Contemporary Clinical Trials 96 (2020) 106086

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

THR1VE! Positive psychology intervention to treat diabetes distress in teens with type 1 diabetes: Rationale and trial design

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ARTICLE INFO

Keywords:
Type 1 diabetes
Adolescents
Positive psychology
Clinical trial
Diabetes distress

ABSTRACT

Adolescents with type 1 diabetes (T1D) experience high rates of diabetes distress, which negatively influence self-management and glycemic control. Building on effective positive psychology interventions to improve adherence in adults, as well as our pilot work to adapt these interventions for adolescents, we developed a positive psychology intervention for adolescents with T1D. The goal of THR1VE! is to reduce diabetes distress in adolescents with T1D and improve their diabetes outcomes. This multi-site randomized controlled trial compares a Diabetes Education + text-message-based Positive Affect intervention, to a Diabetes Education control condition. In the ongoing trial, we are evaluating the effects of the intervention on adolescents' diabetes distress, self-management, and glycemic control. This paper describes the rationale, trial design, and methodology of the THR1VE! Study.

1. Background and rationale

Type 1 diabetes (T1D) affects 1 in every 400 individuals under the age of 20, with the peak age of onset in early adolescence [1,2], and recent studies suggest that the incidence of T1D is rising [3,4]. The recommended treatment regimen for T1D is demanding, requiring frequent monitoring of blood glucose (BG) levels, multiple daily insulin doses (4+ injections/day or dosing through insulin pump several times per day), careful monitoring of carbohydrate intake, altering insulin dose to match diet and activity patterns, and checking urine for ketones when necessary [5]. Adherence to this complex regimen is associated with better glycemic control, reducing the risk for both acute and long-term medical complications [6]. However, this intensive level of responsibility can also lead to diabetes distress (DD), or emotional distress in response to the daily burden of living with diabetes. Further, despite increased use of diabetes devices (e.g., continuous glucose monitors, insulin pumps), few adolescents meet treatment goals; in a recent national sample, an overwhelming 83% of adolescents did not meet the recommended target for glycemic control (A1C < 7.5%) [7], and with the most recent guidelines recommending A1C < 7.0% [8], even fewer adolescents are likely to meet glycemic targets.

Adolescence is a difficult period that involves many physical and emotional changes related to puberty. This is also a time when youth are seeking independence, and families typically begin to shift responsibility for diabetes management from parents to youth [9]. Several barriers to adherence exist during this period of transition, including family and peer involvement, hormonal changes and their effects on blood glucose, and lower levels of diabetes device use compared to other age groups [10,11]. All of these factors negatively affect glycemic control in adolescents, and novel approaches are needed to improve self-management and glycemic control in this population.

It is critical to target DD during this stage, as DD has been more strongly linked to diabetes outcomes than depression in adults and adolescents [12,13]. A recent study found that over half of adolescents experienced clinically significant DD [14]. For many adolescents, every blood glucose check is a test that they could fail, and many report feeling guilty about "bad" numbers, [15] or avoiding diabetes care in front of peers [16]. Further, these negative emotions linked with diabetes management can lead to detrimental outcomes in adolescents' health; in fact, clinically significant levels of DD are related to significantly poorer glycemic control and lower levels of diabetes management [14,17]. Studies in adults with T1D show that DD remains stable over time without intervention [12], and therefore targeting DD may improve both psychosocial and glycemic outcomes.

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https://doi.org/10.1016/j.cct.2020.106086
Received 4 March 2020; Received in revised form 8 July 2020; Accepted 13 July 2020
Available online 17 July 2020

Table 1
Intervention content.

Group assignment	Components	Frequency and timing
Positive Affect + Education	Gratitude	Weekly
	Self-Affirmation	Weekly
	Mood Boosters	Twice or Three Times Weekly (Every Other)
	Unexpected Gifts	Biweekly
	Parental Affirmations	Weekly
	Educational Materials	Given at Time of Enrollment
	Health Behavior Contract	Completed at Time of Enrollment
Education	Educational Materials	Given at Time of Enrollment
	Health Behavior Contract	Completed at Time of Enrollment

1.1. Positive psychology framework

Positive psychology emphasizes an individual's strength, values, wellbeing, happiness, and positive subjective experience [18]. Positive affect, a central component of positive psychology, is the experience of pleasant emotions (e.g., cheerful, happy, proud). According to the Broaden-and-Build theory of positive emotions [19], positive affect increases the ability to use creative and complex coping strategies by broadening skills in attention and cognition. While experiences that induce negative affect often limit or restrain the range of reactions available (e.g., fear leading to avoidance or anger leading to aggression), increased positive affect results in the greater use of adaptive coping strategies and a decrease in the use of avoidant or disengagement coping strategies [20]. Thus, by inducing positive affect, we may broaden the range of thoughts and actions in adolescents, thereby increasing adaptive responses to stress, decreasing DD and ultimately improving diabetes self-management and glycemic control.

Positive psychology interventions in children and adolescents with chronic health conditions have not been researched extensively, but several studies have investigated the efficacy of positive psychology interventions in adults with chronic health conditions. Charlson and colleagues studied the effects of a positive psychology and self-affirmation intervention on self-management and medication adherence in adults with chronic health conditions such as cardiopulmonary disease [21]. In these studies, induction of positive affect was correlated with a significant improvement in health behavior change and a decrease in stress as compared to the control group [22]. Positive affect (PA) was also shown to act as a protective factor against perceived stress, as those with the PA intervention were more successful at completing their health goals in the face of stress than those in the control condition [22].

In youth with T1D, no interventions have specifically targeted DD; however, several researchers have examined the effect of interventions on DD as a secondary outcome in adolescents. For example, Ellis and colleagues found improvements in diabetes stress after an intensive multicomponent psychotherapy intervention for high-risk adolescents [23]. In contrast, the DEPICTED study found that motivational interviewing training for providers did not significantly improve DD [24]. Most recently, the STePS study compared a depression-prevention, resilience promoting intervention to an education intervention for adolescents with T1D and found a significant reduction in DD over 12 months in the adolescents who received the resilience intervention [25]. THR1VE! builds on a series of pilot studies that adapted and tested positive psychology interventions for adolescents with T1D [26,27]. These pilot studies also demonstrated the feasibility and acceptability of delivering the mhealth intervention via automated text messages [27,28], which allows for wider dissemination None of these pilot studies were powered to detect intervention effects, however, and follow-up data collection was limited.

1.2. Study aims

The current THR1VE! study builds on our pilot work to evaluate the positive psychology intervention in a larger, multi-site study, with a focus on adolescents who are experiencing DD. The aims of the current study are as follows: Aim 1: To evaluate the effects of a Positive Affect + Education intervention for distressed adolescents (age 13–17) with T1D on glycemic control, we will conduct a randomized controlled trial of the intervention. Aim 2: To evaluate the effects of a Positive Affect + Education intervention for distressed adolescents with T1D and their caregivers on diabetes distress, coping and self-care behavior with a randomized controlled trial. We hypothesize that adolescents who receive the Positive Affect + Education intervention will demonstrate lower HbA1c, reduced diabetes distress, and better diabetes management over time, as compared to those who receive the Education only intervention. Exploratory Aim: Examine the differential impact of intervention effects across demographic (i.e., age, race/ethnicity, sex,) and treatment (i.e., insulin injections, pumps, continuous glucose monitors) variables.

2. Research design and methods

The current study is a two-arm, parallel group randomized control trial. Participants are randomized to receive either an Education intervention (Diabetes Education, see Table 1) or an Education + Positive Affect mHealth intervention (see Table 1), with reminders delivered via automated text messages. This study was registered as a clinical trial on ClinicalTrials.gov (NCT03845465).

2.1. Study population

The target sample size is 200 adolescents with T1D and their parents from two clinical sites (100 dyads from each site): academic medical centers in the Southeast and in the MidAtlantic (population of 1.8 million and 6.2 million, respectively). The sampling goal for this study across the two sites is 70% white, non-Hispanic, in line with recent studies conducted in these settings. Based on findings from earlier studies, we expect to enroll more females and more older adolescents because they report higher levels of DD than males and younger adolescents [13,17]. Adolescents are eligible if they (1) are between the

ages of 13–17; (2) have been diagnosed with T1D for at least 12 months; (3) report moderate distress on a screening tool for DD; (4) speak and read English; and (5) have a phone with calling and texting capabilities. Adolescents are not eligible for the study if they have another health condition that significantly interferes with diabetes management. This age range was selected because it captures a key developmental stage, during which glycemic control often deteriorates [7]. Adolescents diagnosed at least 12 months were selected to avoid confounding the effects of the initial adjustment period after diagnosis. A validated scale of DD in adolescents, the Problem Areas in Diabetes-Teens scale (PAID-T) [17], is used to screen adolescents for Diabetes Distress, with a score of ≥34 required for eligibility. Parents/guardians are eligible if they are currently living with the adolescent and are involved in diabetes management.

2.2. Recruitment

A member from each research team checks upcoming clinic schedules at each site to identify patients who meet eligibility criteria for age and time since diagnosis using electronic medical records. A trained Research Assistant (RA) then approaches the families who meet criteria in the pediatric diabetes clinic during regularly scheduled appointments to describe the study and determine if they are interested in participating in a program to improve mood and diabetes management. The RA meets with interested families in a private space to describe the study, answer questions, and administer the DD screening tool (14-item PAID-T) to the adolescent (both parent and child give verbal consent for adolescent to complete the screening survey). The initial screening survey also confirms that the adolescent has a phone with texting capabilities. If the adolescent is eligible, the RA takes the family to a private space before or after the adolescent's clinic appointment to explain the study in greater detail. In line with the approved single Institutional Review Board protocol, the RA obtains informed consent from the parent/guardian and assent from the adolescent to participate in the study.

2.3. Randomization

After consent/assent has been obtained, the adolescent and their parent complete the baseline measures, and participants are randomly assigned to one of two conditions: Positive Affect + Education (n = 100) or Education only (n = 100). Randomization is stratified by use of diabetes devices (insulin pump and CGM), to avoiding confounding effects. A computer program created by the biostatistician generates the randomization scheme. In order to maximize the likelihood of response, adolescents in both conditions are asked the best time of day to receive texts, honoring restrictions on texting during school hours. Families are provided compensation (Amazon gift cards) for their time at each data collection and for participating in an optional exit interview.

2.4. Study activities

The active phase of the intervention is 8 weeks, and study participants are followed for 12 months.

2.5. Education control condition

Adolescents randomized to the Education group are given a packet containing diabetes educational materials. This 14-page packet was developed based on publicly available information on topics relevant for adolescents with T1D on the American Diabetes Association website (diabetes.org), including BG levels, A1C, driving, exercising, and traveling with T1D. Adolescents also complete and sign a Health Behavior Contract, a document intended to help people commit to making a healthy change in some aspect of their diabetes management, which has been used successfully in other studies of adolescents with T1D and in positive psychology interventions with adults [21]. While a health behavior contract is not part of regular diabetes education, we included this in the protocol to equalize the attention and time spent with participants in the different study arms. The RA explains the Health Behavior Contract and works with the adolescent to identify an appropriate goal for improved diabetes management. Guided by the RA, the adolescent writes their goal, when they plan to do it, and how often they plan to do it. Adolescents are encouraged to share their goal with friends and family members so they can be held accountable. The adolescent and the RA both sign the document, and the participant is asked to put it somewhere that they can see it, so they are frequently reminded of their commitment.

2.6. Education + Positive affect

Adolescents randomized to the Positive Affect intervention group receive the same education packet also complete the Health Behavior Contract with the RA, making a commitment to make a change in some aspect of their diabetes management (as described above).

Adolescents in the Positive Affect group also complete a Positive Affect Interview at the baseline study visit. Using a worksheet developed to induce positive affect, the RA guides the adolescent to identify things that make them happy (gratitude), even if it is just for a few minutes at a time. The RA encourages the adolescent to choose things that are regularly accessible (everyday occurrences, such as hearing a favorite song, or playing with a pet) that the teen feels grateful for having or being able to do. Next, the RA asks the adolescent to choose three items from a list of things that they consider important to them: Enjoying sports, Having a sense of humor, Music, Relationships with friends, Following politics/current events, Belonging to a social group or club, Working hard in school, Being creative, Art, Relationships with family members, and Faith or spirituality. This list was based on earlier work in social psychology, demonstrating that a self-affirmation exercise can improve academic outcomes in high-risk students [29]. The RA prompts the adolescent to choose their top value, think about why this value contributes to their own feelings of self-worth and importance, and write a few words about why that value is important to them. Finally, the adolescent writes about a positive experience or an accomplishment that they have had with the value that they chose as a self-affirmation.

Automated text messages are sent to participants to prompt them to engage in reflecting on gratitude and their important value. These messages are sent via the integration of Twilio with REDCap. The RA enters information into REDCap for each participants' role (adolescent or parent), including their assigned condition (Education + Positive Affect or Education), age group (13–14 years old or 15–17 years old), mobile phone number, and preferred time to receive the text messages. This information is used to send the appropriate text message content to the respective participant groups. Messaging begins the Monday after enrollment, and each message type is sent according to a defined weekly schedule for 8 weeks (see Fig. 1).

Thrive Study Participant Experience

The following two-week experience example sequence continues for 8 weeks

1st Week, all participants start the Monday after enrollment

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Teen	Gratitude		Important Value		Mood Booster	Mood Booster	Mood Booster
Parent							Positive Message

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Teen	Gratitude	★	Important Value		Mood Booster	Mood Booster	
Parent							Positive Message

*Teens assigned to education group get only this message every other Sunday, parents in the education group do not receive any messages

Component	Frequency	Description
Gratitude Reminder	1x/week	Teens are asked to notice small things that make them feel good, even for a few minutes
Important Value Reminder	1x/week	Teens are asked to think about a value they identified as important when they are in a situation that makes it hard to do diabetes care
Mood Booster Text	2-3x/week	Inspirational quotes or jokes
Unexpected gift	1x/biweekly	$5 gift card code to online store delivered via text message
Parent Affirmation Reminder	1x/week	Caregivers are asked to provide praise or positive message to their adolescents, this reminder is sent to the parents phone.

Fig. 1. Automated text message schedule.

Several of the text message types for the Education + Positive Affect group are tailored to the adolescent. The younger adolescents (age 13–14 years) and older adolescents (age 15–17 years) receive 'Mood Booster' content that is slightly different for each group as determined by preliminary work conducted to obtain adolescents' preferences. Elements of the important values and sources of gratitude identified by adolescents during the Positive Affect interview are used in text messages to tailor the PA intervention over the 8-week period. On Monday of each week, the adolescent receives a text asking if they noticed the specific source of gratitude the past week. They are given the opportunity to respond with a new source of happiness that is used in the subsequent weeks messaging to tailor the experience to each adolescent. Additionally, on Wednesday of each week, the adolescent receives a text message asking if they remembered to focus on the important value they identified during the Positive Affect interview (e.g., sense of humor) when taking care of their diabetes was difficult, and reminding them to do so. On Thursday and Saturday, adolescents receive a Mood Booster message (see Fig. 1). Finally, on alternating Tuesdays, adolescents receive an unexpected gift ($5 USD gift card code).

Parents of adolescents in the Positive Affect intervention group complete a parent praise worksheet with the RA at the baseline study visit. This worksheet was developed to increase the amount of positive interactions that occur between the parent and adolescent, as another way to enhance adolescents' positive affect. The worksheet describes qualities and criteria for effective praise and outlines the effects that positive messages and praise can have on adolescent behavior and home environment. The praise should be unrelated to diabetes or diabetes management, as the goal of this exercise is to recognize the adolescent's strengths aside from diabetes management. The RA reviews the worksheet with the parent and asks the parent to generate examples of how they can effectively praise their child. The RA then gives the parent feedback: A strong example of praise would be the following: "I am proud of you for studying for your test. It's great to see you working

hard at school!" This is enthusiastic, genuine, specific, and praises the process rather than the outcome. A weak example of praise might be, "You're a good kid!" While this statement may be enthusiastic and genuine, it is not specific. The RA works with the parent to modify any examples that are not consistent with the criteria so the parent has a clear idea of the type of praise they should be giving. As part of the intervention, parents receive weekly text message reminders to give their child positive messages throughout the 8-week active phase of the intervention (see Fig. 1).

2.7. Measures

Adolescents and their parents complete questionnaire measures at baseline, 3 months, 6 months, and 12 months, corresponding with their regularly-scheduled diabetes clinic visits. If participants cancel/no-show for their clinic appointment, they are sent a secure link to complete the surveys in REDCap. Clinical data are extracted from the medical record corresponding with the closest outpatient clinic visit. While the RA collecting follow-up data is not blinded to participants' treatment condition, the use of iPads to collect survey data limits the possibility of RAs influencing participants' responses.

2.7.1. Positive affect

The Positive and Negative Affect Scale – Children (PANAS-C) is a 30-item measure of positive and negative emotions in youth [30]. It includes 15 positive emotion adjectives (e.g., happy, proud, calm) and 15 negative emotion adjectives (e.g., sad, upset, lonely). The measure asks participants to indicate the extent to which they have felt each of the emotions in the past few weeks, on a 5-point Likert scale (ranging from *very slightly or not at all* to *extremely*). The PANAS-C has been validated for use across various populations and has strong internal consistency, a = 0.87 for negative affect items and a = 0.92 for positive affect items [31].

2.7.2. Diabetes distress

The Problem Areas in Diabetes – Teen Version (PAID-T) Scale is a 14-item self-report measure that assesses diabetes-specific emotional distress in adolescents [17]. Adolescents rate how much each problem associated with living with diabetes applied to them over the past month, on a 6-point Likert scale. The Parent – Problem Areas in Diabetes – Teen (P-PAID-T) Scale is a 15-item measure that asks parents to rate their own DD over the past month, on a 6-point Likert scale. Higher scores indicate greater DD, with clinical cutoff scores of > 44 and > 54, respectively. Both measures have been validated and have strong internal consistency (a = 0.95 and 0.96, respectively) [17].

2.7.3. Diabetes self-care

The Self-Care Inventory (SCI) is a 14-item self-report measure of perceived adherence to diabetes regimen recommendations among individuals with diabetes [32]. In the current study, the measure has been modified to reflect new methods of BG monitoring (i.e., increased use of CGM) and remove items not relevant to T1D management (i.e., taking the correct dose of diabetes pills). Both adolescents and parents rate how well the adolescent followed their diabetes care regimen in the past month, using a 5-point Likert scale. Higher scores indicate greater adherence to the prescribed regimen. The parent and adolescent measures have both been validated and have demonstrated adequate internal consistency scores (a = 0.71 and 0.73, respectively) [33].

2.7.4. Family conflict

The Diabetes Family Conflict Scale (DFCS) is a 19-item measure of conflict that can arise between children and parents managing diabetes [30]. Both parents and adolescents rate how often they have argued about diabetes management tasks over the past month. Higher scores indicate a greater frequency of conflict. The measure has been validated and has strong internal consistency for both youth report of diabetes-specific conflict (a = 0.85) and parent-reported conflict (a = 0.81) [34].

2.7.5. Coping

The Responses to Stress Questionnaire (RSQ) is a two-part measure of stress and coping for adolescents with diabetes [35]. The first section of the questionnaire asks the adolescent to rate how often they have experienced 10 diabetes-related stressors in the last six months, on a 4-point Likert scale. Then, the adolescent is asked how stressful the problems were and how much control they feel they have over these problems on a scale from 1 (not at all) to 4 (very). The second part of the questionnaire consists of 57 items that represent a range of responses to stress. Adolescents rate how much they engage in each of the behaviors on a 4-point Likert scale (ranging from *not at all* to *a lot*). The items assessing responses to stress are used to determine 3 validated coping factors (primary control coping, secondary control engagement coping, and disengagement coping) and two factors of involuntary stress responses (involuntary engagement and involuntary disengagement) [35]. In the current study, coping factors will be used in analyses. Primary control coping includes strategies to resolve the stressor, including problem solving and emotional expression. Secondary control engagement coping includes strategies to adapt to the stressor, such as positive thinking or cognitive restructuring. Disengagement coping refers to strategies to orient away from the stressor, such as avoidance or denial. Internal consistency has been shown to be good to excellent, ranging from a = 0.74 to a = 0.81 in adolescents with T1D [36].

2.7.6. Resilience

The Diabetes Strengths and Resilience measure (DSTAR-Teen) is a 12-item self-report questionnaire to assess diabetes strengths in adolescents [37]. Specifically, the measure explores adolescents' perceived ability to manage the demands and unpredictability of diabetes and their perceived access to support systems. Adolescents rate how often each item applies to them on a 5-point Likert scale (ranging from *never* to *almost always*). Higher scores indicate greater perceived diabetes strengths. The measure has strong psychometric properties, including good internal consistency (a = 0.86) and construct and criterion validity [37].

2.7.7. Quality of life

The Type 1 Diabetes and Life (T1DAL) questionnaire measures diabetes-specific health-related quality of life in adolescents and their parents [38]. The 23-item measure consists of 5 subscales including *Diabetes and Other People, Diabetes and Family, Diabetes and Activities, Taking Care of Diabetes, and Diabetes and Feelings*. Adolescents and parents rate how much each item describes their experience with diabetes or parenting a child with diabetes, respectively, over the past 4 weeks. T1DAL has been validated across multiple age groups and has demonstrated strong internal consistency (a = 0.89) and test-retest reliability (r = 0.80) [38].

2.7.8. Demographics and device use

Parents report on family demographics, including relationship to the child, gender, race/ethnicity, education, and family income. In addition, to better understand how adolescents use diabetes devices, we included questions to assess participants use of insulin pumps and continuous glucose monitors (CGMs). Parents and adolescents report on CGM use, reasons for CGM discontinuation, how the CGM was set up, and whether participants take "breaks" from their CGM. Demographics and device use will be assessed as potential moderators of treatment effects.

2.7.9. Glycemic control

Hemoglobin A1c (A1C) is measured as part of regular clinical practice at each diabetes visit. A1C is a measure of average blood glucose levels over the previous 8–12 weeks. It is obtained using the

DCA 2000 Analyzer, and point-of-care A1C values will be extracted from the medical record at each data collection. The target for A1C is < 7.0% for most children and adolescents [8].

2.7.10. Blood glucose data and device uploads

Participants' diabetes devices (meters, CGM, etc.) are uploaded to an online blood glucose management program or the patient's electronic medical record during clinic visits. A trained RA extracts this information and enters it into the REDCap database. For adolescents using glucometers, we record average checks per day (frequency of blood glucose monitoring) for the 30-day period preceding the clinic visit. For adolescents using CGM, we record time in use (percentage of days worn), average glucose, percent time in range, and percent hypoglycemic for the 30-day period preceding the clinic visit.

2.7.11. Interim mood assessment

Every other Sunday during the 8-week intervention, adolescents (in both PA and EDU conditions) receive the Child Positive and Negative Affect Scale Short Form (C-PANAS-SF) assessment via text message Fig. 1. The text messages are automated using the Twilio integration with REDCap. Each of the 10 survey questions is sent as a text message with the subsequent survey question sent to the adolescent's phone once a response is received for each question. The adolescents' responses to each question are captured by Twilio and stored in REDCap.

2.7.12. Exit interviews

During the 3-month follow-up visit, families have the option to participate in an exit interview. This audio-recorded interview explores the adolescent's and parent's reasons for participating in the study, the acceptability and feasibility of the intervention, suggestions for improvements that could be made to the program, and qualitative information about mood and diabetes management. These interviews will be transcribed by RAs and analyzed for themes to inform potential future studies.

2.8. Data analysis plan

2.8.1. Power analysis

We plan to enroll 200 adolescent-parent dyads and conservatively assume a 15% dropout rate, leaving 170 subjects for analysis. Power calculations for the repeated-measures design were conducted using a variety of statistical simulations for each of the outcomes. Inputs into the simulation study, based on preliminary data from 46 subjects measured 3 months apart, were baseline mean, baseline standard deviation, and correlation between baseline and 3-month measurement. With the planned sample, we will have power of 0.90 to detect a mean difference of 0.5 on A1C, a clinically meaningful reduction [5].

The primary outcome is change in glycemic control (A1C). To test Aim 1, we will use an intent-to-treat framework using a linear mixed effects regression model to estimate the effect of intervention over time on glycemic control (A1C as a continuous variable). Our secondary outcomes are DD, coping, and diabetes management. To test Aim 2, separate linear mixed effects regression models will be used to estimate the effect of the intervention over time on secondary outcomes, including DD (PAID-T), coping (RSQ), and diabetes management (P-SCI, SCI, device use).

Outcomes are measured at up to four time-points per subject (baseline, 3 months, 6 months, and 12 months), so we will use time, treatment group and the interaction of treatment with time serving as the main explanatory variables. Such a model will allow us to test for any differences between treatment and control groups at 3, 6 or 12 months while accounting for baseline values. In addition, the PANAS repeated measures will allow us to assess short-term effects of the intervention on positive affect. While the randomized block design should minimize confounding, we will adjust for age, sex, and race/ethnicity, and recruitment site to improve precision. The results from the adjusted and unadjusted models will be compared with respect to their estimates of the treatment effects. We will include a random intercept to account for within-subject correlation arising from taking repeated measurements on the same subject over time. The error structure of the model is assumed to be compound symmetric, and the validity of this assumption will be examined by computing Akaike Information Criteria against other common structures. By using a longitudinal repeated measures regression model, we will be able to generalize repeated measure ANOVA to allow for mis-timed or missing variables.

2.8.2. Exploratory aim

To examine the differential impact of intervention effects across demographic (i.e., age, race/ethnicity, sex) and treatment variables (i.e., diabetes devices), we will examine these factors as potential moderators of the intervention effects. Moderators will be tested by including an interaction term with treatment group in the regression models.

2.8.3. Feasibility/Acceptability

We will collect information about acceptability using the satisfaction survey, collected at the 3 month data collection. In addition, the exit interviews with participants will help determine which aspects of the intervention they found helpful or unhelpful. Feasibility will be assessed by examining participation rates and engagement with the text messaging component. Our benchmark for engagement is at least 70% response rate to the messages across the 8-week intervention period.

2.9. Safety

As a behavioral intervention, the current study confers few risks to study participants. It is possible, however, that participants may experience increased distress related to completing surveys asking about their feelings and problems related to diabetes management. In addition, there is the possibility of release of confidential information. To minimize these risks, all research staff at both sites will complete annual training in Good Clinical Practice and HIPAA.

3. Discussion

The current study is one of the first randomized clinical trials to evaluate the effects of a positive psychology intervention in a pediatric population and one of the first interventions aimed at reducing DD in adolescents with T1D. Given that adolescents with T1D are at high risk for problems with diabetes management and suboptimal glycemic control, this novel approach has the potential to treat DD as a mechanism to improve outcomes in this high-risk population.

In line with the American Diabetes Association's recommendation to assess for and address DD [39], the current study targets adolescents who report at least moderate levels of distress. Using a positive psychology framework, which emphasizes positive emotions and strengths rather than problems, is an innovative approach to treating DD and improving glycemic outcomes. The demands of treatment management are a chronic source of stress for adolescents with T1D [15], and inducing positive affect may provide a respite, allowing them to build social, intellectual, and physical resources that become depleted under chronic stress [40]. Backed by empirical evidence from basic behavioral science and earlier work in adults with chronic health conditions [22], the current study is based on the premise that boosting positive affect in adolescents with diabetes will enhance the use of adaptive coping

strategies and reduce DD, thereby improving glycemic control.

The intervention effects may be moderated by demographic or clinical variables; for example, older age and ethnic minority status have been associated with poorer glycemic control and adherence, and rates of DD are higher in females and older adolescents [13,17]. The use of diabetes devices, such as insulin pumps and continuous glucose monitors (CGMs), has been linked with better glycemic control [41,42], but it is unknown how these devices relate to DD in adolescents. Additionally, females typically exhibit higher levels of engagement with mHealth interventions than males [43]. Therefore, we plan to explore these factors as potential moderators of the intervention effects.

4. Limitations

The current study is limited by including adolescents and parents who agree to take part in a longitudinal study, which may not generalize to other populations. In addition, despite evidence that DD is strongly linked to diabetes outcomes, including glycemic control and self-management [13,17], we may find that the intervention has positive effects on DD but not on diabetes outcomes. In addition, by only recruiting adolescents who attend diabetes clinic appointments, we may be excluding youth who have higher levels of distress or poorer glycemic control.

5. Conclusions

The current study aims to evaluate the effects of a positive psychology intervention to treat DD in adolescents with T1D. This text message-based intervention builds on prior work in positive psychology and our earlier pilot studies in adolescents with T1D to maximize feasibility and acceptability. If demonstrated to be efficacious, the use of automated text messages will allow for future low-cost, wide dissemination of this innovative intervention.

Acknowledgements

This work was supported by the National Institutes of Diabetes and Digestive and Kidney Diseases, R01DK121316.

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