer
- Fluency in English at a 5th grade level or higher (based on investigator assessment of grade level in school or highest grade level achieved and presence in mainstream academic classes)

Exclusion criteria:

- Physical or mental health condition that in the determination of the investigators may limit the ability to fully participate in the study (e.g., autism)
- Participation in another intervention study within the last 3 months
- Currently pregnant or intending to become pregnant during the study *(assessed by self-report)*

Special populations: Children ages 14-17 will be included in the study. Adults unable to consent and prisoners will not be included in the study. Women who self-report that they are pregnant or intend to become pregnant will not be included in the study. If a female participant becomes pregnant during the course of the study, they will complete a final study visit and will be referred to a pregnancy clinic.

c. Number of Subjects

We will enroll 180 participants across both sites, with approximately 90 at each of the 2 study sites.

Power calculations indicate that 148 participants (74 participants per group) are needed to test the intervention vs. the control group. This number does not account for attrition, which we estimate at 15-20%. Thus, we will enroll 180 participants to account for attrition in order to have 148 analyzable participants. This assumes an alpha of 0.05, power (1-beta) of 0.90, a one-sided test, and effect size of 7% TIR change (Cohen's d of 0.58) for the intervention vs. control group. We are assuming this effect given outcomes data that showed this effect size and little change in the control group. In the recent CGM Intervention in Teens and Young Adults with T1D (CITY) study, there was close to a 7% TIR change [13]. While clinical guidelines recommend 5% as being clinically significant, we will power off the CITY findings and a more robust clinical effect. Considering these assumptions and estimates based on data, a total enrolled sample size of 180 will be sufficient to conduct all planned analyses with sufficient statistical power.

d. Study Timelines

Each participant will be in the study for 2 years.

We anticipate that enrollment of all participants will be completed by May 2023.

We anticipate that analyses of the primary outcomes will be completed by March 2025

e. Study Endpoints

Primary endpoint: Time-in-range (TIR) (70-180 mg/dL), measured by CGM

- Hypothesis 1a: The intervention will improve glucose TIR by at least 7%.
- Hypothesis 1b: The intervention will show statistical improvement versus usual care.

Secondary endpoints: Diabetes distress, A1c, and attitudes toward diabetes device use

- Hypothesis 2: In comparison with usual care, intervention participants will show statistical and clinically significant improvements in diabetes distress, A1c, and diabetes device attitudes.

f. Study Procedures

After participants provide informed consent, they will be randomized 1:1 to either the intervention or control group. Randomization will be stratified on two variables, A1c (7-<8.5% vs. 8.5-13%) and age (14-18 vs. 19-25), using a permuted block design. We will also monitor enrollment regularly to ensure representation of the lower and higher A1c strata as well as the younger and older age strata, with the goal that at least 40% (up to 60%) of the sample will have A1c values 7-<8.5% and 40% (up to 60%) will be aged 14-18 years old. Separate randomization lists will be generated for each site to prevent an imbalance in group assignment across sites. Randomization will be overseen by a member of the study team who is not directly involved in recruitment.

Intervention Group: Participants in the intervention group will participate in monthly one-on-one intervention sessions (see below) during the first year of the study, followed by 12 months of follow-up to assess durability of the intervention. During the 12-month follow-up period, these participants will receive a monthly contact (by phone, email, or text) as brief check-ins, similar to the contacts for the control group during year 1.

Control Group: During year 1, participants in the control group will receive a monthly contact (by phone, email, or text) as attention control. These contacts will be brief check-ins and reminders about what the next study procedure will be. During year 2, participants in the control group will receive the monthly intervention sessions.

Both Groups: Participants in both groups will have an in-clinic study visit every 6 months (for biomedical data collection, A1c, and surveys) and have their CGM data downloaded every 3 months, as described below.

	Mo. 0	Mo. 3	Mo. 6	Mo. 9	Mo. 12	Mo. 15	Mo. 18	Mo. 21	Mo. 24
CGM	X	X	X	X	X	X	X	X	X
A1c	X		X		X		X		X
Surveys	X		X		X		X		X
Biomedical data	X		X		X		X		X

- ***CGM wear.*** CGM data will be collected every 3 months. Participants who are using CGM will wear their own CGM system. Participants who are not using CGM will wear the FDA-approved Dexcom CGM system. If a participant's downloaded CGM data reveals <10 days, they will be asked to complete 14 additional days of CGM wear. Participants who are using their own CGM system will be asked to provide the study with access to their personal CGM account (e.g., Clarity) for the duration of the study so that study staff can download their CGM data.
- ***A1c.*** Every 6 months, a fingerstick blood sample will be collected from the study participant and sent to the central laboratory at the University of Minnesota. Remote visits may be used for A1c collection if a participant cannot come to the study site. In these cases, a home collection A1c kit and instructions will be mailed to the participant and study staff will video conference the participant to instruct them on procedures if desired.
- ***Surveys.*** Every 6 months, participants will complete the following surveys on REDCap (completion time: ~20 minutes). In the case of technical problems, the surveys will be completed on paper and entered into REDCap by study staff after the visit.
  - Demographics survey (baseline only)
  - PROMIS Global Health Measure
  - Problem Areas in Diabetes – Pediatric Version (PAID-Peds)
  - Problem Areas in Diabetes – Emerging Adult Version (PAID-EA)
  - Diabetes Distress Scale
  - Diabetes Eating Problem Survey – Revised
  - Diabetes Technology Attitudes Scale
  - CGM Benefits and Burdens Scale
  - Glucose Monitoring Satisfaction Survey
  - Blood Glucose Monitoring Communication (BGMC) Questionnaire
  - Hypoglycemia Confidence Scale
  - Fear of Hypoglycemia Screener
  - Accepting Diabetes and Personal Treatment (ADAPT) survey
  - Diabetes Strengths and Resilience – Teen (DSTAR-Teen)
  - Readiness for Independent Self-Care Questionnaire – Teen (RISQ-T)
  - Social determinants of health survey (completed at 6 months only)
- ***Demographic/biomedical data.*** Every 6 months, demographic/biomedical data (e.g., medical history, diabetes treatment, adverse events, medical or psychological services received during the study) will be collected by chart review and participant self-report (in REDCap or on paper).

All participants will continue to receive their routine diabetes care from their usual diabetes providers throughout the study.

Study staff will contact participants before each visit/session as a reminder.

In-person visits may be conducted remotely if necessary.

If a participant misses a study visit, the study procedures from the missed visit will be completed at the participant's next study visit.

Intervention Sessions

There are 12 monthly intervention sessions: 4 sessions focus on improving glycemic outcomes and 8 sessions focus on reducing diabetes distress. The distress sessions occur at twice the frequency to allow sufficient time to teach the problem-solving and cognitive behavioral components of the intervention. The intervention is rooted in the individual's daily experience by targeting diabetes situations such as experiencing a high or low blood glucose with the need to adjust and administer insulin. These situations have glycemic and psychosocial consequences. Our collective data suggest both kinds of sessions (glycemic and diabetes distress) are necessary to optimize outcomes in this age group.

The intervention sessions will be led by an interventionist who is trained and supervised by study staff. Each session will last about 30 minutes.

Intervention Session Schedule:

Session	Month Received by Intervention Group	Month Received by Control Group
Glycemic #1	0	12
Distress #1	1	13
Distress #2	2	14
Glycemic #2	3	15
Distress #3	4	16
Distress #4	5	17
Glycemic #3	6	18
Distress #5	7	19
Distress #6	8	20
Glycemic #4	9	21
Distress #7	10	22
Distress #8	11	23

Sessions may be conducted in-person or remotely. Remote intervention sessions will be conducted using a secure web-based platform. Technology and set-up instructions will be given to participants after they agree to participate. Study team members will help with set-up and troubleshooting. Participants and study staff can view the electronic worksheets, materials, and video images of each other simultaneously. Parents of participants <18 years old may attend study sessions if desired. However, the content of the sessions will be focused on the adolescent.

Participants will be contacted between sessions to follow up on session content, goals, etc.

Intervention sessions with participants will be recorded so that study staff can evaluate the delivery of intervention materials and retrain study staff as needed to ensure integrity and fidelity of intervention delivery. A random sample of approximately 10-25% of sessions will be reviewed by study team members to evaluate intervention delivery.

g. Data and Specimen Banking

No biospecimen samples will be maintained after the study is over.

h. Data Management

Data Management

Research data will be obtained from electronic medical records, clinician reports, computerized databases, surveys, participant interview, and data downloaded from CGM devices. After data are obtained from these sources, they will be coded in compliance with HIPAA regulations to protect the identity of participants. Each participant will be assigned a unique study ID code and data will be linked by this study ID rather than by name or other personal identifiers. Data will entered into password-protected electronic databases with access limited to appropriately assigned and trained staff. Our study database will utilize REDCap (Research Electronic Data Capture), a secure, HIPAA-compliant web-based

software platform designed to support data capture for research studies. The REDCap project for this study will be hosted on the Stanford server and managed by the data analyst for the Stanford study team. Study data sent between sites will be encrypted and identified only by study ID. Access to study data at each site will be limited to the PIs and appropriately-trained study staff.

Analysis Plan

Quantitative data will be analyzed using simple descriptive statistics; for continuous data, we will assess distributions and need for transformations for parametric statistics. In addition, we will analyze survey scores at baseline to determine the characteristics of the sample and degree of representativeness to other published samples of young persons with T1D. Baseline variables will be compared between treatment groups and any observed imbalances will be adjusted for in the longitudinal analyses.

All analyses will follow intent to treat (ITT) principles, with participants analyzed according to their group assignment. All participants will be included who completed at least 1 visit post randomization. While the primary goal is to document the efficacy of the interventions, we will also determine the feasibility and acceptability of these interventions to the adolescent and young adults. We will document this with a review of descriptive statistics for all relevant metrics (e.g., recruitment rate, proportion enrolled relative to patient population) as well as indicators of the acceptance of randomization and overall intervention components (i.e., variability in attendance between face-to-face visits and remote sessions, variability in retention and satisfaction between treatment arms).

CGM data will be assessed at each time point (every 3 months in year 1, totaling 5 separate collections) for the primary outcome of glucose time-in-range (TIR) of 70-180 mg/dL. A1c (measured by central lab) and diabetes distress as well as other patient-reported outcomes (surveys) will be assessed at the collection points of 0, 6, and 12 months in year 1. Mean and standard deviation or summary statistics appropriate to the distributions will be reported. Durability of the intervention will be assessed in year 2, following the same analytic plan outlined for the year 1 RCT with the year 2 analysis planned as a within group comparison (year 2 compared with year 1 for the intervention group). Outcomes related to the effects of the delayed intervention delivered to the usual care group in year 2 will follow a similar analytic plan with a within group comparison of year 2 to year 1 for the usual care group as well as a comparison of outcomes between the intervention group in year 1 and the usual care group in year 2 regarding intervention effects.

The analytic plan reflects both the feasibility of conducting this work and ensuring the most rigorous approaches to addressing the aims. The primary goal is to determine the efficacy of the current dual pronged intervention on glycemic control and diabetes distress. Linear mixed effects models were deemed most appropriate for primary analyses due to the continuous nature of the variables, the longitudinal nature of the design, and our interest in testing within-individual change over time. Mplus using Full Information Maximum Likelihood (FIML) to handle missing data and PROC MIXED in SAS will be used for these analyses with site as a random effect variable. The primary analysis of the 1-year RCT will test the difference in change in CGM glucose TIR of 70-180 mg/dL between the intervention and usual care groups. Additional models will evaluate change in centrally measured A1c and change in diabetes distress measures and other patient-reported outcomes in between treatment group comparisons. The models will adjust for baseline covariates as needed and site as a random effect. In addition, pre-specified exploratory models will test for differences in intervention effect by various subgroups, such as sex/gender, race/ethnicity, age strata, A1c strata, pump/MDI, previous CGM use yes/no, public/private insurance.

In addition to calculation of CGM percent TIR 70-180 mg/dL, outcomes of other CGM metrics will be explored, including CGM-measured % time >180 mg/dL, % time >250 mg/dL, % time <70 mg/dL, % time <54 mg/dL, CGM-measured mean glucose/standard deviation, and glucose variability measured with the coefficient of variation (CV). Type 1 error for these exploratory analyses will be controlled by using a more rigorous alpha of <.01 or by other methodologies to limit the false discovery rate.

Secondary analyses will include mediation and moderation analyses. Mediation analyses will determine the specific mechanisms of action (mediators) that explain intervention effects on outcomes and may also reveal possible intervention effects that could go undetected by traditional outcome analyses. Structural equation modeling (SEM) will be used to construct mediator path models to assess intervention effects through specific mechanisms targeted by the intervention on outcomes. The direct effect of the intervention on the outcome that is unaccounted for by the mediators will also be evaluated. Moderation analyses will evaluate the contextual factors (moderators) that influence the

magnitude and/or presence of an intervention effect. Analysis of covariance (ANCOVA) will test interactions between treatment assignment and factor/moderator (e.g., previous CGM use, age, baseline distress) on outcomes. Binary moderators (e.g., gender) will be probed based on "simple" effects conditioned upon each of the two levels. Continuous moderators will be assessed using the "pick-a-point procedure," which defines the range in values of the factor (e.g., age) at which the intervention effect is significant.

i. Confidentiality

Protecting the confidentiality of participants' personal information is of utmost importance. Study staff at both sites will be trained in the appropriate safeguarding of confidential study data and records, including pertinent training required by the respective sites (e.g., protection of human subjects, HIPAA). Face-to-face study visits will be conducted in private locations. Study data will be identified using study IDs, not participant names. Study data sent between sites will be identified only by study ID and will be sent in an encrypted manner. Remote intervention sessions and online data collection will only occur through tools and resources that have acceptable security features. Online data collection will be conducted using REDCap (Research Electronic Data Capture), a secure HIPAA-compliant web-based platform designed to support data capture for research studies. At each site, data will be stored in locked file cabinets and entered in secure, password-protected computer systems/databases. Only authorized members of the study team will have access to study data and documentation. Neither participant names nor identifying information will appear in any publication based on this research.

j. Provisions to Monitor the Data to Ensure the Safety of Subjects

Data and safety monitoring will be conducted on an ongoing basis by PI Laffel and Stanford PI and grant co-PI Hood. As the study involves two sites, additional data and safety monitoring will be performed by a Data and Safety Monitoring Board (DSMB), which will convene approximately every 9-12 months. The DSMB will consist of 3 members with expertise in adolescent and young adult T1D who are independent of the study. The DSMB will provide independent oversight of study progress and participant safety through review of study progress, biomedical and psychological outcomes, and adverse events. Drs. Hood and Laffel will be available to meet with the DSMB as needed.

All participants will receive careful monitoring for any adverse event. The site PI or a senior member of each study team will be available at all times to respond to any urgent issues that arise. Detection of clinically significant depressive symptoms or suicidal ideation will be followed promptly by a referral for further evaluation by a mental health professional. All safety-related information will be collected, tracked, and reported in a timely manner to the CHS and the DSMB. Adverse events and unanticipated problems will be reported in accordance with federal regulations for clinical research, Good Clinical Practice, and CHS requirements.

k. Withdrawal of Subjects

Participants may be withdrawn from the study without their consent if they fail to follow study procedures or the Investigator determines it is not safe for them to continue. If this occurs, participants will be notified by the Investigator or member of the study team.

If a participant chooses to withdraw from the study, they will be asked to complete a final study visit. In addition, study staff will collect data from their medical record for the duration of the time that they would have been participating in the study.

IV. Risks to Subjects

The risks to participants are relatively minor and most are similar to those associated with usual care for T1D. Potential risks associated with the study are:

- ***Bruising, pain, and/or infection from capillary fingersticks to measure A1c.*** We will use standard

laboratory procedures for capillary fingersticks. This risk is no greater than usual diabetes care.

- ***Bruising, pain, skin irritation, and/or infection at site of CGM sensor insertion; hypo- or hyperglycemia from inaccurate CGM values.*** Participants will receive standard CGM training/education according to their level of experience/previous use. The risks associated with CGM use are no greater than usual diabetes care.
- ***Discomfort when completing surveys or discussing intervention session topics.*** Participants will be instructed that they may skip any questions that make them feel uncomfortable or stop any intervention session discussions that cause discomfort. Many of the surveys that will be used in the study have been used in prior research by the Investigators without significant concerns being expressed by participants. However, based on studies documenting elevated risks of depression and diabetes distress in the study population, it is likely that some participants will experience the onset or exacerbation of serious psychological or behavioral problems during the study. Detection of clinically significant psychological or behavioral disorders will be followed promptly by a referral for further evaluation by an appropriately qualified mental health professional.
- ***Loss of privacy and/or confidentiality of personal information.*** Protecting the privacy of participants and the confidentiality of their personal information is of utmost importance. Risks to privacy and confidentiality will be minimized by very careful selection, training, and supervision of all study staff. Study staff at both sites will be trained in the appropriate safeguarding of confidential study data and records, including pertinent training required by the respective sites (e.g., protection of human subjects, HIPAA). Study visits will be conducted in private locations. Study data will be identified using study IDs, not participant names. Study data sent between sites will be identified only by study ID and will be sent in an encrypted manner. Remote intervention sessions and online data collection will only occur through tools and resources that have acceptable security features. Online data collection will be conducted using REDCap (Research Electronic Data Capture), a secure HIPAA-compliant web-based platform designed to support data capture for research studies. At each site, data will be stored in locked file cabinets and entered in secure, password-protected computer systems/databases. Only authorized members of the study team will have access to study data and documentation. Neither participant names nor identifying information will appear in any publication based on this research.

V. Potential Benefits to Subjects

Participants will receive 4 intervention sessions targeting glycemic outcomes and 8 intervention sessions targeting diabetes distress (intervention group in year 1; control group in year 2). If the intervention sessions are effective, participants may experience an improvement in glycemic outcomes and/or a decrease in diabetes distress. Participants may benefit from the additional contact with study staff at the remote and in-person visits. In addition, the glucose information provided by CGM may also be helpful for participants' diabetes management and may contribute to improved glycemic control.

Evidence of clinically significant psychological or behavioral disorders that are uncovered by participants' survey responses will be followed promptly by a referral for further evaluation by an appropriately qualified mental health professional. Study participants will be more closely monitored in this regard than may be routine at the two study sites. Therefore, it is possible that participants may benefit from detection and ensuing treatment for such conditions.

VI. Provisions to Protect the Privacy Interests of Subjects

Face-to-face (in-clinic) study visits will be conducted in private locations. Remote study visits will be conducted using a secure, HIPAA-compliant web-based platform. When reviewing participants' medical records, study staff will access the minimum necessary information needed for the study.

VII. Compensation for Research-Related Injury

This study does not present more than minimal risk to participants. Participants will not be compensated in the event of a research-related injury.

VIII. Economic Burden to Subjects

All study-related tests and procedures will be paid for by the study.

Participants will be responsible for extra costs (unpaid time off from work, child care costs, etc.) that they incur due to their study participation.

As compensation for time and effort, participants will receive $75 for each 6-month survey/A1c data collection (must complete surveys AND A1c) and $75 for each 3-month CGM data collection (for a total of $1050 if they complete all surveys/A1cs and all CGM data collections).

IX. Consent Process & Documentation

The study protocol and informed consent/assent forms will be reviewed and approved by the CHS before any patients are recruited for the study. The informed consent/assent process will be conducted in a manner that allows potential participants/parents to make an informed decision about enrolling in the study. A trained member of the study team will provide a full description of the study, including requirements of participants during the study and potential risks and benefits of the study. Potential participants/parents will be informed that study participation is completely voluntary and that they may withdraw from the study at any time. Study staff will not coerce or unduly influence anyone to participate. Study staff will answer all questions and address all concerns raised by potential participants/parents, with additional assistance from the PI or other study staff if necessary. Potential participants/parents will be given ample time to review the informed consent/assent forms and discuss participation in the study with family members/others if they desire. Participants <18 years old will provide written assent and a parent/legal guardian will provide written consent. Participants 18 years and older will provide written consent. Electronic written consent will be obtained either in-person or remotely, using REDCap. Each site will host the electronic consent on their local REDCap server and consent documents containing PHI will not be shared between sites. Paper forms may be used if participants prefer or if there are technical problems using the electronic version. Participants/parents will be sent a copy of the signed consent/assent forms. The signed electronic consent/assent forms will be stored securely and access to these files will be limited to research staff, regulatory personnel, and individuals who have legitimate legal rights and authority to inspect such records. Participants who turn 18 during the study will provide written consent as adults after they turn 18. As informed consent is an ongoing process, participants/parents will be informed about any new information that arises during the study that may impact their willingness to continue in the study. Written informed consent/assent for continued participation will be obtained when the new information indicates an increased risk to participant safety and/or it is deemed necessary by the CHS.

X. Vulnerable Populations

Study participants will be ages 14-25 years. Therefore, some participants will be children (<18 years old). Most children ages 14-17 have the maturity and cognitive ability to provide informed assent for studies such as this. Therefore, we will obtain written assent from children ages 14-17 years and written permission (consent) from a parent or legal guardian. Parents of participants ages 14-17 will be notified if any safety concerns arise during the study. Parents of participants ages 14-17 may attend intervention sessions; however, the focus of the sessions will be on the adolescent (not on the parents).

XI. Drugs and/or Devices

Participants who are not using CGM will use the FDA-approved Dexcom CGM system, which will be provided to Joslin and Stanford by Dexcom at no cost for the purposes of the study. Dexcom has no other involvement in the conduct of the study and will not receive any study information/data. Study devices will be stored in a secure location at each study site. Study staff at each site will maintain inventory/accountability logs of receipt, dispensing, and return of devices.

XII. Sharing of Results with Subjects

If clinically significant psychological or behavioral disorders are uncovered during the study, this information will be shared with participants, parents of participants <18 years old, and participants' health care provider. A1c results will be shared with participants upon their request.

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