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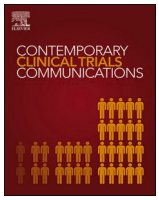

Design of the type 1 diabetes and life (T1DAL) pilot and feasibility study: A brief telehealth intervention targeting health-related quality of life across clinical settings

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ABSTRACT

Background: Type 1 diabetes (T1D) management is demanding and can impact quality of life among persons with diabetes (PWDs) and their family members. Behavioral intervention research has largely focused on adolescents, and previous interventions that have benefitted quality of life have limited potential for implementation in routine care. This trial is piloting a brief behavioral intervention that targets health-related quality of life (HRQOL), which can be implemented with PWDs of all ages in a range of clinical care settings. The aims are to (1) evaluate intervention feasibility and acceptability, (2) explore pre-post change in psychosocial and clinical outcomes, and (3) explore costs related to intervention development and implementation.

Methods: Participants are PWD of all ages who receive T1D care in pediatric subspecialty, adult specialty, and primary care settings (target n = 120, 40/site) and a parent (for children) or partner (for adults). Certified diabetes care and education specialists deliver the intervention during two ~30-45-min remote sessions over 6 months. In the sessions, interventionists review a "quality of life profile" generated from participants' pre-session responses to a measure of T1D-specific HRQOL, and provide behavioral strategies and resources tailored to their individual strengths and challenges. Feasibility and acceptability data include recruitment/enrollment/retention rates, intervention fidelity, satisfaction surveys, and qualitative interviews. Pre-post measures of psychosocial and clinical outcomes are collected at baseline and 6 months.

Conclusion: This pilot study will generate preliminary data about a brief intervention targeting HRQOL for youth and adult PWDs and family members, designed for implementation across a range of care settings.

Type 1 diabetes (T1D) is a relentless and demanding chronic health condition that impacts around 2 million people in the United States (US) [1]. The constant requirements of T1D management include self-monitoring glucose levels, calculating and administering insulin, considering food intake, physical activity, and stress on insulin needs and glucose levels, attending routine and specialty diabetes care appointments, and maintaining access to medications and devices [2]. These demands impact many areas of life, including psychological

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well-being, social functioning, and everyday activities [3]. Living with and managing T1D can take a significant emotional toll on a person with diabetes (PWD), evidenced by elevated risk for depressive symptoms, diabetes distress, anxiety symptoms, cognitive challenges, and other psychological comorbidities from childhood through late adulthood [4–6]. There are also psychological impacts on family members, including parents of youth PWDs [7] and partners of adult PWDs [8]. Depressive symptoms, anxiety symptoms, fears about short- and long-term health complications for their child, and other aspects of emotional distress are common among parents, both immediately following a child's diagnosis of T1D and for many years [7]. Parent-youth conflict about T1D management is a significant source of distress [9]. Partners of adults with T1D also describe various impacts of T1D on their relationship and other aspects of life, including worry about hypoglycemia in their partner, disrupted activities, and distress [10,11]. Given the far-reaching impacts of T1D on PWDs of all ages and on their parents and partners, emotional and behavioral support is warranted [3].

Health-related quality of life (HRQOL) is a person-reported outcome (PRO) that represents physical, psychological, and social well-being in relation to one's health and includes satisfaction with daily life, ability to function in everyday activities, emotional status, engagement in family and social interactions, satisfaction with health status and treatments, and health-related worries [12,13]. T1D-specific HRQOL focuses on these issues specifically concerning living with and managing T1D and applies to PWD and their parents and partners. HRQOL is increasingly recognized as a key PRO related to health outcomes [14–16]. Though HRQOL is well researched in PWDs, far less attention has been paid to HRQOL among parents and partners, who are often primary diabetes-related support persons for PWDs.

Behavioral interventions for people with T1D have been shown to impact HRQOL, psychological outcomes, self-management, and glycemic outcomes [17–19]. However, effects are often modest [17] and many people continue to have hemoglobin A1c (HbA1c) values (i.e., average blood glucose over previous 2–3 months) above the American Diabetes Association (ADA) target of <7.0 % [20]. There are more behavioral intervention data for adolescents with T1D compared to the smaller body of intervention research conducted with PWDs of other ages. Additionally, behavioral intervention studies targeting HRQOL rarely address the experiences or needs of parents or partners in their roles as support persons for PWDs in their lives. Despite national and international guidelines calling for integration of psychosocial and behavioral support for PWDs and their family members [3,21,22], such care is often not available in routine T1D care settings [23,24]. There are factors that limit the potential for widespread dissemination of behavioral interventions that have shown promise. Prior behavioral interventions have often been complex, with multicomponent protocols delivered across multiple in-person sessions. Interventionists typically have extensive training and are often not part of the medical team. Thus, the resources required to employ and train behavioral interventionists, time required for intervention delivery, and time demands for participants need to be addressed.

The ADA and other organizations recognize that healthcare professionals, including diabetes care and education specialists (CDCES), are well-positioned and capable of addressing common behavioral concerns, including diminished HRQOL [21,25,26]. There is a growing literature to support training healthcare professionals to deliver brief behavioral interventions during clinical T1D care [19–28]. In the Monitoring Individual Needs in Diabetes (MIND) Study in Europe, diabetes nurses provided adults with type 1 and type 2 diabetes brief supportive feedback based on reports of depressive symptoms and diabetes-related distress and made referrals to psychological care if indicated. Results suggested small but significant improvements in diabetes distress and HbA1c [29]. A similar approach with pediatric endocrinologists in The Netherlands focused on addressing adolescents' T1D-specific HRQOL during routine care, with improvements in HRQOL and HbA1c [30,31]. These interventions indicate potential benefits of healthcare professionals addressing T1D-specific HRQOL. However, there is little research to guide CDCES to effectively deliver such interventions during routine patient care. Limited access to CDCES in adult diabetes clinics and primary care settings calls for innovative methods to increase access to this care. This approach has not been tested in the US healthcare system, especially using telehealth. Remote delivery of both diabetes care and behavioral interventions has become increasingly common over the past 25 years (and especially since the COVID-19 pandemic) and may increase access to healthcare [32,33], with evidence suggesting comparable or better outcomes compared to in-person delivery [34].

1. Study design

The purpose of this pilot study is to evaluate feasibility and acceptability of the Type 1 Diabetes and Life (T1DAL) intervention. We will explore pre-post change in behavioral and clinical outcomes from baseline to post-intervention (6 months post-baseline) and examine costs of intervention delivery and implementation. The T1DAL intervention is a brief, behavioral intervention, delivered remotely by CDCES interventionists, that addresses HRQOL of individuals with T1D and their parents (for youth) or partners (for adults). Each intervention session is tailored to the unique HRQOL experiences of each participant, based on their responses to the T1DAL measure, a self-report measure that assesses T1D-specific HRQOL [35–37]. We previously developed the suite of T1DAL questionnaires to be brief, clinically actionable PRO measures to guide diabetes care providers in tailoring clinical efforts to support HRQOL. This pilot intervention study is conducted with PWDs who receive T1D care in 3 different healthcare settings: a pediatric subspecialty endocrinology clinic, an adult subspecialty endocrinology/diabetes clinic, and from a primary care provider. Each site obtained IRB approval and participants provided informed consent/assent. In this non-randomized design, all participants receive the intervention, to maximize information to inform feasibility and acceptability. Non-randomized designs are appropriate for initial pilot studies primarily designed to explore a new intervention's feasibility and acceptability, prior to fully powered efficacy trials [38–40]. The study is registered on clinicaltrials.gov (NCT05234944).

2. Participants

Diagnosis of T1D with duration ≥12 months is an inclusion criterion for PWD. The pediatric site enrolls parents of young children with T1D (age <8), youth with T1D (age 8–17) and one parent, and young adults with T1D (age 18–25) with or without a parent or partner. The adult subspecialty site enrolls adults with T1D (age ≥18). The final site enrolls adults with T1D age ≥18 whose primary care provider manages their T1D. Each adult PWD may invite a partner (defined as an adult spouse, romantic partner, child/sibling, or friend in a diabetes caregiving/support role; care professional; or other adult who is a major part of the person's life with diabetes) to participate with them. English or Spanish fluency is an inclusion criterion at the pediatric subspecialty and adult primary care site, and English fluency is an inclusion criterion at the adult specialty care site. Receiving T1D care at Texas Children's Hospital (Houston, TX) is an inclusion criterion for the pediatric site, and receiving T1D care at the Joslin Diabetes Center at State University of New York Upstate Medical University (Syracuse, NY) is an inclusion criterion for the adult specialty care site. For the primary care site (Stanford University, Palo Alto, CA), participants may receive T1D care from a primary care provider in any location in the US and are not required to receive T1D care at Stanford. At the pediatric and adult specialty sites, T1D diagnosis and duration are confirmed through electronic health record review; at the primary care recruitment site, T1D diagnosis and duration are self-reported by the participant. Participants are required to have access to the internet to participate in

remote intervention delivery. Exclusions include plans to move to another clinical care setting during the study and any comorbid condition that would limit the ability to participate.

The target sample size is 40 participants per site, totaling n = 120. This sample size was selected to achieve data adequacy for the purpose of assessing feasibility and acceptability, while balancing the constraints of a pilot study [41,42]. The T1DAL measure of T1D-specific HRQOL has distinct versions for PWDs in seven age-bands (detailed below) [35–37]. To ensure adequate representation in each age-band, we aimed to enroll ~5–8 participants per age-band per site. To ensure adequate representation across the three clinical care settings, we aimed to enroll 40 participants per site. This sample size is sufficient to conduct rigorous qualitative analyses and reach thematic saturation regarding feasibility and acceptability [43–45] and to generate preliminary estimates of pre-post change in outcomes.

3. Recruitment

At the subspecialty care sites, study staff pre-screen electronic health records for potentially eligible patients and send recruitment materials via mail and patient portals. In the primary care site, study staff circulate recruitment flyers through multiple methods: online and community-based diabetes organizations, Extension for Community Healthcare Outcomes (ECHO) Diabetes Weekly Announcements, previous research participants at Stanford University School of Medicine, and Stanford Research Registry. Interested recipients then contact study staff to learn about the study.

Study staff follow-up with interested individuals by phone or in-person to verbally review study information, answer questions, and confirm eligibility. Study staff review the informed consent document with individuals, which they then sign electronically. Paper consent forms are available if preferred. For youth age <8, only parents are enrolled, as youth do not directly participate in study activities due to age. For youth ages 8–17, youth and parents participate in the recruitment conversation, parents provide informed consent, and youth provide verbal assent. After adult PWDs enroll, they are invited to have a partner join them in the study and provide their partner's contact information to study staff, who contact partners individually to describe the study, answer questions, and confirm eligibility. Interested partners provide informed consent.

4. Intervention

4.1. Overview

The remote T1DAL intervention targets HRQOL of PWD and their parents or partners, with intervention content tailored to each participant's HRQOL responses to the self-report T1DAL measure. Pre-intervention, participants complete the age-appropriate T1DAL measure [35–37]. The T1DAL measures assess T1D-specific HRQOL through multiple developmentally specific versions that were developed and validated for PWDs across seven age-bands (<8 years, 8–11 years, 12–17 years, 18–25 years, 26–45 years, 46–60 years, and >60 years), as well as for parents and partners. The T1DAL is a self-report measure for all respondents; PWDs ages 8 and older self-report about their own HRQOL, parents of children ages <8 years, 8–11 years, 12–17 years, and 18–25 years self-report on their own HRQOL as the parent of a young person with T1D, and partners of adults age 18+ years self-report on their own HRQOL as the partner of someone with T1D. Each version of the T1DAL was developed to address specific aspects of HRQOL relevant to the life stage of the PWD and the respondent type (PWD, parent, or partner). T1DAL measures are scored on a 100-point scale, with higher scores indicating better T1D-specific HRQOL See Appendix for sample items for each T1DAL version. In this pilot study, T1DAL results from the PWD and parent or partner inform the focus of the individualized intervention. In each session, conducted via a secure videoconferencing platform, the CDCES selects which modules in the intervention manual to deliver based on each participant's T1DAL responses. Aligned with multidimensional definitions of HRQOL [12,13], intervention content includes the impact of T1D on daily life activities, relationships, emotional wellbeing, diabetes-related finances, and T1D management. The intervention addresses strengths and challenges. Two study sessions occur over 6 months. Each session follows a manual and is audio-recorded for supervision and fidelity monitoring. Participants continue to receive routine diabetes care with their healthcare provider throughout study participation.

4.2. Development of intervention

Two diabetes-focused clinical research psychologists and a licensed clinical social worker developed this intervention. Multidisciplinary team members (pediatric and adult endocrinologists, diabetes psychologists, developer of a previous intervention model in The Netherlands, CDCES, and research staff with training in psychology and public health) shared ideas to conceptualize and develop the intervention components and format and provided feedback to refine its focus and content. Two study team members live with T1D, and all have research and/or clinical experience in this population.

Because the intervention was conceptualized as being tailored to an individual's HRQOL strengths and challenges as assessed by the T1DAL measure, we first reviewed the T1DAL measure items [35–37] to identify common HRQOL issues to address in the intervention. We developed four modules, each addressing a broad theme of HRQOL: Diabetes Stress and Mood Management, Diabetes Management Challenges, Social Support, and The Financial Costs of Diabetes. Interventionists deliver the appropriate module based on participants' T1DAL responses. Table 1 illustrates how each T1DAL measure topic area maps onto an intervention module. We created an algorithm in the data management platform (REDCap) to generate HRQOL profiles based on individuals' T1DAL measure responses (Fig. 1). Each profile includes three areas of relative HRQOL strengths (i.e., sections with relatively higher mean responses) and one area of relative HRQOL challenge (i.e., section with relatively lower ratings).

We selected brief behavioral strategies to address each HRQOL theme, with 2–4 skills per theme, designed to help participants address their identified HRQOL challenge. Table 1 lists specific intervention strategies for each module. We wrote an intervention manual and interactive script for CDCES interventionists to follow during session delivery. Interventionists use a conversational style to promote participant engagement. One intervention protocol is used for all participants, with prescribed delivery adaptations to ensure appropriateness and relevance at different life stages. We developed this intervention to be delivered remotely for several reasons, including to increase convenience for participants to access the intervention sessions beyond clinic appointment times and locations, to reach participants who receive T1D care in settings other than specialty T1D clinics in academic medical centers, and to maximize feasibility of intervention delivery by a group of centralized CDCES interventionists for this pilot research study.

4.3. Intervention description

Two intervention sessions occur over 6 months (approximately 2–4 months apart: session #1 in first 3 months, session #2 in second 3 months) at the participant's convenience. Study staff schedule sessions and send virtual session links via a HIPAA-compliant videoconferencing platform. Before each session, the PWD and parent/partner (if participating) complete the appropriate version of the T1DAL measure, then the study team generates a profile for each session. The purpose of each session is to review each participant's T1DAL results, discuss their HRQOL strengths, and introduce a brief behavioral skill to address the identified HRQOL challenge. At each session, the CDCES uses "screen-share" to display the T1DAL profile and intervention content slides.

Table 1
HRQOL topics and associated intervention modules and strategies for the T1DAL intervention, based on self-reported responses to the T1DAL measure.

	T1DAL Topics	Intervention Modules	Strategies
Person with Diabetes	• Diabetes and My Feelings	Diabetes Stress and Mood Management	• Relaxation Strategies- Square Breathing • Finding Ways to Care for Yourself • Managing Feelings- Practicing Gratitude
	• Diabetes and My Activities • Taking Care of My Diabetes • My Diabetes Care Team	Diabetes Management Challenges	• Setting Goals for Diabetes Management • Planning Ahead and Being Prepared • Supportive Relationship with Medical Team
	• Diabetes and My Family • Diabetes and Other People	Social Support	• Growing Your Social Support • Issues with Family and Close Friends
	• Financial Costs of Diabetes	The Financial Costs of Diabetes	• Understanding Insurance and Health Care Coverage • Making Costs and Budgeting a Priority • Finding Ways to Lower Diabetes Costs • Being Prepare for Diabetes Emergencies
Parents	• Diabetes and My Feelings	Diabetes Stress and Mood Management	• Relaxation Strategies- Square Breathing • Finding Ways to Care for Yourself • Managing Feelings- Practicing Gratitude
	• Taking Care of My Child's Diabetes • Diabetes and My Child's Activities • My Child's Diabetes Healthcare	Diabetes Management Challenges	• Financial Costs of Diabetes • Planning Ahead and Being Prepared • Supportive Relationship with the Medical Team
	• Diabetes and Our Family • Diabetes and Other People	Social Support	• Growing Your Diabetes Support • Issues with Family
Partners	• Diabetes and My Feelings	Diabetes Stress and Mood Management	• Relaxation Strategies- Square Breathing • Finding Ways to Care for Yourself • Managing Feelings- Practicing Gratitude
	• My Partner's Diabetes Management • The Financial Costs of Diabetes	Diabetes Management Challenges	• Financial Costs of Diabetes • Planning Ahead and Being Prepared • Supportive Relationship with the Medical Team
	• Diabetes and Our Family • Diabetes and My Relationship with My Partner	Social Support	• Growing Your Diabetes Support • Issues with Family • Offering Support to Your Partner

Fig. 1. Example T1DAL profile.

CDCES interventionists follow the T1DAL study manual, which includes detailed education about the brief behavioral skills for each theme, as well as conversation starters and open-ended questions to guide the tailored, supportive discussion and promote interaction.

Each session begins by presenting the PWD's HRQOL profile and engaging in discussion of how to use their strengths to improve HRQOL. The CDCES then guides the participant in discussing the HRQOL challenge identified on the profile and follows the corresponding module. The participant is encouraged to share a current struggle within the challenge topic. However, if the participant states the challenge does not resonate with them, the CDCES can suggest a different module based on the challenges the participant describes, or they can pivot to the default module of Diabetes Stress and Mood Management. The CDCES then presents 2–4 options of brief behavioral skills targeting their identified challenge (Table 1) and introduces the selected skill. They discuss the potential benefit and application of the skill, then create a plan to use the skill. Each session is designed to last ~30 min. If a parent/partner is participating, intervention with them immediately follows the discussion with the PWD, following the same protocol. Sessions take place if the PWD is present (i.e., not delivered to parent/partner alone), except for parents of children age <8, who participate alone due to children's young age. The second intervention session follows the same format (using data from a second completion of the T1DAL measure), plus a brief review of the participant's experiences using the skill discussed at the first session. Following each session, study staff send participants a copy of their T1DAL profile and a handout of educational information and resources related to the topics discussed in the session. For participants treated at subspecialty clinics, study staff share PWDs' T1DAL profiles (not parent/partner profiles) with the treating diabetes care team via secure file transfer within the electronic health record system.

4.4. Interventionist training

A clinical social worker on the study team who collaborated with the investigators to develop the intervention serves as the intervention supervisor and oversees all aspects of intervention delivery, including screening, training, and supervising the CDCES interventionists. The diabetes psychologist who previously implemented a similar intervention protocol in The Netherlands provides consultation about her experiences.

The CDCES interventionists received intervention manuals that included discussion prompts, education on each HRQOL topic, and brief behavioral strategies to address common HRQOL issues. Training took approximately 40 h and consisted of an introduction to HRQOL through readings and discussion, independent review of the study protocol and intervention manual, instruction on key intervention concepts, live demonstrations of the intervention, and role-playing with *in vivo* feedback. Training topics included evidence-based behavioral strategies, including basic motivational interviewing/counseling techniques, open-ended questions, identifying individual motivations for behavior change, emphasizing strengths rather than problems, ensuring comprehension through simple language, and supportive/nonjudgmental communication.

Training also reviewed research ethics and confidentiality, treating participants with respect (e.g., right to autonomy, choice, degree of participation), and a safety plan for managing any concerns related to mental health and/or insulin access if those issues should arise in intervention sessions. The CDCES were instructed not to offer medical or mental health guidance during the intervention sessions, and to refer participants to their medical or mental health provider to address concerns.

Of the four CDCES who completed training, three proceeded to deliver the intervention for the study (the other resigned due to a change in availability). The interventionists participate in ongoing group supervision with the intervention supervisor to review intervention delivery, discuss challenges and experiences, and get feedback. These meetings decrease in frequency as the interventionists become more comfortable with the protocol and tailoring the intervention. Individual discussions with the intervention supervisor take place as needed. Intervention sessions are audio-recorded and reviewed by the intervention supervisor, who monitors fidelity and provides constructive feedback as needed.

5. Spanish language procedures

After preparing all study procedures and materials in English, they were adapted to the Spanish language. A bilingual member of the study team led the translation process. As many people speak both English and Spanish and some families include both English- and Spanish-speaking members, we prepared to conduct all study activities (e.g., recruitment, consent, intervention delivery) in English, Spanish, or a combination. Two CDCES are bilingual.

To conduct recruitment processes in Spanish, all recruitment materials and the informed consent form were translated by a professional translation company, then reviewed by bilingual team members. Study staff at the pediatric site pre-screen patients whose medical charts note previous medical encounters were conducted in Spanish or with a translator, and recruitment materials are sent in both Spanish and English. For these individuals, study staff initiate recruitment calls in Spanish then ask about the preferred language to continue the call. The intervention manual and handouts were professionally translated into Spanish.

To conduct data collection in Spanish, all study measures are available in Spanish. When Spanish translations of validated measures were available from measure developers, they were used. For validated measures that had not been previously translated, we had them professionally translated for use in this study. For measures that were developed by this study team (e.g., demographics survey, satisfaction questions), bilingual study team members translated measures.

Bilingual study team members and interventionists reviewed all study materials and measures that were translated professionally or by our study team, to ensure use of appropriate terminology for psychosocial/behavioral concepts, terminology is neither too colloquial nor too formal to be understood, understandable terminology for Spanish speakers from various countries, and consistent use of terminology across all materials. Final decisions about all Spanish translations were made by consensus of 2+ bilingual team members.

6. Data collection

Data are collected at three time points: (1) baseline, following consent, (2) prior to 2nd intervention session (~3 months later), and (3) 6 months post-baseline. Questionnaires are collected from PWD ≥8 years and parents/partners via a secure, HIPAA-compliant REDCap database managed by BCM. All participants are asked to complete their measures independently through unique links. Study data are stored within REDCap using ID numbers. To encourage completion of outcome assessments, modest financial incentives are offered for completing each data collection time point. In total, each family can receive up to $120 for full data completion ($40 baseline, $20 mid-intervention, $60 post-intervention).

6.1. Participant characteristics

Demographic information (i.e., age, race, ethnicity, gender, education level, insurance) are collected via self- or parent-report, depending on age. Major life events (e.g., change in residence, change in work, births, divorces, deaths, financial stressors, etc.) are collected via self-report. Parents provide data about youth age <18. Youth age 12–17 self-report their date of birth, gender, race, and ethnicity. Adults and partners self-report all data.

The Area Deprivation Index (ADI) [46,47] is calculated to capture

neighborhood-level socio-demographic characteristics based on the PWD's primary residential address. The ADI generates a state decile and national percentile that represents relative socioeconomic status of the neighborhood, with higher scores indicating greater deprivation.

6.2. Feasibility

Measures of feasibility include recruitment/consent rates, participant retention/data completion rates through the post-intervention follow-up, intervention session completion rates, and interventionist adherence to the intervention manual (Table 2).

6.3. Acceptability

Measures of acceptability include reasons for participating and experiences with the intervention at the mid-point and post-intervention (Table 2). All study participants are invited to participate in individual or parent-youth dyad qualitative interviews to provide feedback at the end of the study about their experiences in the study. These optional interviews are conducted by telephone at the post-intervention data collection timepoint, following completion of study surveys. Study staff members trained in qualitative interviewing skills conduct the semi-structured interviews following a script. Qualitative interview questions probe about perceptions of study logistics (e.g., survey length, intervention scheduling, incentives) and intervention content (e.g., experiences with the CDCES, opinions on the skills taught). Interviews are audio-recorded and transcribed verbatim, with identifying information censored for privacy.

6.4. Psychosocial and behavioral outcomes

Participants complete psychometrically validated, self-report questionnaires assessing HRQOL, diabetes strengths, diabetes distress, and engagement in diabetes self-management behaviors Each measure is validated for use with specific age ranges and respondent types, thus participants in different age-bands complete unique sets of measures. Table 2 reports which measures are completed by which participants by age-band and participant type (i.e., PWD, parent, partner).

6.5. Medical data and glycemic outcomes

At baseline, participants self-report date of diabetes diagnosis, method of insulin delivery (pump – automated/not, injections/pen), use of continuous glucose monitor (CGM), types of healthcare professionals seen for diabetes care over the previous 6 months, and number and reasons for diabetes-related emergency/urgent care visits and hospitalizations over the previous 6 months. All except disease duration are repeated at 6 months.

The primary glycemic outcome is HbA1c, assessed at baseline and 6 months. At the subspecialty clinics, the most recent HbA1c collected in clinical care is extracted from the electronic health record. For adults who receive diabetes care from a primary care professional, HbA1c is collected in two ways: (1) Participants self-report their most recent HbA1c and upload a photo/scan of the lab results, or (2) Participants complete a home HbA1c kit analyzed by the University of Minnesota. Study staff mail the kit to participants with written and video instructions and offer to walk participants through completing the kit via videoconference if desired. Participants send the kit to the University of Minnesota in a pre-paid shipping container, and results are sent to study staff to enter into the REDCap database. Home kit HbA1c values are shared with participants by request.

As a secondary measure of glycemic outcome, for participants who use CGM, study staff download 14 days' worth of data at each time point to calculate percent time in range 70–180 mg/dL.

6.6. Intervention costs

Cost data are collected to estimate the potential costs associated with intervention implementation in routine care and evaluate participants' hypothetical willingness to pay for this intervention.

Intervention costs are defined as the labor and non-labor (e.g., hardware, software) costs associated with start-up (one-time costs) and operation (recurring costs). To assess labor, study staff prospectively document time spent in start-up activities (e.g., creating intervention training materials, the T1DAL measure completion platform in REDCap, and the algorithm for generating T1DAL profiles) and implementation activities (e.g., training and supervising interventionists and preparing for and delivering each session).

Participants incur no costs related to participating in study activities. However, if implemented in the real-world the structure of this intervention could potentially incur costs, such as payment for clinical services (direct payment, or payment of deductibles, co-payments). To assess acceptability of potential intervention costs (e.g., time, co-payments, out of pocket costs) to participants, the 6-month satisfaction survey includes questions about their willingness to pay for this intervention as part of clinical care (Supplemental Table 1). Qualitative interviews with adult participants, parents, and partners also include questions about potentially paying for a service like this intervention if it were part of their routine diabetes care, using insurance benefits or paying out of pocket.

An important next step will be to evaluate cost-effectiveness of the intervention, an aim which requires understanding the pathways via which the intervention may impact healthcare costs. To inform future economic evaluations, data are collected on healthcare utilization (e.g., hospitalizations, emergency department visits, urgent care visits).

6.7. Planned analyses

6.7.1. Quantitative

Feasibility and acceptability data will be analyzed through descriptive summary statistics to determine the percentage of participants who meet criteria for enrollment, retention, and satisfaction. Because gathering preliminary data on change in outcomes from pre-to post-intervention is the secondary aim of this pilot study, the sample is not powered for robust change analyses. To explore change pre-to post-intervention, paired t-tests will be conducted for each outcome, comparing scores at baseline to follow-up. Regression models will be conducted with change scores in relation to demographic, behavioral, and clinical covariates to explore whether individual, family, or provider characteristics need to be considered in the future refinement and evaluation of this intervention. Cost data will be used to conduct an exploratory budget impact analysis and describe potential intervention provision costs. Descriptive statistics will also be summarized to describe acceptable costs to families to inform intervention refinements. These analyses will be conducted for the study overall and separately for each site (i.e., pediatric specialty, adult specialty, adult primary care) and participant age/type (e.g., children, adolescents, adults, parents, partners).

6.7.2. Qualitative

Thematic analysis [56] will be used for the qualitative data. Study team members trained in qualitative analytic skills from the three study sites will review transcripts to identify unique or common concepts, develop a codebook with codes and definitions, and use Nvivo software to apply the codes to the transcripts. When new concepts are observed that do not match any existing code, new codes and definitions will be created and applied to all transcripts. This iterative process will continue until all transcripts are fully coded and no new concepts are observed. The study team, which includes investigators with expertise in behavioral intervention research, diabetes psychology, pediatric and adult diabetes care, CDCES roles, and qualitative analysis, as well as

Table 2
Measures of feasibility, acceptability, and psychosocial/behavioral outcomes. Measures are administered to participants based on the validated age range/respondent type for each instrument.

Measure	Construct	Time Points	Completed By	# of Items	Notes	References	Translation
FEASIBILITY							
Participant Recruitment and Retention Rates	Recruitment – percent of people approached for participation who provided consent. Retention – percent of consented participants who completed each data collection timepoint.	• Recruitment-Consent • Baseline • Mid-Intervention (~3 mos) • Post-Intervention (~6 mos)	Study staff	N/A	Tracked in study databases	N/A	N/A
Intervention Completion Rate	Percent of consented participants who complete each intervention session.	• Intervention Session #1 • Intervention Session #2	Study staff	N/A	Tracked in study databases	N/A	N/A
Intervention Fidelity Forms	Intervention delivery – adherence to manual, time spent in preparation and delivery.	• Intervention Session #1 • Intervention Session #2	• Interventionist • Supervisor	• 23–30 items • 11 items	Two forms – rated by interventionists and intervention trainer/ supervisor.	Created by study team	N/A
ACCEPTABILITY							
Reasons for Participating	Participant-reported reasons for participation in study	• Baseline	All participants age ≥8 years	5-6 items	Response options: Not a reason, Minor reason, Major reason.	Created by study team	Spanish translation by study team
Mid-Intervention Satisfaction	Participant-reported experiences with skills taught in study intervention session – how much remembered, how much used, how helpful.	• Mid-Intervention (~3 mos)	All participants age ≥12 yrs.	3 items	Response options: Remembered: nothing, a little, to very much, not sure Used: not at all, a little, very much, not sure Helpful: strongly disagree, disagree, agree, strongly agree	Created by study team	Spanish translation by study team
Post-Intervention Satisfaction	Participant-reported satisfaction with participation in the study, including study activities, incentives, experience with intervention, and feedback to improve the intervention.	• Post-Intervention (~6 mos)	All participants age ≥8 yrs.	11-17 items	Response options: Remembered: nothing, a little, to very much, not sure Used: not at all, a little, very much, not sure Helpful and Other Questions: strongly disagree, disagree, agree, strongly agree	Created by study team	Spanish translation by study team
Qualitative Interview	Participant feedback about thoughts and experiences in the study	• Post-Intervention (~6 mos)	All participants age ≥8 yrs invited (optional)	~15–30 min	Semi-structured interview guide	Created by study team	Spanish translation by study team
PSYCHOSOCIAL OUTCOMES							
Type 1 Diabetes And Life (T1DAL)	Type 1 diabetes-specific health-related quality of life (HRQOL)	• Baseline • Mid-Intervention (~3 mos) • Post-Intervention (~6 mos)	All participants age ≥8 yrs.	22-30 items	Participants completed age- and respondent-specific forms: PWD age 8–11, 12–17, 18–25, 26–45, 46–60, >60 years Parents of PWD age <8, 8–11, 12–17, 18-25 Partners of PWD age 18+ Higher scores on 100-point scale indicate better HRQOL.	[35–37]	Professionally translated into Spanish
Diabetes Strengths and Resilience (DSTAR)	Diabetes strengths and protective factors	• Baseline • Post-Intervention (~6 mos)	PWD age 8-25	12-16 items	Specific forms for PWD age 8–11, 12–17, 18-25 Higher scores indicate self-perception of greater diabetes strengths	[48–50]	
Diabetes Distress Scale (DDS)	Diabetes distress	• Baseline • Post-Intervention (~6 mos)	• PWD age ≥18 • Parents of PWD age 18-25 • Partners of PWD age ≥18	20-28 items	Person with diabetes age ≥18 completed T1-DDS. Parents of young adults (age 18–25) completed Parent DDS. Partners of adults completed Partner DDS. Higher scores indicate greater diabetes distress	[8,9,51,52]	Professionally translated into Spanish and provided by measure developer.

(*continued on next page*)

Table 2 (*continued*)

Measure	Construct	Time Points	Completed By	# of Items	Notes	References	Translation
Problem Areas in Diabetes (PAID)	Diabetes distress	• Baseline • Post-Intervention (~6 mos)	• PWD age 8-17 • Parents of PWD age 8-17	11-16 items	Youth completed age-appropriate version: PAID-Child (age 8–11), PAID-Teen (age 12–17). Parents completed the accompanying version: Parent-PAID-Child, Parent-PAID-Teen. Higher scores indicate greater diabetes distress	[53,54]	Spanish translation provided by measure developer.
Self Care Inventory (SCI)-Short Form	Diabetes self-management behavior	• Baseline • Post-Intervention (~6 mos)	• PWD age ≥12 • Parents of PWD age <12	9 items	Adapted version of SCI-Revised. Participants with diabetes age ≥12 years complete SCI-Short Form. Parents of youth age <12 complete parent version. Higher scores indicate higher engagement in diabetes self-management behaviors.	[55]	Professionally translated into Spanish

individuals with lived experience with T1D, will review the coded transcripts and generate themes that summarize core concepts. Qualitative themes will be reported across the full sample, and exploratory mixed-method analyses will examine if there are patterns in themes by site, participant age/type, or other specific characteristics (e.g., diabetes duration, insurance type).

7. Study strengths and limitations

This protocol has strengths and limitations that must be considered. Strengths include the lifespan perspective, intervention individualization, engagement of family members/support persons, remote intervention delivery, and consideration of varied care settings. Given the stage of this research as a pilot study, the sample size, scope of outcomes measured, and time frame for data collection are limited. A larger, fully powered clinical trial may be warranted to evaluate efficacy of this intervention over time. Because all study activities are conducted remotely, it is not possible to confirm that children or other participants complete their measures independently, which may introduce bias. However, we use measures that are validated for the appropriate age ranges and study staff instruct participants to complete study surveys independently. The intervention is delivered remotely, which may reduce accessibility for individuals with limited internet access, low digital health literacy, or less familiarity and comfort with videoconferencing for telehealth and other aspects of technology [33]. The study team uses multiple strategies to help participants overcome such challenges (e.g., problem-solving access issues, offering telephone-based sessions when needed), and satisfaction data from participants includes preferences about how individuals would prefer to receive this type of intervention (in-person or via telehealth). The intervention was developed by investigators largely within the United States and is delivered within this healthcare system, so there may be some aspects of the T1DAL measure or intervention that do not apply to individuals in other countries or healthcare systems (e.g., topics related to insurance and diabetes-related costs). Modifications to this protocol may be appropriate for use in other regions. Finally, the CDCES interventionists provide this intervention through a research study and thus have different roles than CDCES affiliated with medical care teams. Implementation research may be warranted in the future to evaluate the best ways of integrating this intervention into routine diabetes care processes in various healthcare settings.

8. Conclusion

Given substantial psychosocial burdens experienced by PWD and their families, there is an unmet need for brief, low-burden, and easily translatable behavioral interventions in routine diabetes care that enhance well-being. Training CDCES to systematically screen and discuss T1D-related HRQOL with PWD and their parents/partners as a remotely delivered supplement to medical care holds great promise to more effectively address individual needs and potentially improve diabetes outcomes for PWDs of all ages. Identifying strategies that can be delivered remotely and that are feasible, acceptable, and potentially beneficial for people who receive T1D care in a wide variety of care settings – including pediatric and subspecialty care and adult primary care – is necessary to expand the reach of behavioral interventions in T1D. Ultimately, the goal is to flexibly deliver a brief, individually-tailored behavioral intervention targeting HRQOL in real-world settings to improve the lives and outcomes of all people with T1D.

CRediT authorship contribution statement

Marisa E. Hilliard: Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition. **Wendy Levy:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Project administration, Methodology, Investigation. **Ruth S. Weinstock:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Korey K. Hood:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Paula M. Trief:** Writing – review & editing, Methodology, Conceptualization. **Daniel J. DeSalvo:** Writing – review & editing, Methodology, Conceptualization. **Yuliana Rojas:** Writing – review & editing, Writing – original draft, Visualization, Software, Project administration, Methodology, Investigation, Data curation. **Kyrah Holland:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation. **Aika K. Schneider-Utaka:** Writing – review & editing, Investigation. **Selma A. Alamarie:** Writing – review & editing, Investigation. **Lynn Agostini:** Writing – review & editing, Investigation. **Se-Kang Kim:** Writing – review & editing, Methodology, Data curation. **Maartje de Wit:** Writing – review & editing, Methodology, Conceptualization. **Meghan E. McGrady:** Writing – review & editing, Methodology. **Laurel H. Messer:** Writing – review & editing, Methodology. **Barbara J. Anderson:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Disclosures

RSW – Participation in clinical trials, through her institution, sponsored by Eli Lilly, Insulet, Tandem, Diasome, MannKind, and Amgen. DexCom provided devices at reduced or no cost for some studies, separate from this work. DJD – Serves as an independent consultant with Dexcom and Insulet separate from this work. LMH – employee and shareholder of Tandem Diabetes Care.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Disclosures: RSW – Participation in clinical trials, through her institution, sponsored by Eli Lilly, Insulet, Tandem, Diasome, MannKind, and Amgen. DexCom provided devices at reduced or no cost for some studies, separate from this work. DJD – Serves as an independent consultant with Dexcom and Insulet separate from this work. LMH – employee and shareholder of Tandem Diabetes Care.

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Appendix A. Supplementary data

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