Published in final edited form as:

Contemp Clin Trials. 2018 March ; 66: 64–73. doi:10.1016/j.cct.2017.12.006.

The Flexible Lifestyle Empowering Change (FLEX) Intervention for self-management in adolescents with Type 1 Diabetes: Trial design and baseline characteristics

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Abstract

The Flexible Lifestyle Empowering Change (FLEX) Intervention Study is a multi-site randomized controlled trial to test the efficacy of an adaptive behavioral intervention to promote self-management for youth with type 1 diabetes mellitus (T1D). This paper details FLEX design, demographic characteristics of the sample, and outcome variables at baseline. Participants were randomized to either an intervention or control arm after their baseline standardized measurement visit. Baseline data for the primary (glycemic levels) and secondary outcome variables (e.g., motivation and problem-solving, health-related quality of life, risk factors associated with T1D complications) as well as the potential mediator variables (e.g., self-management behavior, family conflict and responsibility) suggest that the study sample was representative of the general population of adolescents with T1D and their parents. The FLEX adaptive intervention is an innovative application of a tailored treatment intervention designed to be readily adopted in real-world practice to meet each adolescent's individualized T1D self-management goals.

Keywords

Type 1 Diabetes; Health Interventions; Adolescents; Parents

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Type 1 diabetes (T1D) is a complex disease with an intensive medical regimen¹ that requires active disease management by the patient throughout the day and night to maintain appropriate blood glucose concentrations. Adolescence is an especially difficult time for the consistent execution of disease management processes; therefore, there is a higher risk for both short- and long-term consequences for those not able to achieve and maintain in-target glycemic levels during this developmental period^{2, 3}. The Flexible Lifestyle Empowering Change (FLEX, previously FL3X) Intervention Study is a multi-site randomized control trial to test the efficacy of an adaptive behavioral intervention to promote self-management and improve glycemic levels for adolescents with T1D. FLEX uses Motivational Interviewing (MI);^{4, 5} to create a motivational framework and Problem-Solving Skills Training (PSST)^{6, 7} to teach practical problem solving tailored to the patient and family's context and needs⁸.

Combining both PSST and MI approaches, by providing information, motivation, and behavioral skills to prevent poor outcomes in a single intervention is novel as previous interventions typically use one or the other⁹. Moreover, it is developmentally appropriate for adolescents, who are negotiating their emerging autonomy, to use an intervention that combines MI with other behavioral strategies targeting adherence, such as PSST. This type of patient-centered intervention facilitates the adolescent's own agency by creating a framework for them to explore their own motivations. Once the adolescent's own motivation is in place, then practical problem-solving skills can be readily integrated. Further tailoring occurs through the use of a flexible 'toolbox' that includes elements of Behavioral Family Systems Therapy – Diabetes [BFST-D]¹⁰, as well as T1D education materials (e.g., diet and physical activity), social support, and the use of communication technology. FLEX is based on a conceptual framework (See Figure 1) in which both motivational factors and T1D-specific information lead to acquisition of skills needed to adhere to T1D self-management recommendations (all potential mediating variables) to improve both primary and secondary health outcomes.

FLEX also addresses practical clinical considerations that have been recommended in the literature¹¹ as next steps for behavioral intervention research in two pragmatic ways. First, it uses interventionists as 'coaches' who are already members of an existing T1D medical care team (e.g., dietitian, nurse, and certified diabetes educator) in order to be responsive to existing personnel constraints in clinical settings. To date, most MI intervention studies for T1D used psychologists/psychology trainees or only briefly trained health care providers to implement the MI interventions, and these studies have not yielded much success;¹² therefore, FLEX provides more extensive of training and follow-up support for coaches to use MI as part of a behavioral intervention. Second, FLEX uses an adaptive intervention approach, based on treatment response to a priori decision rules, to provide the least restrictive intervention to enhance future scale and replication while still managing cost and maintaining effectiveness^{13–15}. Although adaptive intervention designs have been used in addiction¹⁵, community¹⁶, general child clinical interventions¹⁷ and family-centered prevention program settings¹³, FLEX is one of the first studies to use an adaptive intervention design in pediatric chronic care, including T1D.

The previous FLEX pilot study's⁸ preliminary data demonstrated improved glycemic levels (measured by Hemoglobin A1c) by 0.5% ($d = -0.58$; $p = 0.09$) for 57% adolescents with T1D in the intervention group. However, the FLEX pilot was only a 3-month intervention and was a small scale randomized control trial. Therefore, the FLEX study described here extends the pilot in several ways: 1) it is fully powered, 2) it is an adaptive clinical intervention trial, and 3) the 18-month intervention allows for long-term assessment of how the behavioral intervention impacts T1D adherence. The overarching FLEX study aims are to test the efficacy of the intervention; evaluate cost/cost effectiveness; and ensure applicability in T1D management. In the present paper, we describe the FLEX design as well as the sample baseline characteristics.

Methods

Study Participants

Participants were adolescents with T1D, age 13–16 years, T1D duration >1 year, and Hemoglobin A1c (HbA1c) between 8% and 13%, based on the most recent HbA1c in the medical record, reflecting glycemic control in the previous 8–12 weeks. One primary caregiver, who was involved with the T1D management, was also required to participate. English and Spanish-speaking youth and parents were eligible as well as youth who were already involved in mental health treatment or taking psychotropic medications. Youth were excluded if they were pregnant or had a serious medical condition that was physical (e.g., cancer), developmental (e.g., cognitive impairment), or psychiatric (e.g., severe psychopathology) in nature. Our planned study sample size was 200 to allow for detection of a clinically meaningful intervention effect on the primary outcome variable (HbA1c) of 0.60%, which translates to an effect size of 0.40.

Design and Procedures

Recruitment—Medical records at two major tertiary pediatric T1D centers in the Mountain West and Midwest were used to identify patients who initially met study eligibility criteria. The FLEX website (www.type1fl3x.com), study posters, and brochures were also used for recruitment. All participants and their parent(s) were assented and consented to FLEX after undergoing a 2-step recruitment process. Step 1 consisted of an initial contact to introduce the study and a follow-up phone call to further explain the study, answer questions, and determine if the adolescent and parent were interested in participating. After mailing additional information about the study, Step 2 consisted of a scheduled phone call to both the parent and the adolescent to review the study in detail and address barriers/issues to participation and to obtain commitment to the study. These conversations allowed the parent and adolescent to identify, express, and discuss concerns and potential benefits about participation. If the parent and the adolescent agreed to participate, then the baseline visit was scheduled. Written consent and assent were obtained at the first in-person baseline standardized measurement visit. IRB approval was obtained at each participating site and registered with www.clinicaltrials.gov.

Standardized Measurement Visits—Using the conceptual model in Figure 1 to guide measure selection, the *Primary Outcome Measure* was HbA1c. *Secondary Outcome*

Measures included motivation and problem solving skills, depression, health-related quality of life (HRQOL), hypoglycemia derived from continuous glucose monitoring (CGM), and risk factors for T1D complications. *Potential Mediator Measures* included diabetes knowledge, self-efficacy, and self-management behaviors, as well as family conflict and T1D responsibility. Standardized measures (and their corresponding theoretical constructs) collected at baseline 3, 6, 12, and 18 months from both adolescent participants and their parents/caregivers are summarized in Table 1.

Table 1 also lists measures that were administered, but not hypothesized to be primary outcome, secondary outcome, or potential mediator variables. These additional measures included: Specific Health Care Use (designed specifically for FLEX), FLEX Cost Survey [adapted from ¹⁸], Food Security Questionnaire ¹⁹, Diabetes Eating Problem Survey ²⁰, Health Behaviors and Home Environment [adapted from ^{21–23}], External Eating ²⁴, 24-hour Diet & Physical Recall ^{25–28}, and Hypoglycemia Fear Survey ^{29–31}. In order to determine cost effectiveness, we will compare the total cost of FLEX to usual diabetes care, and we will estimate cost per unit change in HbA1c and per quality adjusted life year using the Health Utilities Index ³². At the 18 month Standardized Measurement Visit, participants were interviewed for Recruitment/Retention feedback and the intervention group also completed the Intervention Acceptability Interview. Adverse events, such as a positive screen for high risk of depression and/or suicidal ideation were monitored and a safety protocol was in place for study personnel to respond to high-risk patients. The Standardized Measurement Visits each took approximately 1–2 hours to complete.

FLEX Intervention Condition

Overview: The FLEX intervention was designed to improve T1D self-management including medical management (e.g., blood glucose monitoring and insulin dosing), diet, and physical activity, in a manner sustainable and conducive to improved outcomes using a clinical setting approach. The FLEX intervention uses MI and PSST as the primary basis for the counseling strategy and incorporates tools from: 1) family communication and teamwork through BFST-D; 2) individualized T1D education in response to knowledge gaps relevant to behavioral goal attainment; and 3) use of communication technology for participant-defined reminders and motivational boosters.

Motivational Interviewing, as used in FLEX, serves to help the participant create a motivational frame for change. In this way, it enhances engagement with the other intervention components and increases the likelihood that the intervention content (i.e., problem-solving skills) will be well-received and used effectively. Thus, FLEX coaches deliver a behavioral intervention (PSST) within a MI context designed to identify each youth's unique behavioral, cognitive, or affective barriers and resources pertaining to optimal T1D self-management, negotiate a plan addressing the identified targets, and assist in implementing, evaluating and refining strategies with the youth as needed during the 18-months of the study.

In addition to the FLEX coaches' primary use of MI and PSST approaches, they used other supportive components during the FLEX intervention such as family communication skills and individualized T1D education, and use of communication technology. The family

communication intervention strategies from BFST-D included enhancing parent-youth teamwork and collaborative problem-solving. This approach used standard behavior therapy techniques of providing instructions as well as feedback, modeling, rehearsal, and individualized behavioral homework, with particular attention to parental support of goals established by the youth regarding T1D self-management. The T1D education resource information (i.e., ‘toolboxes’) included materials likely to be useful to study participants, which were tailored, based on participants’ specific needs. Topics in the ‘toolboxes’ included enhanced family communication and teamwork activities, T1D education, social support, and diet and physical activity, which are all consistent with American Diabetes Association (ADA) ³³ and International Society of Pediatric and Adolescent Diabetes (ISPAD) ³⁴ clinical practice guidelines. These toolbox materials were available to all participants initially, and then the coach selected and implemented specific materials from the toolbox based on participant needs as the intervention progressed. Referrals to appropriate health professionals were made as needed. Any additional mental health care received by the participants was assessed throughout the course of the FLEX study.

The FLEX intervention also used communication technology, such as cell phone prompts and telehealth, to enhance youth engagement, problem solving, and flexible intervention delivery. FLEX coaches encouraged the use of participants’ cell phones to set user-defined behavioral prompts or reminders, as well as to allow health coaches to provide text message encouragement to engage participants in their FLEX plan.

Coach Training: FLEX coaches were trained by experienced psychologists with expertise in both MI and behavioral interventions, which included initial in-person training on the theory of MI and PSST in general as well as specific training on the FLEX intervention on a session-by-session basis for an initial 6 months period. They were then provided on-going weekly support and feedback throughout the study on sessions from the same psychologists. Eventually, this support tapered to bi-monthly and monthly support. Treatment fidelity was measured using both FLEX Content Fidelity checklists (goal >90% fidelity) and the MI-specific MITI fidelity checklist (goal >4.0 on all subscales). Coaches had to achieve this treatment fidelity with 3 pseudo participants prior to initiating the intervention. All intervention sessions were audiotaped and a random 10% sampling was selected for treatment fidelity review. All of the coaches were research personnel, even if they had separate clinical duties with their respective diabetes clinics. Although coaches tried to coordinate sessions in conjunction with routine diabetes clinic visits to decrease burden on the family, these sessions were conducted separate from the medical appointments. The participants were randomly assigned to coaches when there was more than 1 coach at a site. A FLEX Training Manual of Procedures (MOP) was developed for future dissemination to other potential coaches, who want to implement the FLEX intervention.

FLEX Intervention Schedule: All participants who were randomly assigned to intervention received FLEX-Basic, the initial 3-month intervention that includes 4 in-person sessions (40–60 minutes in length) with a FLEX coach, with additional brief contacts as needed (e.g., text, voice, or internet). Participants were assigned to different intensities of in-person follow-up sessions (FLEX Check-in or FLEX-Regular), according to the rules for selecting

the adaptive intervention after the FLEX Basic sessions as well as every subsequent standardized measurement visit. Specifically, the decision rule was based on a pre-determined HbA1c change as measured at each standardized FLEX measurement visit. Participants were assigned to FLEX Check-in if the following criteria were met: 1) HbA1c < 7.5%; or 2) previous HbA1c was between 7.5% and 9.0% and there was a decrease of > 0.5%; or 3) previous HbA1c was > 9% and there was a decrease of > 1.0%. This is consistent with ADA and ISPAD clinical practice guidelines^{33–36} and with other clinical trials that use HbA1c change of > 0.5% in youth with T1D as a marker of success³⁷. (See Figure 2).

Participants who met the HbA1c targets were assigned to FLEX Check-in and received brief (15–20 minutes each), but ongoing support from the FLEX coach to reinforce their progress through monthly contacts [e.g., phone conversation (not text) or video-enhanced call]. Participants who did not meet HbA1c targets were assigned to FLEX-Regular, which provided a minimum of 3–4 in-person, full-length sessions (40–60 minutes each) with the FLEX coach over each 6-month period between standardized measurement visits, and brief contacts as needed (e.g., text, voice, or internet) until the next standardized measurement FLEX visit at which time the next HbA1c was measured and the adaptive rule applied again.

Structure of FLEX Intervention Sessions: The FLEX intervention was formalized through a MOP that includes session goals, materials, and sample scripts for each session. These scripts were written for FLEX Basic, FLEX Check-in, and FLEX Regular sessions using a modular format where the content for each of the intervention strategies (i.e., MI, PSST, Family Communication, T1D education ‘toolboxes’ and Behavioral Homework contracting) were then provided in a uniform manner across sessions. There were multiple decision trees for the FLEX coach to assess participants’ success (or lack thereof) in behavioral goal attainment to determine which treatment module was best used during the session. Table 2 outlines the specific components of the FLEX intervention sessions, including when and how parents were integrated.

In addition, youth (primarily in FLEX Check-in) were given the option of using telehealth options to complete monthly brief contacts with their health coaches, including secure, HIPAA-compliant video teleconferencing platforms. There were occasions when telehealth options were offered to participants in FLEX Regular, if this approach was the best option for maintaining participants’ involvement in the intervention.

FLEX Usual Care Control Condition—Participants received a brief report describing key clinical results from the study standardized measurement visits and a copy of the Pink Panther™ *Understanding Diabetes*, a T1D educational book for patients and families. Usual care was used as the control condition to demonstrate that FLEX is a more effective way to deliver T1D self-management skills training to improve adherence in a clinical setting than current practice.

Compensation for Participation—All participants received incentives for completing the standardized measurement visits (\$120 for baseline, \$200 for 6-month, \$250 for 18-month; and \$50 for each of the brief visits at 3 and 12 months), but not for any of the

intervention visits. Participants received an additional incentive for completion of CGM data collection at baseline, 6 months, and 18 months (\$50 for wearing the CGM device for 7 days and \$25 for returning the device) and completing the 24-hour dietary and physical activity recalls at baseline and 6 months (\$10 for the first call and \$15 for the second for up to \$25 at baseline and 6 months). Parents received a \$20 for participating in each of the 5 standardized measurement visits.

Randomization—Following the baseline measurement visit, participants were randomized to intervention or control (1:1) using a block size of 4, stratified by site and, within site, by HbA1c (< 9% or > 9%). All participants were informed of their group assignment (control versus intervention) and were instructed to continue usual care with their T1D provider.

Statistical Analyses—All analyses were conducted using SAS, version 9.3. Probability levels of $p < 0.05$ were used as a cut-off for statistical significance in all analyses. Descriptive analyses provide a summary of demographics, primary and secondary outcomes, as well as the potential mediating variables at baseline for the entire youth cohort (i.e., intent to treat) and their parents. In the present study, both the parent and the youth reports are presented whenever assessed, but in future analyses we will determine the concordance between the two reporters and to determine whether a composite variable is warranted.

Results

From a pool of 855 potential participants across 2 sites, 258 (31%) enrolled and completed a baseline visit with their parent ($n = 150$ from site 1 and $n = 108$ from site 2). The remainder of the potential participants who did not enroll in the study were ineligible ($n = 141$), declined to participate ($n = 321$), unable to be contacted ($n = 115$), or in process when full enrollment was reached ($n=20$). Ineligibility was primarily related to not meeting the study HbA1c enrollment criteria. Common reasons for declining to participate were travel distance and treatment burden. Of the parents who participated in the intervention with their adolescents, 84.4% ($n = 217$) were maternal caregivers. Demographic characteristics are presented in Table 3.

Baseline Primary Outcome, Secondary Outcome and Potential Mediator Variables

The means and frequencies of these baseline outcome variables are presented in Tables 4 and 5. To examine baseline differences as we employed targeted recruitment efforts to ensure that those with elevated HbA1c levels were equally represented, participants with higher HbA1c (>9.0%, $n=170$) were compared to those with lower HbA1c levels (< 9.0%, $n=88$). Participants with higher HbA1c levels were older (15.0 vs. 14.7 years, $p=.04$) and had higher LDL cholesterol (101 vs. 91, $p=.006$), total cholesterol (176 vs. 162, $p=.002$), and triglycerides (95 vs. 73, $p=.001$). Participants with higher HbA1c levels had lower overall motivation scores (7.5 vs. 7.9, $p=.047$), including being less motivated to take insulin (8.14 vs. 8.80, $p=.006$). Those with higher HbA1c levels had lower DSMP scores from both youth (53.4 vs. 58.2, $p=.001$) and parent (49.9 vs. 55.0, $p=.001$) reports, and higher DFCS scores based on parent report only (1.46 vs. 1.38, $p=.04$). There were no significant differences according to HbA1c levels on any of the other measures.

For secondary outcomes and potential mediator variables, the scoring patterns of participants in this study were comparable to the literature outlined in the Tables 4 and 5 (including the available means, ranges, and Cronbach's alphas). The one exception was CES-D scores, which were lower ($M = 9.2$, $SD = 8.3$) in the present study than other studies of youth with T1D⁴². However, there was a wide range of responses (Range = 0–45) provided by FLEX participants, reflecting that some ($n = 16$, 6.2%) were screening positive for possible depression (i.e., Total Score > 24).

Discussion

The innovative and novel FLEX intervention to improve adherence provided by FLEX coaches creates a motivational framework and teaches practical problem solving as well as provides a 'toolbox' of education and communication strategies with adolescents who have T1D and their parents. The innovative adaptive intervention presented here is a tailored treatment intervention designed to meet an individual adolescent's T1D self-management goals and is potentially scalable for real-world adoption. Our aim was to enroll a generalizable sample of adolescents aged 13–16 years with T1D and their parents who reasonably represent a population with suboptimal glucose levels into an adaptive intervention (FLEX) to improve health outcomes. Scoring patterns of baseline primary outcome, secondary outcomes, and potential mediator variables were similar to previously published norms for each measure, except that participants in the present study had a lower mean depression score. Therefore, the findings suggest that even though recruitment targeted a higher risk sample of adolescents with elevated glycemic control, our study sample still appears to be generally representative to the populations of adolescents with T1D and parents⁵¹. It is important to note that both sites either already had or initiated during the study recruitment time period regular depression screening as part of routine T1D clinical care, so the exposure to depression screening and the subsequent mental health interventions provided to these patients separately may be impacting the number of adolescents reporting higher risk of possible depression in this study.

Although recruitment for the FLEX Study was successful and clinical data appear to be comparable to the overall population sampled even for those with elevated glycemic levels, it will be important for future studies to also examine whether this participant engagement can be maintained without financial incentives as well as whether there are other subpopulations for which this intervention may be useful (e.g., newly diagnosed, younger adolescents, young adults). As mentioned previously, some of the recruitment barriers identified by potential participants were travel distance and treatment burden. Although the FLEX study team attempted to use telehealth resources with some families to engage them in the intervention, future research is necessary to explore other mechanisms to increase the accessibility of the FLEX intervention to families living long distances from their T1D centers.

Future FLEX publications will present whether the FLEX adaptive intervention demonstrates efficacy in the promotion of T1D self-management for adolescents. In addition, information will be provided about unique contributions of the study design including more detail about the 2-step recruitment strategy discussed briefly and its

implications for study retention, as well as the cost effectiveness of FLEX. It will be important for future publications to describe the potential long-term benefits of the FLEX intervention over time in improving glycemic levels, T1D management, and HRQOL for adolescents with T1D.

Acknowledgments

This work was supported by the National Institute of Diabetes and Digestive and Kidney Diseases (UC4 DK 101132). The authors have no competing interests to declare.

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Figure 1.
Flex information-motivation-behavioral skills (IMB) conceptual model.

Figure 2.
FLEX Flow

Table 1

Overview of Standardized Measurement Visits for Participants and Parents/Caregivers.

	Baseline	3 mo	6 mo	12 mo	18 mo
Demographic Characteristics					
Demographics (e.g., age, education)	A, P		A, P		A, P
Health History and Diabetes Care	A, P		A, P		A, P
Outcomes					
<u>Primary Outcome Measure</u>					
Hemoglobin A1c (HbA1c)	A	A	A	A	A
<u>Secondary Outcome Measures</u>					
Physical Exam (e.g., Height, Weight, Blood Pressure, Waist Circumference)	A		A		A
Fasting Lipids	A		A		A
Continuous Glucose Monitor (CGM)	A		A		A
Motivation and Intention	A	A	A	A	A
Social Problem-Solving Inventory-Revised: Short (SPSIR-S)	A	A	A	A	A
Centers for Epidemiological Study – Depression Scale (CES-D)	A	A	A	A	A
Pediatric Quality of Life™ – Generic (PedsQL)	A, P	A, P	A, P	A, P	A, P
Diabetes Specific Quality of Life	A, P	A, P	A, P	A, P	A, P
Potential Mediators					
<u>Information</u>					
Diabetes Knowledge Survey (DKS)	A		A		A
<u>Motivation</u>					
Outcome Expectations for Diabetes Self-Management (OEDM)	A	A	A	A	A
Self-Efficacy for Diabetes Self-Management Questionnaire (SEDM)	A	A	A	A	A
<u>Adherence</u>					
Diabetes Self-Management Assessment Profile – Self Report (DSMP-SR)	A, P	A, P	A, P	A, P	A, P
<u>Barriers to Adherence</u>					
Diabetes Family Conflict Scale (DRCS)	A, P	A, P	A, P	A, P	A, P
Diabetes Family Responsibility Scale (DFRQ)	A, P	A, P	A, P	A, P	A, P
Additional Measures					

	Baseline	3 mo	6 mo	12 mo	18 mo
Specific Health Care Use	P		P	P	P
FLEX Cost Survey	P		P	P	P
Health Utilities Index	A		A	A	A
Diabetes Eating Problem Survey	A		A		A
Health Behaviors and Home Environment	A		A		A
External Eating	A		A		A
24-hour Diet & Physical Recall	A		A		
Hypoglycemia Fear Survey	A		A		A
Intervention Acceptability Interview (for intervention group only)					A, P
Recruitment/Retention Interview					A, P

Note: A = Adolescent respondent, P = Parent/caregiver respondent; cells left blank denote measure not completed at that time.

Table 2

Behavioral Strategies Utilized during FLEX Intervention Sessions.

FLEX Basic Sessions (40–60 minutes) All intervention participants	
<i>Session 1 (week 1)</i>	
<ul style="list-style-type: none"> • Review about what was hard and what bothered participant about their T1D • Introduction of MI and PSST to participant • Behavioral Homework contracting with the participant • Integration of parent into the session and outline to parent how they can best support the participant in reaching his/her goal 	
<i>Session 2 (week 3)</i>	
<ul style="list-style-type: none"> • Review with the participant whether the Behavioral Homework was achieved • Based on the participant's success (or lack thereof), either: <ul style="list-style-type: none"> – enhance motivation to make the change, or – work through another PSST cycle to set a new goal • Integration of parent into the session to introduce joint PSST • Behavioral Homework contracting together with participant and parent 	
<i>Session 3 (week 8)</i>	
<ul style="list-style-type: none"> • Review about what was hard and what bothered participant about their T1D <ul style="list-style-type: none"> – Reflect what may (or may not) have changed since starting the intervention • Review with the participant whether the Behavioral Homework was achieved • Based on the participant's success (or lack thereof), either: <ul style="list-style-type: none"> – enhance motivation to make the change, or – work through another PSST cycle to set a new goal • Integration of parent into the session to: <ul style="list-style-type: none"> – discuss successes (or lack thereof) in reaching their joint Behavioral Homework goals, and – assess for parent/adolescent conflict • Based on determination of conflict during the parent/adolescent interaction, the health coach decides to introduce one of 3 topics: <ul style="list-style-type: none"> – family communication strategies (if there is a high level of conflict), – T1D education 'toolbox' (if there is no conflict and they reached their Behavioral Homework goals from last time), or – another joint PSST cycle (if there was not much conflict, but they also did not attempt their previous Behavioral Homework goals). • Behavioral Homework contracting together with participant and parent 	
<i>Session 4 (week 12)</i>	
<ul style="list-style-type: none"> • Review with participant whether the Behavioral Homework was achieved • Based on the participant's success (or lack thereof), either: <ul style="list-style-type: none"> – enhance motivation to make the change, or – work through another PSST cycle to set a new goal • Integration of parent in the session, and depending on what module was provided previously in Basic Session 3, either: <ul style="list-style-type: none"> – present the T1D education 'toolbox' (if not provided previously), or – complete another cycle of joint PSST (if the T1D education 'toolbox' was provided previously) • Behavioral Homework contracting together with participant and parent 	

FLEX Basic Sessions (40–60 minutes) All intervention participants	
FLEX Regular (40–60 minutes) & Check-In (15–20 minutes) months 4–18	
<ul style="list-style-type: none"> • Review with the participant whether the Behavioral Homework was achieved • Based on the participant's success (or lack thereof), either: <ul style="list-style-type: none"> – enhance motivation to make the change, or – work through another PSST cycle to set a new goal • Use of T1D education 'toolboxes' to participant, as needed • Review what was hard and what bothered participants about T1D, as needed • Integration of parent in the session (optional) <ul style="list-style-type: none"> – Another cycle of joint PSST with participant and parent (if warranted) • Behavioral Homework contracting together with participant (and parent if needed) 	

(Note: MI = Motivational Interviewing; PSST-Problem-Solving Skills Training)

Table 3

Baseline demographics of the FLEX participant cohort.

	Mean (SD) or N (%)
Youth (<i>n</i> = 258)[†]	
Race/Ethnicity	
Non-Hispanic (NH) White	200 (77.5%)
Hispanic	33 (12.8%)
NH Black/African American	11 (4.3%)
NH Multiracial/Other	14 (5.4%)
Sex (male)	130 (50.4%)
Age (years)	14.9 (1.1)
English Speaking	255 (98.8%)
Pump versus Injections (pump)	181 (70.7%)
T1D duration (years)	6.4 (3.8)
Tanner Stage (pubic)	
Stage 2	13 (5.4%)
Stage 3	28 (11.6%)
Stage 4	113 (46.7%)
Stage 5	88 (36.4%)
Caregivers/Parents (<i>n</i> = 257)	
Annual Primary Household Income	
<\$25,000	15 (6.0%)
\$25,000–\$49,999	40 (16.0%)
\$50,000, \$74,999	44 (17.0%)
\$75,000 or greater	150 (58.0%)
Declined to answer	8 (3.0%)
Maximum education in primary household	
< High School	2 (0.8%)
High School	28 (10.9%)
Some College	70 (27.2%)
4-yr college	109 (42.4%)
Graduate degree	47 (18.3%)
Don't know	1 (0.4%)

Note:

[†]N=256 for Pump versus Injections; N=242 for Tanner Stage (120 males, 122 females)

Table 4

FLEX baseline primary and secondary outcome variables.

Measure	Construct Measured/Relevant Points	Alpha in Study Sample	Mean (SD) or N (%) in Study Sample	Norms
Primary outcome variable (n = 258) [†]				
HbA1c (%)	Venous blood draw was obtained and measured in a central laboratory using standard clinical chemistry methods. ³⁴	--	9.6 (1.2)	Goal <7.5
Total Percent >9.0% HbA1c		--	170 (65.9)	
Secondary outcome variables				
Body Mass Index (BMI)	Height, weight, waist circumference, and systolic and diastolic blood pressure were measured using standard research protocols.	--	23.4 (8.4)	Goal BMI z-score = 0
Body Mass Index z-score (BMIz)		--	0.7 (0.1)	
Blood Pressure (mm/Hg) SBP		--	101 (9.0)	Goal <130/80 mg/Hg
DBP		--	67 (8.0)	
Total Percent >130/80 mg/Hg		--	2 (0.8)	
Waist Circumference (cm)		--	64 (23.0)	
Fasting Lipids (mg/dl) HDL	Fasting blood draw was obtained using standard laboratory methods.	--	55 (13)	Goal LDL <100 mg/dL
LDL		--	98 (29)	
Total Percent LDL > 100 mg/dL		--	107 (42.0)	
Triglycerides		--	87 (52)	
Total Cholesterol		--	171 (33)	
Continuous Glucose Monitoring (CGM): Total number of hours worn over 7 day period	The iPro®2 Professional CGM (Medtronic Diabetes, Northridge, CA) was placed for 7-days of interstitial glucose data collection.	--	147 (29.0)	Goal = 168 hours
7-day Average Interstitial Glucose (mg/dL)		--	211.1 (37.7)	Goal Range: 70–180 mg/dL
Motivation and Intention <u>Total Motivation</u>	Modified from an asthma measure for the present study. Assesses adolescents' motivation for adherence (4 items) and intention in managing their T1D (4 items), using a scale of 1–10, where higher scores indicate more motivation/intention. ⁶	0.73	7.6 (1.6)	Ms = 6.9–8.1 (SDs = 0.6–0.7)
Blood Glucose		--	7.1 (2.0)	--
Insulin		--	8.4 (1.8)	--
Diet		--	7.1 (2.3)	--
Exercise		--	7.9 (2.4)	--
<u>Total Intention</u>		0.74	9.1 (1.0)	Ms = 8.7–8.9 (SDs = 0.3–0.4)
Plan to manage diabetes			9.3 (1.2)	--
Trying to manage diabetes			9.0 (1.4)	--
Important to manage diabetes			9.6 (0.9)	--
Can manage diabetes			8.5 (1.7)	--
Social Problem-Solving Inventory Revised: Short (SPSI-R:S) <u>Total Score</u>	Assesses adolescents' cognitive, affective, and behavioral abilities to resolve problems, using a 0 (not at all true of me) to 4 (extremely true of me) scale ^{38,39} .	0.86	13.2 (2.6)	M = 9.1 (SD = 3.8) α = 0.86
Positive Problem Orientation (PPO)	Two adaptive problem-solving dimensions.	0.80	12.8 (4.2)	M = 11.9 (SD = 3.9) α = 0.80

Measure	Construct Measured/Relevant Points	Alpha in Study Sample	Mean (SD) or N (%) in Study Sample	Norms
Rational Problem Solving (RPS)		0.77	10.1 (4.0)	M = 11.0 (SD = 3.8) $\alpha = 0.84$
Negative Problem Orientation (NPO)	Three dysfunctional problem-solving dimensions.	0.82	5.0 (3.8)	M = 8.1 (SD = 4.7) $\alpha = 0.88$
Impulsivity/Carelessness Style (ICS)		0.70	6.6 (3.5)	M = 7.1 (SD = 4.0) $\alpha = 0.83$
Avoidance Style (AS)		0.77	5.4 (3.6)	M = 7.0 (SD = 4.8) $\alpha = 0.89$
Centers for Epidemiologic Study–Depression Scale (CES-D) Total Score	Assesses adolescents' depressive symptoms, using a 0 (rarely) to 3 (most days) scale ⁴⁰ . The suicidal ideation from the Child Depression Inventory ⁴¹ was also added.	0.88	9.2 (8.3)	M = 10.7 (SD = 8.6)
Total Percent >24 Total Score	The 3 category stratification of the CES-D scores of minimal risk (015), mild risk (1623), and moderate/severe risk (24–60) were utilized in the present study. ⁴²	--	16 (6.2%)	8.6%
Pediatric Quality of Life™ – Generic (PedsQL) Youth	Assesses youths' HRQOL in four general domains: physical, emotional, social, and school functioning, where higher scores reflect better HRQOL ^{43, 44} .	0.90	80.8 (12.4)	M = 80.4 (SD = 12.9) $\alpha = 0.89$
Parent		0.91	77.5 (14.4)	76.6 (SD = 14.1) $\alpha = 0.92$
Diabetes-Specific Quality of Life (PDQ) Youth	Assesses diabetes-specific QOL in terms of how much various aspects of T1D management are 'hard' or 'bothers' adolescents, with higher scores indicating better diabetes-specific QOL ⁴⁵ .	0.89	70.0 (13.7)	$\alpha = 0.81$
Parent		0.88	60.3 (12.5)	$\alpha = 0.87$

Note:

[†]N=234 for CGM; N=255 for HDL, LDL, and Total Cholesterol, Youth Motivation and Intention & Parent PDQ, N=253 for Triglycerides (after excluding two observations with Triglycerides >1000 mg/dL), N=257 for Waist Circumference, Youth & Parent PedsQL™, Youth SPSS-R:S & PDQ

Table 5

FLEX baseline potential mediator variables.

Measure	Construct Measured/Relevant Points	Alpha in Study Sample	Mean (SD) in Study Sample	Published Norms
Potential Mediator Variables (n = 258) [†]				
Information				
Diabetes Knowledge Survey (DKS)	Adapted for the present study from the Nutrition Knowledge Survey (NKS), which was developed to assesses general and diabetes-specific nutrition knowledge in youth with T1D, where a higher % correct scores indicate more knowledge ⁴⁶ .	0.49	6.7 (2.8) 55.8% Correct	Mean = 56.9% Correct (SD = 16.4)
Motivation				
Outcome Expectations for Diabetes Self-Management (OEDM)	Assesses adolescents’ expectations of negative and positive T1D care outcomes, using a 10 point scale ranging from “not at all” to “a lot”, where higher scores indicate better outcome expectations ⁴⁷ .			
Lower Negative Expectations		0.91	7.19 (2.0)	M = 7.3 (SD = 1.8) α = 0.89
Higher Positive Expectations		0.80	6.01 (1.6)	M = 6.1 (SD = 1.6) α = 0.84
Self-Efficacy for Diabetes Self-Management (SEDM)	Assesses how adolescents feel about their ability to complete T1D self-management tasks, using a 10 point scale ranging from “not sure at all” to “completely sure”, where higher scores indicate more self-efficacy ⁴⁷ .	0.90	7.18 (1.8)	M = 7.5 (SD = 1.6) α = 0.90
Adherence				
Diabetes Self-Management Assessment Profile – Self Report (DSMP-SR) Youth	Assesses the usual T1D management practices across 5 domains: exercise, hypoglycemia management, diet, blood glucose testing, and insulin administration and dose adjustment, where higher scores indicate more T1D self-management ⁴⁸ .	0.88	55.0 (11.6)	M = 54.3 (SD = 12.2) α = 0.82
Parent		0.79	51.6 (12.0)	M = 54.7 (SD = 12.6) α = 0.80
Barriers to Adherence				
Diabetes Family Conflict Scale (DFCS) Youth	Assesses T1D-related family conflict on a 3-point scale, where higher scores indicate more conflict about T1D management tasks ⁴⁹ .	0.88	1.36 (0.3)	Ms = 1.2–1.4 α = 0.85
Parent		0.86	1.43 (0.3)	Ms = 1.2–1.4 α = 0.81
Diabetes Family Responsibility Questionnaire (DFRQ) Youth	Assesses how families handle responsibilities regarding various T1D tasks and situations on a 3-point (1 = child takes responsibility, 2 = parent and child share responsibility, and 3 = parent takes responsibility) scale ⁵⁰ .	0.80	2.21 (0.3)	α = 0.84
Parent		0.80	2.01 (0.3)	α = 0.85

Note:

[†]N=253 for Youth OEDM, N = 257 for Parent DFCS