Evaluating an Eating Disorder Prevention Program for Young Women With Type 1 Diabetes

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1. PURPOSE OF THE STUDY

a. Brief Summary

This study aims to test the effectiveness of an evidence-based eating-disorder prevention program specifically targeted for individuals with Type 1 Diabetes (T1D) compared to an educational control group. The Diabetes Body Project (DBP), is an adaptation of the Body Project which is the only eating disorder prevention program to have repeatedly produced effects when evaluated by independent researchers, produced stronger effects than credible alternative interventions, and affected objective outcomes. DBP has been adapted slightly for individuals with T1D who are at ultra-high risk for eating disorders. The study aims to test the effectiveness of the DBP of reducing body image concerns and reducing eating pathology and improving glycemic control.

b. Objectives

Aim 1 is to test the hypothesis that participants who complete the Diabetes Body Project will show significantly greater improvements in glucose control (HbA1c and Time in Range [TIR]), the primary outcomes, as well as reductions in diabetes distress, illness perceptions, and quality of life (secondary outcomes) over follow-up than control participants who view educational lectures of diabetes management and EDs. Although HbA1c is the most common measure of long-term blood glucose management (ADA, 2018), with the advent of continuous glucose monitoring (CGM), the ability to classify sensor glucose levels into various ranges has been feasible. Time in Range (TIR), which reflects the amount of time an individual had glucose values between 70 and 180 mg/dL, has shown a robust inverse association with development of diabetic retinopathy and microalbuminuria (Beck et al., 2019). As of July 2022, we are making the CGM optional, this will decrease our power to detect changes in TIR.

Aim 2 is to test the hypothesis that Diabetes Body Project participants will show significantly greater reductions in ED risk factors (pursuit of the thin ideal and body dissatisfaction), ED behaviors (dietary restriction, insulin omission), and ED symptoms (additional secondary outcomes) than control participants, and whether reductions in ED outcomes correlate with reductions in HbA1c and increases in TIR and mediate the effects of the Diabetes Body Project on improvements in HbA1c and TIR.

If this pilot study shows that the Diabetes Body Project is effective in decreasing eating disorder symptoms and behaviors in this population than it would provide support for a larger trial testing the effectiveness of DBP and the dissemination of DBP thereby helping to decrease eating disorder symptoms and increase quality of life and overall health of individuals with T1D.

c. Rationale for Research in Humans

The purpose of this study is to test the effectiveness of an eating disorder prevention program, the Diabetes Body Project.

2. STUDY PROCEDURES

a. Procedures

Participants will be recruited through flyers, online postings, and other postings at various clinics treating Type 1 Diabetes (T1D) in the Bay Area. To determine eligibility, during screening participants will be asked their age, gender, how long they have had T1D, if they are taking insulin, if they have visited their diabetes care provider in the past year, and basic questions assessing body dissatisfaction.

On the flyers and other recruitment materials, participants will be directed to a short survey on a secure platform that only asks for contact information (see section 16) to show interest in the study. The study team will use the contact information provided to set-up a phone screen for interested individuals. IF the participant shows interest through one of the Honest Broker methods (such as MyChart) or through ResearchMatch.org which shares the contact information with the research team, then a member of the research team will reach out to the individual using the contact information provided to thank them for their interest and schedule a phone screen. See section 13 for the phone screen.

For participants who are under the age of 18, we will complete the phone screen with the parent. During this phone screen, we will ask for permission to contact the adolescent to conduct the same phone screen. The second phone screen with the adolescent will be to establish rapport with the study coordinators and to make sure we know the level of self-reported body dissatisfaction from the adolescent, as it is unlikely the parent will know the level of body dissatisfaction the adolescent experiences. After the participant completes the phone screen, a member of the study team will contact them to confirm eligibility. Informed parental consent and adolescent assent (for ages 15-17) or consent (for ages 18- 30) will be secured prior to enrollment. If an adolescent turns 18 during their participation in the study, they will be consented at their first assessment or group session after turning 18.

Baseline Assessment: After eligibility is confirmed but before groups begin, the research assistant will email participants a Redcap link to complete the surveys for baseline assessment. At the baseline assessment, participants will complete a survey involving the following questionnaires:

1) the 8-item Ideal-Body Stereotype Scale-Revised (Stice et al., 2017) which assesses pursuit of the thing ideal

2) the 9-item Body Dissatisfaction Scale (Berscheid et al., 2973) which assesses dissatisfaction with various body parts

3) the 16-item Diabetes Eating Problem Survey-Revised (Markowitz et al,. 2010)

4) the 28-item Type 1 Diabetes Distress Scale (Fisher et al., 2015) which assesses distress related to diabetes

5) the 5-item World Health Organization Well-Being Index (deWit et al., 2007) that assess health related quality of life

6) Negative affect will be assessed with the sadness, guilt, and fear/anxiety subscales (totaling 20 items) from the Positive Affect and Negative Affect Scale-Revised (PANAS-X; Watson & Clark, 1992)
7) 10-item Dutch Restrained Eating Scale (van Strien et al., 1986) that measures dieting behaviors.
At the baseline assessment, participants will also complete an Eating Disorder Diagnostic Interview (EDDI) over the phone. The EDDI can take between 30 to 60 minutes to complete depending on the number of behaviors endorsed by the participant. The EDDI will be administered by a trained research assistant. At baseline, participants will also be asked to report their A1Cs. We will only ask for self-reported A1Cs.
For the last part of the baseline assessment, Glucose monitoring data will be collected via glucose monitors that are already in use, among participants already using these devices at the time of enrollment, with data being shared by the participant with the research team via secure online portals created and run by their corresponding device company. For participants who are not already using glucose monitors at the time of enrollment, they will be given the option of us sending them one. If they agree to wearing a CGM then a Libre 2 glucose monitor devices will be provided by study staff, as well as training on use following FDA-approved self-start guides that are available online. See section 16 for the Libre 2 informational brochure. However, if a participant does no already have a CGM and does not want to wear one, then we will not send them one. This means they will not receive the $25 at baseline and at the 3-month follow-up that is set aside for the two-week CGM information. They will be made aware of this when they decide not to wear the Libre2. The CGM is invasive, but it is a quick process that participants do at home. It is quick and often painless. Also in section 16 is a link to a video illustrating how to apply the sensor. Research staff will also provide support throughout use, and will be used to collect 2 weeks of data at each time point.
Prevention Program:
After baseline assessments are completed, participants will be randomized to either the Diabetes Body Project groups or the educational control.
Randomization:
We will use a random number generator to determine if participants will be in Diabetes Body Project or the educational control. If an even number is generated, the participant will be assigned DBP. If an odd number is generated, the participant will be assigned to educational control. As there is a 50% chance the number will be either even or odd, there is a 50% chance that someone will be assigned either to DBP or the educational control. It is only after the baseline assessment that individuals will be randomized. This will prevent the assessor at baseline from being influenced by which group the participant will be in. The assessor completing the EDDI at post-test and 3-month follow-up will be blind to the participant's condition.
Diabetes Body Project: The Diabetes Body Project is an adaptation of the Body Project. The original Body Project involves weekly 1-hour sessions for 4 weeks. The adapted version includes weekly 1-hour sessions for 6 weeks. Sessions will be co-led by a clinician and a peer educator with Type 1 Diabetes. The adaptation involves diabetes-specific content in the sessions as well as the inclusion of a peer educator with Type 1 Diabetes. In session 1 participants volunteer to participate verbally in the session, collectively define the thin appearance ideal, discuss costs of pursuing this ideal, and are assigned home exercises (e.g., write a letter to a younger girl about the costs associated

with pursuing the thin ideal). In session 2 participants discuss each home exercise, dissuade facilitators from pursuing the thin ideal in role-plays, and are assigned more exercises (e.g., generate a top-10 list of things young women can do to challenge the thin ideal). In session 3 participants discuss home exercises, conduct role-plays challenging thin-ideal statements, discuss personal body image concerns, and are assigned home exercises (e.g., engage in two activities that challenges the thin ideal). In session 4 participants discuss home exercises, discuss the negative effects of social comparison, the advantages and costs of social media, and are assigned home exercises (e.g., track situations in which they engage in social comparison and state alternative ways of thinking). In session 5 participants discuss home exercises, discuss strategies of living well with diabetes and maintaining good self-care, as well as the physiological and psychological advantages of insulin, and are assigned home exercises (e.g., writing a letter to a younger girl with T1D with advice on having a positive relationship with her diabetes). In Session 6 participants review each home exercise, discuss the benefits of the group and what was learned, and how to continue some of the exercises introduced in the Diabetes Body Project; as a final home exercise, participants are encouraged to engage in at least one more self-affirmation exercise and email the facilitators to tell them how it went. This is different from standard of care, as most times individuals with Type 1 Diabetes don't have the opportunity to discuss body image concerns and eating pathology, especially specifically in relation to Type 1 Diabetes. This is the first eating disorder prevention program designed specifically for this high-risk population. Participants will continue to receive usual care from their diabetes care team during their participation in the study

Educational Control:
We selected a T1D management/ED psychoeducational comparison condition previously tested (Olmsted et al., 2002) to control for expectancy effects and demand characteristics. To match the Diabetes Body Project, the educational lectures by Dr. Olmsted will be delivered in 6 1-hour blocks. Topics include basic information about the various eating disorders, complications of ED behaviors, diabetes and body image, effects of dieting on blood glucose, and the risk of complications. Strategies to develop a healthy relationship with food, how to overcome binge eating and purging behaviors (including intentional insulin omission), and how to improve body image are also discussed.
If participants are randomized to the Diabetes Body Project, they will meet in groups of 6 individuals co-led by a peer educator with T1D and a clinician. Groups will meet once a week virtually for an hour, for six weeks. Each week involves homework that participants are asked to complete before the next session. If participants are assigned to the Education intervention, they will be asked to watch one-hour of videos including information about diabetes management and eating disorders each week for six weeks.
Post-Test:
After the six weeks of either Diabetes Body Project or the educational control, participants will be asked to complete the same questionnaires that they assessed at baseline and the EDDI.
3-Month Follow-up:
At 3-month follow-up, participants will again complete the questionnaires and the EDDI, but will also wear the continuous glucose monitor (either the one they already have or the

Libre 2 provided by the research staff) and be asked to self-report A1c. After the 3-month follow-up, participants have completed all study responsibilities.

b. Procedure Risks

These research procedures provide minimal risk to subjects. We are Using current and empirically evaluated measures and research staff available who have been fully trained both in administrating physiological interviews. The Body Project has also been tested in multiple trials and has produced only positive effects, there has been no history of symptoms worsening as a result of participating in the program. The above procedures present minimal risk. Engaging in the intervention modules carries minimal risk for emotional discomfort or stress. Subjects will have the option of not participating in conversations or exercises in the intervention modules that cause them any discomfort. They will also be free to withdraw from participating in the intervention and/or overall study at any time. Survey measures are non-invasive and present minimal risk. Glucose monitors are minimally invasive and provide no added level of risk or discomfort beyond routine diabetes management tasks.
Adolescent and caregiver participants will be advised of their rights to withdraw from the intervention at any time without penalty or consequence on their receipt of future health care services at Stanford University's Lucile Packard Children's Hospital or affiliated clinics.

c. Use of Deception in the Study

Deception will not be used.

d. Use of Audio and Video Recordings

Participants will be informed that we will make video recordings of the Diabetes Body Projects groups for clinical supervision and quality assurance purposes. These recordings will be reviewed by the primary investigator to assess intervention fidelity and therapeutic competence of the group leaders. Email supervision based on these ratings will be provided to facilitators which has been found to maximize intervention effects. After they are viewed and rated for fidelity and competence, all records of the recordings will be deleted from devices and destroyed. Recordings are not optional. As the group sessions are virtual and conducted via Zoom, it is impossible for someone to "go out of view of the camera" and recording is an important part of the intervention. Also, recording is an important part of the intervention so turning off their camera on Zoom is not an option. There are three main factors that increase cognitive dissonance: public accountability, level of effort, and voluntary basis. By recording the sessions, public accountability is greatly increased and the effect of the intervention improves. Thus, if they are in DBP individuals must be willing to be recorded.

e. Alternative Procedures or Courses of Treatment

Currently, there are not any eating disorder prevention programs specifically designed for individuals with Type 1 Diabetes. Therefore, no standard treatment is being withheld from participants.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

If the Diabetes Body Project (DBP) produces significantly larger improvements than the educational lectures, we will offer the DBP to educational controls.

g. Study Endpoint(s)

It is important to test whether effects persist at 3-month follow-up even if there are good effects at posttest, as it is possible that the effects may not persist. The effects of this brief prevention program typically have shown good persistence through 1- to 2- year follow-ups but tend to fade partially by 4-year follow-up.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Type 1 diabetes (T1D) is a chronic illness caused by autoimmune selective destruction of the insulin-producing beta cells in the pancreas, wherein the lack of insulin leads to elevated blood glucose levels (American Diabetes Association [ADA], 2018). Poor glycemic control is associated with higher risk of diabetes complications, such as cerebrovascular and cardiovascular disease, retinopathy, neuropathy, nephropathy, and mortality (Patterson et al., 2019). The lifetime prevalence of T1D is 9.5% and is increasing (Mobasseri et al., 2020), implying that over 32 million people in the US have this chronic life-compromising disease.

The continuous self-regulation task of adjusting insulin to diet, physical activity, and emotional state to maintain recommended blood glucose levels to avoid serious diabetes complications places a high burden on youth with T1D and their families. Diabetes self-care and glycemic control are associated with anxiety, depression, and eating disorders (EDs) (Colton et al., 2015). Indeed, young females with T1D are an ultra-high-risk group for EDs. Young women with T1D show 200%-400% greater prevalence of ED compared to females without T1D (Colton et al., 2015; Mannucci et al., 2005; Young et al., 2013). For instance, a prospective study of adolescent girls with T1D found that the lifetime incidence of EDs was 60% over a 14-year follow-up (Colton et al., 2015), which is 462% greater than in young women without T1D (Stice et al., 2013). Youth with T1D are also at elevated risk for ED behaviors, such as dietary restriction and intentional insulin omission, and ED symptoms, such as binge eating, fasting, excessive exercise, vomiting, and laxative/diuretic misuse (Olmsted et al., 2008). Longitudinal studies of people with T1D reveal that ED behaviors and symptoms are likely to persist and become more severe in young adulthood (Peveler et al., 2005).

Critically, ED pathology is associated with poorer glycemic control, as indexed by higher Hemoglobin A1c (HbA1c) (Young et al., 2013). Intentional insulin omission for weight control is reported by 37% of females with T1D (Rodin et al., 2002) and is associated with a 300% increase in mortality (Goebel-Fabbri et al., 2008). Of note, 61% of young women with T1D and a history of EDs report intentional insulin omission versus 26% of young women with T1D without a history of an ED (Peveler et al., 2005). Insulin omission or restriction increases risk for diabetic ketoacidosis (DKA) and frequent presence of ketones in the body can cause heart complications, kidney failure, cerebral edema, coma, and death (Hanlan et al., 2013). Comorbid T1D and EDs are associated

with increased risk of diabetes complications and mortality (Nielsen et al., 2002), underscoring the importance of effective prevention efforts for this population. For example, 84% of youth with T1D and ED pathology showed some degree of retinopathy compared to 24% of those without ED pathology (Rydall et al., 1997). Comorbid T1D and EDs also increases risk for nephropathy (Takii et al., 2008). No intervention has been shown to prevent this co-morbidity.

The Body Project is the only ED prevention program that has repeatedly reduced future onset of EDs, produced effects when evaluated by independent researchers, produced stronger effects than credible alternative interventions, and affected objective outcomes (Stice et al., 2019). The Body Project is a dissonance-based ED prevention program wherein high-risk young women with body image concerns collectively critique pursuit of the thin appearance ideal in verbal, written, and behavioral exercises. It has produced greater reductions in risk factors (pursuit of the thin ideal, body dissatisfaction, dieting, negative affect), ED symptoms, and future ED onset over a 2- to 4-year follow- ups than assessment-only control conditions and alternative interventions in over 25 controlled trials (e.g., Becker et al., 2010; Ghaderi et al.,2020; Halliwell & Diedrichs, 2014; Stice et al., 2000, 2006, 2008, 2011, 2013, 2017, 2020). The effectiveness of the Body Project in reducing ED risk factors, behaviors, and onset led to a call to test its efficacy for young women with T1D (Hanlan et al., 2013). Wisting et al. (2021) tested an adapted version of the Body Project (Diabetes Body Project) in an uncontrolled pilot trial in Norway. The adapted version added 2 sessions focused on T1D-specific content. Participants who completed virtual Diabetes Body Project showed significant reductions in pursuit of the thin ideal (d = .81), body dissatisfaction (d = .67), dieting (d = .63), diabetes eating pathology (d = .83), diabetes distress (d = .48), and diabetes illness perceptions (d = .41). Qualitative data collected from participants in this initial pilot trial allowed us to refine the intervention script to improve acceptability of the Diabetes Body Project.

Given the robust evidence for the effectiveness of the Body Project and the promising preliminary data for the Diabetes Body Project, we propose to conduct a controlled efficacy trial of this ED prevention program for young women with T1D.

b. Findings from Past Animal Experiments

None

4. PARTICIPANT POPULATION

a. Planned Enrollment

(i) All subjects will be enrolled at Stanford. We expect to enroll 60 participants. (ii) N/A (iii) Participants are female-identifying individuals between 15-30 years old with a Type 1 Diabetes diagnosis of at least six months. We are recruiting 15-30 females with T1D as they are at an elevated risk of eating disorders due to T1D and their gender. As this is the first test of the Diabetes Body Project, recruiting a sample that will most likely benefit from it is important in testing its effectiveness.

b. Age, Gender, and Ethnic Background

All participants will be female-identifying 15–30-year-olds. All ethnicities will be recruited and included.

c. Vulnerable Populations

Participants aged 15-17 years-old may be considered potentially vulnerable subjects as they are not yet adults. Adolescents (aged 15-17), especially female adolescents, are at an elevated risk of eating disorder onset and serve to benefit from the eating disorder prevention program. Parental consent will be required before adolescents' assent to partake in the study. Parents will be informed of all tasks the adolescents will be asked to complete (surveys, glucose monitoring, diagnostic interview, and treatment group).

d. Rationale for Exclusion of Certain Populations

Women, minorities, and adolescents (aged 15-17) are included in the study. Children younger than 15 are not included in the study as they are less likely to have an eating disorder or body dissatisfaction. Additionally, the Diabetes Body Project was designed for older adolescents.

e. Stanford Populations

None.

f. Healthy Volunteers

None.

g. Recruitment Details

Recruitment will take place using both online and in person strategies.
Online - Ads will be posted on the internet using social media sites: Twitter, Facebook, and Instagram, community forums: Craigslist and Reddit, and the study website. We will manage an instagram and facebook page with postings about the study using the approved images and captions. All posts on the page will be moderated by the research team and set to block commenting or posting by the public. Posting of online ads will be managed based on inclusion criteria, i.e., within the United States, age, etc. Social media recruitment posts will be set up such that the security settings do not allow participants or others from the public to post on the wall/public forum. If this is not possible due to the social media platform's settings, the social media posts will be monitored and any disclosures of PHI removed.

Additionally, all families who call the Stanford clinic for services are asked about their willingness to be contacted for research. Parents of youth who indicated they are willing to be contacted for research and who may potentially meet study inclusion criteria will be called and asked if they are willing to hear about a Stanford research study. We will put flyers in the community and around middle and high schools as well as send postcards via email and mail.

Due to Dr. Hood's clinical practice, we will be able to recruit at 3 clinics that specialize in T1D treatment (Stanford, UCSF/Oakland, Kaiser). Additionally, we will be able to recruit more broadly in the Bay Area by posting to clinics involved in the Stanford Diabetes and Research Center (SDRC) Type 1 Diabetes Exchange Clinic Network clinical registry to increase generalizability.

Potential participants will also be contacted through our endocrine and IRB approved patient recruitment lists, including the Stanford Diabetes Research Center's clinical registry (in which subjects have already consented to be recruited for research studies). Stanford Diabetes Research Center's clinical registry is composed of individuals who have expressed interest in participating in research and have voluntarily included their name in the registry to be contacted for potential participation in studies. More information on the SDRC registry can be found at: https://sdrc.stanford.edu/clinical-research-registry.

Participants will also be recruited through online flyers sent out through established diabetes-related listervs run by diabetes organizations.

The IRB-approved recruitment flyer and email will also be circulated through online websites, forums newsletters, emails listervs, and social media pages (primarily run by diabetes organizations such as DYF and JDRF) and shared with diabetes providers and clinics within and outside of Stanford. These online avenues are often used to disseminate information to families of youth with type 1 diabetes offering various information and resources, including opportunities to participate in studies similar to the current study.

We will partner with the Research Participation team for Honest Broker outreach. Potential participants are identified via STARR and invited by Research Participation team (honest broker) on behalf of study team. See Section 16 for Honest Broker study invitation letters. We will be using Children's Epic MyChart, Postal Mail honest broker outreach. For Epic MyChart, study team receives only the interested responses via Epic MyChart InBasket. For Postal Mail, study team may support the process by sticking pre-printed address labels (created by honest broker) on the envelopes. Invitations will not be sent to the same individual via more than one honest broker outreach method, unless as a separate reminder.

The Research Participation team informed us of Study Pages. We are going to be part of the University's pilot program with Stanford. They are testing Study Pages with 100 studies to see if it helps with recruitment and outreach. Through the StudyPage we can text and call participants in a HIPPA-compliant manner. We can also schedule participants.

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h. Eligibility Criteria

i. Inclusion Criteria

I)female-identifying
II) aged 15-30 years old
III) diagnosis of T1D for at least a 6-month duration per ADA criteria who are taking insulin
IV) have visited their diabetes care provider in the past year
V) body image concerns

ii. Exclusion Criteria

I) not female identifying
II) not in age range
III) does not have a diagnosis of T1D for at least 6 months per ADA criteria
IV) not taking insulin
V) have not visited their diabetes care provider in the past year
VI) do not report some level of body dissatisfaction
VII) do not live in the United States
VIII) Unwilling to be video-recorded if assigned to Diabetes Body Project
IX) restricted English proficiency, and pervasive developmental, cognitive, or psychiatric limitations that compromise participation in the intervention sessions and study.
Glucose monitors will be provided to participants who are not already using these devices such that device use will not be a criterion of eligibility or exclusion.

i. Screening Procedures

Participants will indicate interest by completing a short survey on a secured platform, such as REDCap, that asks them for contact information. From there, a member of the research team will contact them to conduct the telephone screening where verbal consent will be obtained. For adolescents, a member of the research team will first screen the parent and ask them about the adolescent. We will ask the parent for verbal consent to contact the adolescent to ask similar questions. A second phone screen will occur with the adolescent where verbal assent will be obtained. The second phone screen serves to increase rapport and to obtain the adolescents own body image concerns.

j. Participation in Multiple Protocols

As a part of the informed consent process, subjects will be asked if they are participating in any other research projects. Their participation in other protocols will not exclude them from participation in this study.

k. Payments to Participants

Participants will be paid $15 for the pretest assessment, $20 for the posttest, and $25 for the 3-month follow-up assessment (baseline, post-test, and three-month follow-up) and $25 for each complete wear of glucose monitoring. In total, then, participants could receive $110. They will be paid for whatever portions of the study they complete (i.e., it is prorated). If they do not wear the CGM/provide CGM data, total possible payout is $60.

l. Costs to Participants

There will be no cost to participants.

m. Planned Duration of the Study

It is estimated that the study will take one year. The screening is expected to take 10-15 minutes. Active participation will last about 5 months. Participants will complete the baseline assessment (1.5 hours), then wear the CGM for two weeks, then complete the six-week intervention (each session is one hour), and then a post-test assessment (about 1.5 hours). After the initial baseline assessment, intervention, and the post-test

participants will have completed all necessary tasks until the 3-month follow-up where they will complete the same tasks as the baseline assessment and where the CGM for two weeks. While the groups are running, data analysis on baseline data will begin. Once we have complete data for posttest and 3-month follow-up, we will conduct data analysis on the outcome measures.

5. RISKS

a. Potential Risks

i. Investigational devices

None

ii. Investigational drugs

None

iii. Commercially available drugs, biologics, reagents or chemicals

There are no risks of commercially available drugs, reagents, or chemicals as none will be used.

iv. Procedures

Data Collection: Self-reported survey will be kept confidential and collected online via secure RedCap database system. The diagnostic interviews will require phone numbers as they will be conducted over the phone, but the interview forms will only be labeled with the participant ID number. All stored and collected interview data will not include names or phone numbers. There are no known psychological risks to subjects completing self-report subjective rating scales or participating in the intervention sessions. However, the survey and intervention may contain items or questions that make the subjects feel uncomfortable in that they ask about their physical and psychological health and feelings/emotions. Subjects will be informed that any items on questionnaires or topics discussed in the intervention modules that produce these effects may be skipped or ignored.

Protections Against Risk. All research staff have completed rigorous training in the protection of human subjects, including CITI training. The plan for protecting privacy and confidentiality recognizes that the protection of privacy in studies involving sensitive data is of utmost importance. We will attempt to do this in several ways. The research assistant will introduce the study to eligible participants and explain the purposes, benefits, and risks of the project to the subjects, and offer them an opportunity to ask questions and/or decline participation. The voluntary and confidential nature of the research, as well as limits to confidentiality, will be highlighted during informed consent process. Study participation will not interfere with clinical care and all patients have standard access to the treatment team on a routine (clinical care) and emergency basis. All responses to interview items will be given by subjects in private. Survey data collection will only occur through tools and resources that have acceptable security features. We will minimize all communications that involve names or other identifying information. All clinically-relevant and study information will be kept in locked files in

locked offices or password protected files All recordings of intervention sessions will be saved on a password-protected secure server. Information about subjects will not be accessible to any non-authorized study personnel without the written consent of the subject. In all datasets we will use ID numbers only. A separate dataset linking names with ID numbers will be accessible only to authorized study personnel under the direction of the PI.
There's a small chance there will be some discomfort upon applying and wearing the CGM if you or your child have never worn one before, especially if this is your first time wearing one. Sometimes the discomfort can last a day or two, but often is mild and goes away. If the discomfort persists, please contact us.

v. Radioisotopes/radiation-producing machines

There are no risks of radioisotopes/radiation-producing machines or associated risks as no radioisotope/radiation-producing machines will be used

vi. Physical well-being

Participants may experience slight discomfort upon applying and wearing the CGM, especially if it is the participant's first time wearing one. However, reports like this are not common and mild. Participants will be told to contact us if discomfort persists.

vii. Psychological well-being

Psychological discomfort may result from some of the questions in the questionnaires, but participants may choose not to answer questions if they feel uncomfortable. Additionally, participants may feel uncomfortable sharing in the group setting. If they feel uncomfortable, they will be able to communicate with the group leaders, RA, or principal investigator to express feelings of discomfort and hopefully be comforted. In past trials the Diabetes Body Project and the Body Project, participants have not reported discomfort discussing sensitive materials in group sessions.

viii. Economic well-being

There are no risks to economic well-being

ix. Social well-being

There are no risks to social well-being

x. Overall evaluation of risk

Low

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b. International Research Risk Procedures

N/A

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c. Procedures to Minimize Risk

Confidentiality: All materials, such as questionnaires and interview forms, and data collected from each participant will be identified by an ID number in order to ensure

confidentiality. Additionally, all researchers will have a thorough understanding of the participants' rights to confidentiality.
Emotional discomfort: Participants will be reminded of their right not to answer specific questions during the research visit. Research assistants will be sensitive to signs of exhaustion or other distress and will schedule breaks or will end the visit as warranted to protect the comfort of participants. All participants will receive information about whom to contact if they have lingering questions, concerns, or distress regarding any aspect of the study.
All research staff have completed and will maintain rigorous training in the protection of human subjects, including CITI training. The plan for protecting privacy and confidentiality recognizes that the protection of privacy in studies involving sensitive data is of utmost importance. We will attempt to do this in several ways. Research staff will introduce the study to eligible participants and explain the purposes, benefits, and risks of the project to the subjects, and offer them an opportunity to ask questions and/or decline participation. The voluntary and confidential nature of the research, as well as limits to confidentiality, will be highlighted during informed consent process. Study participation will not interfere with clinical care and all patients have standard access to the treatment team on a routine (clinical care) and emergency basis. All responses to interview items will be given by subjects in private. Survey data collection will only occur through tools and resources that have acceptable security features. We will minimize all communications that involve names or other identifying information. All clinically-relevant and study information will be kept in locked files in locked offices or password protected files.
All recordings of intervention sessions will be saved on a password-protected secure server. Information about subjects will not be accessible to any nonauthorized study personnel without the written consent of the subject. In all datasets we will use ID numbers only. A separate dataset linking names with ID numbers will be accessible only to authorized study personnel under the direction of the PI.

d. Study Conclusion

If the subject wants to end their participation in the study at any time, they can do so. If the investigator determines that participation would be harmful to the subject or investigator in any way, they can terminate the experiment. If not ended early, participate participation will end after the 3-month follow-up.

e. Risks to Special Populations

The study involves no more than minimal risk for the adolescents enrolled and parent consent will obtained both before the screening and actual enrollment in the study. The study is minimal risk as no known risks are known for using the Abbott Libre 2, self-reporting A1C, answering the questionnaires, participating in the Diabetes Body Project or educational control group, or completing the diagnostic interview. If participants experience psychological discomfort the RA is trained in how to recognize distress and comfort. The clinicians and peer educators running the Diabetes Body Project groups will also be assessed for therapeutic competence and be able to provide support should discomfort occur.

6. BENEFITS

Participants, in both the Diabetes Body Project groups and the educational control, may experience a reduction in eating disorder symptomatology, decrease in body dissatisfaction, decrease in thin idealization, and better glycemic control as a result of participation. Thus, we anticipate that participants will show improvements in both mental and physical health, but that improvements will be greater for intervention verses educational control participants. If the DBP is found to be effective there is justification to test it on a larger scale and hopefully implement it broadly among this high-risk population.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.