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Parenting Intervention to Improve Nutrition and Physical Activity for Preschoolers with Type 1 Diabetes: A Feasibility Study

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Abstract

Objective—This study reports the feasibility and acceptability of a healthy eating and physical-activity-focused behavioral intervention for parents of young children with type 1 diabetes (T1D).

Methods—Ten parents of young children (age 2–5 years) with T1D enrolled. The intervention included six behavioral sessions (five by telephone), diabetes nursing consultation, parent coach

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contact, text messages, and a study website. Analyses explored feasibility, acceptability, and preliminary findings.

Results—There was evidence of high acceptability (mean parent satisfaction = 1.11, very satisfied). Although most participants completed all of the assessments, there were some barriers to data collection devices. The number of participants within the American Diabetes Association recommended glycemic range doubled; there was no significant change in hemoglobin A1c, diet, or physical activity.

Conclusion—There was evidence of feasibility and acceptability and initial evidence of change in hypothesized directions. Minor changes were made for the larger randomized controlled trial.

Keywords

Diabetes; pediatrics; eating; physical activity; behavior

INTRODUCTION

Type 1 diabetes (T1D) is among the most common chronic illnesses in childhood, with approximately 1 in 500–600 children diagnosed each year (Mayer-Davis et al., 2017). The American Diabetes Association's (American Diabetes Association, 2017) recent goals for pediatric patients with T1D include: blood glucose levels between 90 and 150 mg/dl, hemoglobin A1c (HbA1c) levels equal to or below 7.5%, BG monitoring at least 4 times per day, and healthy eating. Diabetes management requires strict adherence to a complex lifelong daily medical regimen to achieve these glycemic goals to delay or prevent the onset of acute and chronic T1D-related complications (Bade-White & Obrzut, 2009; Silverstein et al., 2005). Less than a quarter of young children achieve optimal glycemic control (Miller et al., 2015), which increases risk for development of serious diabetes-related complications (Svensson, Eriksson, & Dahlquist, 2004). For young children with T1D, parents, and particularly mothers, assume full responsibility for daily disease management (Streisand et al., 2008). These daily management demands are associated with high levels of parenting stress and leave parents at risk for impairing anxiety and depression (Patton, Dolan, Smith, Thomas, & Powers, 2011). Parenting stress and depression are associated with higher child health care use and costs, showing that these symptoms may also interfere with diabetes management and health (Clayton et al., 2013).

Behavioral interventions supporting T1D self-care among parents of young children have the potential to significantly affect glycemic control and developmental outcomes and reduce the incidence of consequences of T1D. Although the few existing interventions have shown potentially promising psychosocial outcomes (Monaghan, Hilliard, Cogen, & Streisand, 2011; Sullivan-Bolyai et al., 2004), related improvements in children's glycemic control remain elusive and understudied. Families need additional supports, particularly around nutrition and physical activity (PA), to achieve health goals.

Mealtime management is critical for families who have young children with T1D. Serving healthy and balanced food is essential, because BG after meals is one of the most important predictors of long-term health (Dzygalo & Szypowska, 2014). In a pediatric sample,

postprandial glucose readings were highest after breakfast (Boland et al., 2001) and may contribute to erratic glycemic variability through the next day (Nilsson, Radeborg, & Björck, 2012). However, achieving good nutrition is challenging, as parents strive to balance carbohydrates alongside common difficulties with eating behaviors typical of all young children including neophobia, pickiness, and transient preferences (Quirk, Blake, Tennyson, Randell, & Glazebrook, 2014). Moreover, parents of young children with T1D report more negative child mealtime behaviors (e.g., whining, engaging in tantrums) compared with those without diabetes (Patton et al., 2004). Administration of insulin before a meal is medically preferable, because there is a likelihood of lower BG compared with administration after a meal (Goonetilleke, Pollitzer, & Mann, 2004). However, if insulin is administered and a child refuses to eat, BG can decline quickly, leading to hypoglycemia. Parents may give another food to avoid this BG drop, even if it is less healthy, which can inadvertently reinforce child food refusal or delay insulin administration until after a meal (Powers et al., 2002). Mealtimes, including managing child behavior and dietary and medication management, are a source of significant parenting stress for many parents of young children with T1D (Powers et al., 2002).

PA can also be a challenging area for young children with T1D. PA declines begin as young as ages 3 to 4 years (Taylor, Williams, Farmer, & Taylor, 2013), which is concerning for youth with T1D, because maintaining cardiovascular health helps prevent complications associated with diabetes (Yardley et al., 2013). Young children understandably have unpredictable PA patterns (Baquet, Stratton, Van Praagh, & Berthoin, 2007), and parents may avoid activity because of lack of knowledge about how to manage BG during PA or fear of hypoglycemia (Yardley et al., 2013). Afternoon PA may be associated with improved glycemic control in young children, although it also is linked with more time spent below the suggested range of BG values (Mackey et al., 2014). There are large gaps in knowledge regarding the association of PA and glycemic control in young children with T1D, and evaluations of interventions that examine linkages among eating, PA, and glycemic control in young children are needed (Tully, Aronow, Mackey, & Streisand, 2016).

This study presents the findings from a mixed-methods feasibility project of a multicomponent healthy eating and PA intervention for parents of young children with T1D, the Type One Training (TOTs) study. The program is grounded in social cognitive theory and was derived both from the research team's previous interventions and needs assessment interviews with parents of young children with T1D (Bandura, 1986; Mackey et al., 2016). The program uses parent monitoring to increase parental awareness about health behaviors, and counselors help parents set attainable goals to increase self-efficacy and mastery over diabetes management. Parents also have opportunities for vicarious learning through group sessions and peer mentorship. It was hypothesized that the TOTs intervention would be well received by parents and would show feasibility and acceptability. Evidence was also gathered to determine any indication of preliminary change in glycemic variability, child nutrition and physical activity, and parent emotional functioning. Results from this feasibility study informed program revisions for a pilot randomized controlled trial (RCT, $n = 60$) of the TOTs program compared with usual care.

METHODS

Program Design

The 12-week TOTs program includes six behavioral parenting support sessions (see Table 1), a certified diabetes educator consultation, parent mentors (hereafter, parent coaches; a *parent coach* is a parent of a child who was also diagnosed with T1D at a young age), and monitoring technologies (e.g., personal activity monitors, continuous glucose monitors [CGM]) to facilitate knowledge acquisition and promote self-efficacy. Parents completed homework between the parenting sessions focusing on increasing the protein their child consumed at breakfast, expanding their child's diet, increasing physical activity steps per day, and increasing social support. Within these program objectives, counselors worked with parents to set individual goals based on results from the baseline assessment and self- and child monitoring. Parent coaches were paired with participants for the 12 weeks of the program and asked to contact their participant by telephone, text, and e-mail at six regular intervals to provide social support. Finally, study participants received three text messages a week reinforcing study content and access to a resource Web site.

Assessment

The primary aims were to determine the feasibility and acceptability of the TOTs program. Study recruitment, enrollment, and rates of participant data completion were used to examine study feasibility. With regard to acceptability, attrition rates were examined, as was parent reported satisfaction, on a satisfaction survey. Qualitative interviews were conducted by three evaluators using 14 open-ended questions that were collaboratively created by the principal investigator (last author) and study team to probe for participant acceptability, feasibility, and areas in need of program expansion.

One of the aims of this study was to determine if the planned study assessment procedures would be acceptable and feasible to parents of young children with T1D. The study assessments related to health predictors and outcomes included several wearable, objective data-collecting devices (CGM, personal activity monitors), medical record reviews, dietary monitoring data, and a psychosocial battery. Assessment occurred at three time points: baseline, immediately after intervention (mean $\pm$ SD [$M \pm SD$] = 3.26 $\pm$ 0.71 months after baseline), and at a follow-up ($M \pm SD$ = 6.60 $\pm$ 0.67 months after baseline, psychosocial battery only). Details about the study assessment approach follow below.

Dexcom (San Diego, CA) G4 PLATINUM CGM receivers, transmitters, and sensors were used for measuring glycemic variability. CGM provides continuous real-time measurements of glucose in the interstitial fluid with displayed feedback for parents and alarms when the user is outside of the recommended BG range. Participants were either started on CGM ($n = 6$) at study commencement, or those already using CGM before study enrollment had their data downloaded. Participants were asked to use CGM for a minimum of 5 days before and after the intervention, with the option to continue for the study duration. Accelerometers were distributed to participants for child use at orientation and follow-up to record the type, amount, and duration of the child's PA in a blinded fashion, over the course of a 5-day period. The devices were initialized based on the child's age, height, and weight. Fitbit Ones

(Fitbit, San Francisco, CA) were also used to measure PA, but in a method permitting users to review their data in real time. Fitbit is recommended for those older than 13 years, and utility has not been fully explored in young children (Ridgers, McNarry, & Mackintosh, 2016). HbA1c and BG glucometer data were collected from the medical record at each time point.

Families were provided with a waist pouch carrier to store the study equipment and facilitate device wearing. Children were able to choose the waist pouch carrier and a Fitbit case from a selection of colors and patterns. Stickers were given to parents to reward their child for time spent wearing the devices. Text (i.e., short message service) reminders were also used to remind parents of equipment use. Participants were encouraged to continue using CGM and Fitbits for the duration of the 3- to 4-month intervention and were provided with additional supplies (e.g., CGM sensors) as needed.

Breakfast nutritional intake and eating/feeding patterns were assessed using the Remote Food Photography Method (RFPM; Pennington Biomedical Research Center, Baton Rouge, LA). RFPM has shown reliability and validity in adults and children (Martin et al., 2012), and the methods used in this study are discussed in detail elsewhere (Rose et al., 2018). Parents provided 3 days of before and after photos of their child's breakfast meal using personal camera smart phones. Parents were sent reminders via text message to send photos. Grams of protein, carbohydrate, and fat were extracted, and glycemic index calculated. Glycemic load was calculated as a glycemic index–weighted measure of carbohydrate using the formula $\text{glycemic index}/100 \times (\text{grams of carbohydrates in item} - \text{grams of fiber in item})$.

The Behavioral Pediatrics Feeding Assessment Scale (BPFAS; Crist & Napier-Phillips, 2001) assessed child and parent feeding behaviors. Each item has a frequency score (1 = *never* to 5 = *always*) and a problem score (*yes/no*). The BPFAS ($\alpha = .95$) has shown reliability and validity in estimating feeding problems in normative and pediatric samples, including children with diabetes (Allen et al., 2015; Patton, Dolan, & Powers, 2006). The Pediatric Inventory for Parents (PIP; Streisand, Branietcki, Tercyak, & Kazak, 2001), was used as a parent self-report rating of stress associated with caring for a child with a medical illness. The PIP ($\alpha = .90$) has shown good validity and reliability with families of children with diabetes (Streisand, Swift, Wickmark, Chen, & Holmes, 2005). The Center for Epidemiological Studies–Depression Scale (CES-D; Radloff, 1977), a 20-item self-report, measured symptoms of depression ($\alpha = .81$). Evidence supports adequate test–retest reliability and good internal consistency (Streisand et al., 2001).

Participants

Parents of children (ages 2–5 years) were recruited from an outpatient diabetes clinic in an academic medical center in a city in the mid-Atlantic region of the United States. Eligibility criteria included parents being in the adult age range (≥ 21 years of age), English fluency, and having a child with at least 1-year duration of T1D with no other life-threatening diseases or developmental disability that might affect participation. Children following all diabetes regimens, with any level of glycemic control, were eligible. Potential participants were recruited via letter through clinic lists and follow-up phone calls to assess interest and eligibility.

Parent coaches were mothers who previously had a child diagnosed with T1D at a young age (≤ 5 years old, diagnosed > 1 year) and were currently receiving care at the outpatient diabetes clinic. Parent coaches were nominated by diabetes clinical providers and screened by the study team for availability and ability to provide support to other families. Three parent coaches ($M \pm SD = 45 \pm 9.16$ years), 100% married, 100% non-Hispanic White, $M \pm SD$ age of child at diagnosis = 1.33 ± 0.58 years, $M \pm SD$ current age child = 10.33 ± 3.51 years), were recruited and trained (for full details, see Tully et al., 2017).

Data Analysis Plan

The goal of this article is to provide descriptive results of the feasibility and acceptability of TOTs and explore preliminary change scores from before to after intervention. We used mixed methods to describe the sample, with exploration of two participants (responder/nonresponder, as defined by improvements/deteriorations to hemoglobin A1c level) using case-oriented analysis for hypothesis generation about program limitations to inform revisions for the RCT.

In line with other intervention research and this team's prior work with the diabetes clinic, enrollment feasibility was examined via study recruitment response rate and enrollment (Müller et al., 2016). Feasibility of assessments used in the study was also examined. Overall, there was an expectation that most participants would complete each assessment component, and scoring guides for each measure or device were used to determine if data were useable. We defined *acceptability* as retention of the majority of the sample and evidence of parent satisfaction from the satisfaction survey and qualitative interviews.

Parents participated in qualitative interviews by three evaluators using 14 open-ended questions that were collaboratively created by the principal investigator (last author) and study team. Two coders working independently extracted themes from the field notes until saturation was met. Coders met with the remaining study team to review themes and resolve discrepancies.

The study team also conducted an initial examination of preliminary evidence of change from before and after the intervention in BG, nutrition, PA, and psychosocial data. The maximum number of days of biological data (CGM, BG), nutritional data, and PA data were used per person with no imputations for missingness. To measure dysglycemia, glucose fluctuations (percentage of time out of suggested range) and sustained hyperglycemia (duration of high excursions) were assessed. Valid day of wear was defined by ActiLife (Zydus Wellness, Gujarat, India) wear day validation for the accelerometer. Bivariate correlations explored the relationship between PA measurement tools. For psychosocial measures, missing data were handled with imputation of sample mean. Descriptive statistics were calculated for the outcomes and other variables. Generalized estimating equations (GEEs; Allen et al., 2015) were used to provide a preliminary look at intervention effect between baseline and immediately after the intervention. All analyses were completed with SAS, version 9.2.

RESULTS

Feasibility and Acceptability

Overall, 21 letters were sent to recruit families, and the study team was able to reach 14 (67%) to assess eligibility and interest. One family was ineligible because of medical history, and of the 13 that were eligible, 10 (77%) were interested and enrolled (see Table 2). Three parents declined study participation because of lack of interest in research or concerns about the time commitment.

With regard to assessment feasibility and acceptability, at baseline, usable data rates were 78% CGM, 98% accelerometer data, 89% Fitbit data, and 100% RFPM data. One of the participants who had not previously used CGM used it throughout the intervention and follow-up. Only three of the five participants who were new to CGM agreed to use the CGM at follow-up, and of those three, only two returned usable data. Of the nine participants at follow-up, there were 53% with CGM data, 78% with accelerometer data, 73% with Fitbit data, and 89% with RFPM data. Because of the lower than expected rates of CGM use, experiences were explored through surveys and interviews. Based on satisfaction forms, 78% of the participants reported that they found the CGM very useful. Three themes emerged from the qualitative interviews relating to barriers to CGM use: *Device Utility*, *Difficulty Relating to Child Age*, and *Parent Stress*. One participant reported that CGM was “a game changer” for her family because of the precise feedback on her child’s BG levels. Despite the benefits, participants also reported that CGM was “stressful... I was freaked out about keeping it on.” One parent expressed that CGM “might work best on more mature children who understand or can comprehend why the CGM is beeping [due to low or high alerts].” Another parent reported problems with keeping the device on their child. The increased knowledge of ongoing data regarding BG levels was an unexpected stressor for some, including one mother, who stated, “It’s a lot... to know every 5 minutes, and now I have to decide what to do.... It’s made me more scared.” Overall, 89% of parents reported that they liked using Fitbits very much and 78% felt that wearing Fitbits was very or somewhat easy for their child. Three parents expressed concerns about keeping the activity monitors on their child for the 5-day period.

Retention and parent reports of satisfaction were examined for evidence of acceptability. The study had high retention; of the nine families who completed full baseline assessments, all completed the intervention and follow-up data collection time points (90% retention from baseline). Parents reported overall high satisfaction with program participation and with the TOTs program content ($M \pm SD = 1.11 \pm 0.31$; 1 = *very satisfied* to 5 = *not satisfied at all*). Qualitative data showed that parents liked the multimodal nature of the program: “I wouldn’t change any of [the program]. It was actually right on... like my parent coach. We had a great rapport.” A second parent said, “[the skills taught] were so doable. There were a lot of tools taught, and some of them I might come back to later.” Overall, this evidence supports conclusions that the program content was acceptable.

Interviews were examined for areas of program expansion as well. A theme emerged regarding a need for higher-intensity diet attention: “The focus on protein was good, but it’s more complex.... You need to address different carbs ... and fat.” Another recommended

including more culturally inclusive menu items on the study Web site. Participants enjoyed their parent coach, with 80% reporting engaging with their coach by phone more than four times. Parents reported interest in having more contact with their parent coach, although they also recommended trying to match on “life circumstances like [if the parent is] working or not.” Parent coaches also enjoyed their role in the TOTs program and agreed to serve as parent coaches in the larger trial, although they requested more training to practice active listening and instructions on culturally competent communication methods.

Preliminary Evidence of Change

The number of participants within the ADA recommended glycemic range (hemoglobin A1c level < 7.5%) doubled after the intervention (from 2 to 4), although there was no significant change in mean hemoglobin A1c level from baseline ($M \pm SD = 8.1\% \pm 0.9$) to after the intervention ($M \pm SD = 8.0\% \pm 1.2$) or at the 6-month follow-up ($M \pm SD = 8.1\% \pm 1.2$). There were significant BG level declines from baseline to after the intervention ($M \pm SD = 217.5 \text{ mg/dl} \pm 44.5$ to $M \pm SD = 188.9 \text{ mg/dl} \pm 40.3$; GEE = -22.0 , $p = .016$) and no significant change at the 6-month follow up ($M \pm SD = 209.1 \pm 54.6$). As measured by CGM, children spent 29.0% of their time at baseline within the ADA recommended BG range (66.4% above recommended range). Because of the limited number ($n = 6$) who wore CGM at both time points, group-level glycemic changes with CGM were not calculated.

Nutrition, PA, and psychosocial change data are described in Table 3. There was no significant change in carbohydrate, protein, or glycemic load offered or consumed at breakfast. Mean grams of unsaturated fat significantly increased (GEE estimate = 3.46 , $p = .010$), and mean total calories significantly increased (GEE estimate = 34.75 , $p = .008$). Most ate two or three times in the morning, and only one breakfast meal was documented for analyses. Accelerometer and Fitbit data were available for seven children; two did not consistently wear the devices. Child participants spent 64% of time sedentary, 15% of time in light PA, 13% of time in moderate PA, and .07% in vigorous PA as measured by accelerometer. Accelerometer and Fitbit step counts were highly correlated ($r = 0.822$, $p < .001$). There was no significant change in child steps or percentage of day in moderate to vigorous PA as measured via accelerometer or Fitbit. With regard to psychosocial data, there were significant changes in the hypothesized and expected direction for parent depressive symptoms (CES-D = -5.78 , $p = .034$), parenting stress (PIP frequency = -11.40 , $p = .007$; difficulty = -18.10 , $p < .001$) and negative affect relating to feeding (BPFAS, parent feelings/strategies = -1.56 , $p = .014$).

Case Analysis

The first participant was a married mother of a 5-year-old Hispanic boy, diagnosed with T1D at age 3 years. The child was using an insulin pump and used a personal CGM before study participation, and the parents both had graduate degrees. During TOTs, the mother explored applying some of the behavioral feeding skills (e.g., selective attention), first at mealtimes and then generalizing to other problem areas. This parent reportedly made changes to increase PA for herself and her child. In the follow-up qualitative interview, she reported that she appreciated the focus on child behavior, PA, and social support, despite some prior diet

and insulin timing knowledge. This family completed all intervention components and returned 100% data.

This child's hemoglobin A1c level remained within the recommended range, although it increased (from 7.1% to 7.4%). Despite changes in A1c level, there was an improvement in amount of time spent within the recommended glucose range by CGM (23.30% to 36.10%) and glucometer (185 mg/dl to 165 mg/dl). This family increased the protein being offered and consumed at breakfast (+2.09 g and +2.82 g, respectively), with the child starting to consume all protein offered, and decreased glycemic load (−2.04 g). Changes might be attributable to improvements in the child's mealtime behavior (BPFAS child mealtime frequency scale score change from 60 to 55; problem score change from 10 to 3) and the parent's mealtime strategies and feelings (BPFAS parent strategies/feeling frequency score change from 26 to 20; problem score change from 6 to 0). The child and parent participant both increased average steps by more than 3,000 steps/day.

Several hypotheses are possible regarding the benefit that this participant appeared to gain from the TOTs program. The child was previously using a personal CGM and insulin pump, and use of technology has been shown to be associated with improved glycemic control (Tamborlane, Bonfig, & Boland, 2001). The family had a higher socioeconomic status and described higher diabetes and nutrition knowledge. Despite strengths, the family appeared to benefit from TOTs participation. The behavioral feeding parenting skills were reported to have generalized to improving child behavior in general. The parent reported use of the Fitbit as directly relating to changing her own behavior to increase PA.

The second participant was an unmarried mother of a 5-year-old African American boy, diagnosed with T1D at age 4 years, who was receiving multiple daily injections using a basal/bolus regimen. The parent had a high school education. During the TOTs intervention, the parent discussed challenges relating to co-parenting across households and mood management, and expressed low self-efficacy to make health behavior changes. At baseline, the parent's CES-D score (23) was elevated above a cutoff (CES-D 16; Lewinsohn, Seeley, Roberts, & Allen, 1997), and she was referred for mental health services. The family declined the CGM after the intervention and returned 50% usable baseline CGM data, 100% diet data, and 50% PA data.

The child's hemoglobin A1c level worsened during the TOTs program (from 9.8% to 10.9%), although glucometer data supported an overall average improvement in mean daily BG (287 mg/dl to 275 mg/dl), and breakfast BG values increased (236 mg/dl to 287 mg/dl). This family decreased the protein being offered and consumed at breakfast (−5.77 g and −5.17 g, respectively) with a minor decrease in the glycemic load (−0.25 g). The child's behavior at mealtimes did not change significantly (BPFAS child behavior feeding problem frequency score change from 42 to 45), although ratings show that the parent reported slightly fewer perceptions of problems in feeding (child score change from 3 to 0, parent score change from 2 to 1). This mother's mood reportedly improved (CES-D score change from 23 to 9), and parenting stress related to illness management decreased (PIP frequency score change from 115 to 83, PIP difficulty score change from 99 to 77). As measured by

accelerometer, the child decreased steps (change = -2,014 steps/day). No Fitbit data were available at follow-up. There were no significant changes at the 6-month follow-up.

Several hypotheses are possible from this case. The family started the TOTs program with strained family relationships and fewer resources compared with the family of the patient in the first case, who was an intervention responder. Although the parent reported in the interview that CGM was helpful, there were barriers relating to continuing to use a device that the co-parent was not trained to use. Parent mood and stress were likely barriers. Because parent mood may be a more proximal factor in implementation of TOTs skills to improve diabetes management, glycemic change might be found over an even longer follow-up period (e.g., 1 year). A longer intervention/higher program dosage, or pre-intervention preparation adjunct to address some of the initial psychosocial barriers, may have also been beneficial for this family.

DISCUSSION

This was a small feasibility study of a new parenting intervention for parents of young children with T1D to improve health behaviors. The study has strengths in its multicomponent intervention delivery, diverse sample with respects to ethnicity and diabetes management methods, and mixed methods data analysis approach. Use of a small sample allowed for in-depth exploration of responders and nonresponders. These results informed intervention revision for testing in the RCT. There were also limitations regarding the small sample, which was underpowered to detect change and therefore required a trend-based analysis.

The feasibility of the TOTs program as a whole was shown through excellent recruitment and retention rates. Parents who were eligible for the study generally showed interest in enrolling, and those who enrolled tended to finish the full study; all but one participant completed the full intervention and follow-up data collection time points. With regard to acceptability, parents were retained in the study and reported high satisfaction on surveys and in interviews.

The assessment devices used showed different levels of feasibility and acceptability. Most participants successfully used all of the tools for the 5-day data collection periods and reported satisfaction with use. Some challenges remained for the use of multiple wearable technologies, particularly at follow-up for CGM. With only two participants who were new to CGM returning usable data at follow-up, CGM proved to be the most challenging of the devices. More work is needed to generate methods to enhance CGM feasibility and satisfaction for families of young children. Additionally, the CGM devices generate a considerable amount of data that require careful preparation and analysis by trained individuals to be of benefit both for the research and for the families using them. Considerations of these benefits and risks should be evaluated as new continuous measurement devices are used with this age group (e.g., FreeStyle Libre, Abbott Laboratories, Chicago, IL).

There were some changes observed in BG levels, parent mood, stress, feeding practices, and child behavior at mealtimes. No firm conclusions regarding nutrition and BG level are possible, but some hypotheses were generated from CGM pattern analysis for further exploration. Although no significant change was found in diet or PA, there was a heterogeneous mix of responders and nonresponders, and coupled with the small sample size and lack of a control group, it was not surprising to not see an effect of the intervention. There were some similarities among responders, including sociodemographic characteristics (e.g., having two-parent families), diabetes management (prior use/interest in CGM), health behaviors (i.e., more consistent feeding practices), and parent characteristics (e.g., lower depression scores). Some of the modifiable factors (e.g., feeding practices) that may be related to experiencing a positive response to the intervention continue to be a primary focus of TOTs, whereas the social support and self-care modules of the intervention may benefit others such as parent mood.

Changes were made based on the results of this feasibility study for the larger efficacy trial. More inclusive cultural imagery and food traditions were incorporated, and parent coaches were trained in culturally competent communication. Blinded CGM (i.e., no information displayed to family) is used for 5 days at baseline and follow-up, eliminating the need for parent training and interpretation of readings, with the goal of reducing participant burden. Fitbits have been incorporated into the program as an intervention tool only. Nutrition content was revised to include more advanced information regarding glycemic load.

Case exploration provided additional details regarding a family's ability to engage in the TOTs program. Results from our case analysis implies that assessing barriers to care early and using appropriate pretreatment strategies such as extended engagement procedures using motivational interviewing or parental referral for mental health support or resource management support might be beneficial adjuncts to behavioral parenting treatment focusing on health behaviors. Future studies should explore whether designs using variable degrees of intervention to systematically identify families in need of more pretreatment preparation might be useful.

CONCLUSION

The findings from this study support the feasibility and acceptability of the TOTs parenting intervention to promote healthy eating and PA in young children with T1D. Early evidence of change in the expected directions was promising. The RCT using the revised procedures and intervention is currently being tested with a larger sample size to allow for discussions of efficacy and generalizability.

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TABLE 1**TOTS intervention: Session topics**

Session	Mode	Staff	Topics
Orientation	In person	Counselor + CDE	Introduction to study, family diabetes story interview including management style and child's current dietary preferences, begin study devices, initial education on CGM use
1	Phone	Counselor	Eating high-protein breakfast and establishing routines/habits
2	In person	Counselor + CDE	Behavioral feeding techniques to improve child nutritional choices and mealtime behavior using novel/nonpreferred snack task, insulin timing, and feedback on CGM
3	Phone	Counselor	Increasing and monitoring of PA, cognitive restructuring of hypoglycemic fears
4	Group call	Counselor	Social support, problem solving with other participants enrolled in TOTs
5	Phone	Counselor	Parent self-care, shared caregiving
6	Phone ^a	Counselor	Evaluating progress, looking ahead

Note. CDE, certified diabetes educator; CGM, continuous glucose monitor; TOTs, Type One Training study.

^aOne participant out of nine completed Session 6 in person.

TABLE 2Sample characteristics ($N=10$)

Characteristic	Value
Child	
Age in years, $M(SD)$	4.3 (0.5)
Age in years at diagnosis, $M(SD)$	2.6 (1.4)
Male, $n(\%)$	6 (60)
White non-Hispanic	5 (50)
Diabetes regimen, $n(\%)$	
Insulin pump	3 (30)
Basal bolus	6 (60)
Conventional	1 (10)
Family	
Mother's education, $n(\%)$	
12th grade	2 (20)
Partial college	1 (10)
2-year college	2 (20)
4-year college	2 (20)
Graduate/professional	3 (30)
Marital status, $n(\%)$	
Married	5 (50)
Employment, $n(\%)$	
Full time	3 (30)
Part time	3 (30)
Not employed	4 (40)
Household income, $n(\%)$	
< \$100,000	5 (50)

Note. M, mean; SD, standard deviation.

TABLE 3

Nutrition, physical activity, and psychosocial outcomes after intervention

Assessment	Before		After		Change [*]
	% Usable	<i>M</i> (<i>SD</i>)	% Usable	<i>M</i> (<i>SD</i>)	GEE
Nutrition	100%		89%		
Protein, g	—	9.80 (2.70)	—	11.0 (4.10)	.97
Carbohydrates, g	—	38.60 (13.30)	—	39.10 (17.20)	-1.33
Glycemic load	—	19.90 (8.60)	—	18.80 (9.50)	-1.97
PA					
Steps, <i>n</i> (accel)	98	8,637.90 (3,177.40)	78	8,774.70 (3,781.50)	—
MVPA, % (accel)	—	21.30 (11.80)		18.40 (14.0)	
Psychosocial	100		100		
BPFAS ^a	—		—		
Frequency		70.40 (13.60)		69.0 (18.20)	-1.44
Problem		7.10 (6.20)		4.30 (8.40)	-2.78
CES-D	—	12.0 (8.70)	—	6.20 (3.20)	-5.78 [*]
PIP	—		—		
Frequency		100.60 (12.40)		89.10 (18.30)	-11.44 [*]
Difficulty		90.0 (14.10)		71.90 (10.50)	-18.11 [*]

Note. accel, accelerometer; BPFAS, Behavioral Pediatrics Feeding Assessment Scale; CES-D, Center for Epidemiological Studies-Depression Scale; GEE, generalized estimating equation; *M*, mean; MVPA, moderate-to-vigorous physical activity; PA, physical activity; PIP, Pediatric Inventory for Parents; *SD*, standard deviation.

^aBPFAS frequency *M*(*SD*) at 6 months = 67.8 (11.9), change = -1.03 (not significant); BPFAS problem *M*(*SD*) at 6 months = 3.3 (6.0), change = -2.96.^{*}

^{*} If *p* < .05.