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Pilot Study Results for a Novel Behavior Plus Nutrition Intervention for Caregivers of Young Children with Type 1 Diabetes

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Abstract

Objective—This pilot study presents results for a parent-based educational intervention targeting mealtime behaviors plus nutrition among families of young children (M age: 5.0±1.2 years) with type 1 diabetes mellitus (T1DM).

Methods—We recruited nine caregivers who participated in the six-session intervention and completed baseline and post-treatment assessments.

Results—Children's mean daily glycemic levels decreased from 185±46 mg/dl to 159±40 mg/dl ($p < 0.001$). There were also decreases in problematic parent and child mealtime behaviors. There was no change in children's dietary intake indicators.

Conclusions and Implications—It appears promising that our targeted behavior plus nutrition intervention can improve glycemic control and behavior for young children with T1DM. Our next step will be to modify the intervention to improve our nutrition education modules. Ultimately, we plan to test the intervention in a large randomized clinical trial to examine if it can yield improvements to children's diet and glycated hemoglobin levels.

Keywords

nutrition; behavior; child; preschool; diabetes; glycemic control

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INTRODUCTION

Young children with type 1 diabetes (T1DM) are understudied in behavioral treatment outcomes research, despite evidence suggesting that the incidence of T1DM is increasing in young children.^{1,2} Caring for a young child with T1DM is challenging because young children are more vulnerable to hypoglycemia.^{3,4} Additionally, young children can be highly unpredictable in their eating and activity levels, which can complicate dietary planning and insulin administration.^{5,6,7} Unfortunately, the available literature suggests that many young children with T1DM experience problems with glycemic variability and do not achieve targets for measures of chronic glycemia, namely glycated hemoglobin (HbA1c).^{4,7} Mealtime behavior problems have been commonly reported by parents of young children with T1DM and have been shown to correlate with higher daily glucose levels in children.^{8,9} Additionally, studies have shown that many young children with T1DM do not consume a healthful diet, which is also related to poor glucose control.^{5,10} While there are interventions focused on improving support and coping in parents of young children with T1DM,^{11,12} an intervention directly addressing child health outcomes has not yet been developed specifically for these parents.

BEST MEALS (Behavior and Eating Strategies That Make Eating Activities Less Stressful) was created to provide a parent-based behavior plus nutrition education intervention for young children. Drawing from clinical experience, the 'Health Beliefs Model'¹³ and an existing intervention developed for cystic fibrosis,¹⁴ the six weekly sessions of BEST MEALS address age-specific diabetes education topics, healthful eating practices for T1DM, and behavioral parent training in order to promote greater parental knowledge of T1DM and perceived self-efficacy to change maladaptive T1DM care strategies (Table 1). Mealtimes were selected as the primary intervention target based on the extant literature^{8,15} and because mealtimes are a specific goal-directed activity which occur at multiple and distinct times each day, thus providing parents with frequent practice opportunities. Parents were targeted for the intervention because they have a primary role in caring for their young child's T1DM.³

This research brief provides pilot results from BEST MEALS. The primary outcome we tested was a change in child mean daily blood glucose concentration, and we hypothesized that participation in BEST MEALS would result in lower daily glycemic levels. Secondary outcomes were change in family mealtime behaviors and child dietary intake. Acceptability and feasibility data were also collected.

METHODS

Participants

Families were recruited from a hospital-based diabetes clinic in the Mid-Western United States. All of the families had previously indicated an interest in participating in clinical research. Parents or primary caregivers were eligible to participate if they had a child between 2–6 years old, with a T1DM diagnosis made at least six months previously, the child was following an intensive insulin regimen (insulin pump or multiple daily injections), the child was not sick with another serious chronic illness (e.g., liver disease), and parents

spoke English. Thirteen families were recruited, 10 initially agreed to participate, and 9 families enrolled in the study and completed study measures (70% participation rate). The three families who refused to participate cited time and the necessity of having to travel to the medical center for the group sessions as their primary reason for refusing participation. One family agreed to participate, but in the end, was unable to participate because of a scheduling conflict.

Procedure

Institutional Review Board approval was obtained before starting the pilot study and all parents provided written consent at enrollment. Families participated in two home study visits at baseline and post-treatment and parents attended the six session group-based BEST MEALS intervention. Study assessments included parent-completed diet records, video-recorded home dinners, and children's blood glucose data as recorded by their home glucometers. The video-recorded home meals were completed during each of the study visits (one dinner meal at baseline and post-treatment, respectively). Following each video-recorded home meal, caregivers rated how typical the meal was using a survey that asked about meal length, child behavior, foods consumed, and people present at the meal. Meals rated as non-typical were supposed to be replaced based on a standard protocol.¹⁶ However, in the present sample, no video-recorded meals were replaced. Families were paid \$35 for each assessment (baseline and post-treatment, or \$70 total).

Measures

Demographic Form—Child and parent demographics and child medical information were collected at baseline. Children's height and weight were measured at baseline using portable equipment and based on a standard protocol.¹⁷

Children's Mean Daily Blood Glucose—Children's mean daily blood glucose level was calculated based on 14 consecutive days of self-monitoring blood glucose data obtained from children's home glucometer. These data were collected at baseline and at post-treatment, and included glucose levels collected on the days of the video-recorded meals and diet records. At baseline, children averaged 7.3 ± 3.1 glucose checks per day and they averaged 8.0 ± 2.5 checks per day at post-treatment. Mean daily glucose level was calculated based on all of the checks completed by parents. Mean daily glucose level was used to measure outcome instead of HbA1c because of the short duration of the BEST MEALS intervention.

Dyadic Interaction Nomenclature for Eating (DINE)—Family mealtime interactions were examined using the DINE, a validated coding system that has been used previously in children with T1DM.^{8,16} The DINE consists of three categories of behaviors: Child Eating, Child Behavior, and Parent Behavior (See Table 1 for specific behaviors within each category).

Behaviors were coded in consecutive 10-second intervals throughout the meal. Reliability was assessed using a Kappa coefficient for each behavior category based on a random subset of 33% of meals. For this study, Kappa coefficients were 0.91, 0.83, and 0.78, for Child

Eating, Child Behavior, and Parent Behavior, respectively; all values exceeded 0.60, indicating acceptable reliability.¹⁸

Dietary Intake—Children’s typical dietary intake was measured concurrently with children’s video-recorded home meals using daily diet diaries. Caregivers were given a digital scale as well as measuring cups and spoons; they were trained to record their child’s food and beverage intake according to a standard protocol.¹⁷ All diet records were reviewed by a registered dietitian within 1–2 days of recording. Diet records were analyzed for energy intake, percent calories from fat, carbohydrate, protein, and saturated fat using the Nutrition Data Software for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis). Specific nutrition indicators were selected based on the content of BEST MEALS.

Treatment Satisfaction Questionnaire—Acceptability of the BEST MEALS intervention was measured using an 11-item study specific questionnaire. Caregivers responded to each item using a 9-point Likert scale, with higher scores reflecting greater acceptability. A total score was computed by summing ratings across all items.

Statistical Analyses

Children’s mean daily glycemic levels were normally distributed. Thus, to test for a change in glycemic levels we used a paired sample t-test. Because of our small sample size, statistical analyses for the secondary outcome variables (viz., mealtime behaviors and diet) were limited to means, standard deviations, and effect sizes (i.e., Cohen’s *d*). For Cohen’s *d*, an effect sizes of 0.2–0.3, 0.5–0.7, and 0.8 and higher, are considered small, medium, and large, respectively.¹⁹

RESULTS

The sample consisted of 9 young children with T1DM and their caregivers (7 mothers, 1 father, 1 custodial grandparent). Mean child age was 5.0 ± 1.2 years and there were six girls. Mean caregiver age was 38 ± 6.0 years. Mean HbA1c at baseline was $8.2 \pm 1.3\%$. Mean child Body Mass Index (BMI) and BMI z-score were 16.4 ± 2.1 and 0.42 ± 1.3 , respectively. Eight families self-identified as non-Hispanic White and one family self-identified as Black. The majority of caregivers reported that they were married and had a mean household income of $\$75,000 \pm \$30,000$, suggesting an upper-middle class sample.

Daily Glycemic Control

Children’s mean daily glucose was 185 ± 46 mg/dl at baseline and 159 ± 40 mg/dl at post-treatment, suggesting family participation in BESTMEALS was associated with a significant decrease in children’s mean daily glucose ($t(8)=6.707$, $p<0.001$; $d=0.60$).

Mealtime Behavior

Average meal length at baseline was 24 ± 13 minutes and dropped to 19 ± 9 minutes at post-treatment ($d=0.45$). To control for the difference in meal length, we calculated the rate of each behavior per 10-second interval (frequency per interval/number of intervals). Mean

values for behaviors at the baseline and post-treatment meals and effect sizes for behaviors are presented in Table 2.

Diet

Children's mean daily calorie intake at baseline was $1,320 \pm 426$ and $1,423 \pm 150$ at post-treatment ($d = -0.36$). Children's mean daily percent calories from fat, carbohydrate, protein, and saturated fat at baseline were $33 \pm 7\%$, $52 \pm 6\%$, $14 \pm 3\%$, and $11 \pm 4\%$, respectively. At post-treatment, their mean daily percent calories from fat, carbohydrate, protein, and saturated fat were $31 \pm 4\%$, $54 \pm 7\%$, $14 \pm 5\%$, and $11 \pm 3\%$. Examining Cohen's d , there was a small treatment effect for children's percent calories from fat and carbohydrates ($d = 0.36$ and -0.34 , respectively), but other effect sizes were negligible.

Acceptability and feasibility

Caregivers reported very high levels of satisfaction with the BEST MEALS intervention (77 ± 29 , range 0–88). Also, mean group attendance was 75%, suggesting feasibility.

DISCUSSION

Our results provide the first example of an educational intervention targeting behavior plus nutrition specifically in young children with T1DM that has resulted in a decrease in child mean daily glycemic level. While the short follow-up of our pilot study precludes any assumptions about the sustainability of effects over time, if the treatment effect is maintained, it is highly likely BEST MEALS will also result in changes in children's HbA1c. As noted previously, other interventions for families of young children with T1DM have reported decreased parenting stress and increased perceived support, but as yet, these interventions have not reported any changes in children's diabetes-related health outcomes.^{11,12} The literature shows that many young children have trouble maintaining healthy glucose levels which is a risk factor for vascular complications.^{3,4,7} Thus, an intervention that helps young children decrease their overall daily glucose levels may be clinically significant.

Changes in parent and child mealtime behaviors from pre- to post-treatment also suggest several positive treatment effects. Behaviors that decreased in rate from pre- to post-treatment were parent's use of indirect requests to eat, coaxes, and attempts to feed their child during the meal, as well as children's bite refusal, and noncompliance to parental commands. Behaviors that increased in rate were parents' use of praise and child requests for food. In the past, we have noted positive correlations between parents' use of indirect requests to eat and coax and children's mean daily glucose levels. We have also identified positive correlations between children's disruptive behavior and their daily glucose levels.⁸ Because of these associations we specifically targeted mealtime parenting strategies and instructed parents to use direct requests to eat, goal-setting, and contingent attention to shape children's eating behavior. Our preliminary results suggest that BEST MEALS was successful in decreasing the rate of occurrence of some problematic parent and child behaviors, and in increasing parents' use of praise for positive child behaviors.

In addition to reviewing carbohydrate counting, the BEST MEALS curriculum showed parents how to shop for and prepare low-fat meals. We also taught parents how to recognize and reduce their child's saturated fat intake. Unfortunately, there was virtually no change in children's fat and saturated fat intake. The literature has also shown that many youths with T1DM consume a diet that is above American Diabetes Association recommendations for percentage of calories from total and saturated fat.^{5,20} Moreover, new research suggests that many youths with T1DM are not taught how to track fat intake within standard medical nutrition therapy.²¹ Epidemiological data reveal that many youths with T1DM, including young children, evidence at least two risk factors for cardiovascular disease,²² thus underscoring the importance of counseling parents to limit their child's fat intake in addition to tracking carbohydrates. We used handouts and group discussion to convey our nutrition information. In future iterations of BEST MEALS it may be necessary to spend more time on these topics and to incorporate other teaching devices into the intervention (e.g., guided grocery shopping trip, individualized meal planning) to achieve a decrease in child fat intake.

BEST MEALS had high acceptability and feasibility. However, our recruitment rate was only 70% and the most common reasons parents gave for refusing to participate were time and the necessity to attend group sessions at the hospital. It is possible that a telemedicine or community-based intervention might have offered fewer barriers to participation.

The results presented are preliminary and from a very small sample. Therefore, while the results may help to power a future larger trial of BEST MEALS, they may not generalize to a larger population. Likewise, the sample was highly homogeneous, suggesting the results may not generalize to more diverse samples. In the future, it will be important to test the efficacy of BEST MEALS in a more economically and ethnically diverse sample. This pilot recruited a single group in a pre- and post-treatment design. There was no control group, so it is impossible to rule out effects related to increased attention versus the intervention. Several DINE behaviors had large standard deviations relative to their means, which may have decreased their computed effect sizes. Finally, there is the possibility of reporting bias in parents' dietary records and a Hawthorne Effect related to families' videotaped home meals.²³ Asking parents to report on their child's food intake may have changed how they fed their child. However, we note there was relatively little change in children's dietary intake from baseline to post-treatment, despite teaching parents specific strategies to reduce fat and saturated fat intake, giving us greater confidence that parents were not biased in their diet recording. Also, we attempted to minimize a Hawthorne Effect by asking parents to rate each meal and only using meals rated as typical.

IMPLICATIONS FOR RESEARCH AND PRACTICE

The increasing incidence of T1DM in young children, coupled with the inherent risks of the disease, underscores a critical need for targeted behavioral interventions that improve their health.^{1,2} We provide preliminary support that young children with T1DM can experience improved daily glycemic control as a result of our behavior plus nutrition education intervention. Our next step will be to modify BEST MEALS and improve our nutrition education modules by including more information on individual meal planning, healthy

suggestions for low carbohydrate meals and snacks, and strategies for grocery shopping with young children. We will then pilot the modified BEST MEALS to determine if the addition of these modules leads to changes in children's daily intake of fat and saturated fat. In the context of nutrition education for young children with T1DM, it may be helpful to include counseling specific to dietary fat intake and effective parent mealtime strategies.

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Table 1

Description of BEST MEALS intervention

Session	Topic	Content	Format
1	Introduction/Self-Monitoring	Rationale of BEST MEALS; Write out family daily/weekly routines related to type 1 diabetes (T1DM) management; Set goals for treatment	Slide presentation; Group discussion; Handouts
2	Insulin Management/Glucose Targets	Insulin types/action; Insulin dose calculations; Glucose targets for young kids; Challenges to T1DM management	Slide presentation; Group discussion; Handouts
3	Child Behavioral Management-I	Contingent Attention; Applying Contingent Attention at Meals; Specific behaviors to praise versus ignore; Direct requests versus indirect requests or coaxes	Slide presentation; Video clips modeling praise/ignoring; Group discussion; Handouts
4	Carbohydrate Counting/Building a Healthy Plate-I	Review steps to count carbohydrates; ADA recommendations for fat and saturated fat intake; Recognizing/reducing daily fat intake	Slide presentation; Group discussion; Food labels; Sample menus; Handouts
5	Building a Healthy Plate-II and Introducing New Foods	Review recommendations for daily fat intake; Review strategies for recognizing/reducing daily fat intake; Contingent Attention to introduce new foods and non-preferred foods	Slide presentation; Video clips modeling introduction of new/non-preferred foods; Group discussion; Handouts
6	Maintenance/Supporting a Healthy Lifestyle	Reviewed recommendations for daily physical activity; Helped families create a list of physical activity options; Discussed other problem behaviors at meals	Slide presentation; Group discussion; Activity to develop family physical activity lists; Video clips modeling some other problematic behavior at meals (i.e., child only eating if he/she is reinforced); Handouts

Table 2Rate[†] of mealtime behaviors for baseline and post-treatment meals

	Baseline M±SD	Post-treatment M±SD	Cohen's d
Child Eating			
Bites	0.65±0.27	0.54±0.17	0.63
Sips	0.04±0.02	0.03±0.02	0.32
Child Behavior			
Compliance to requests	0.02±0.02	0.006±0.007	1.13
Noncompliance to requests	0.008±0.005	0.004±0.009	0.50
Child talk	0.42±0.16	0.28±0.17	0.88
Request for food	0.007±0.009	0.013±0.023	-0.30
Play	0.009±0.02	0.03±0.04	-0.64
Away from table	0.07±0.06	0.10±0.18	-0.23
Refuse	0.01±0.01	0.008±0.02	0.35
Parent Behavior			
Direct requests to eat	0.14±0.008	0.005±0.01	0.77
Indirect requests to eat	0.02±0.01	0.01±0.01	0.61
Parent talk	0.45±0.24	0.32±0.21	0.56
Coax	0.04±0.03	0.01±0.03	0.79
Physical Prompt	0.009±0.01	0.006±0.01	0.31
Reinforcement	0.01±0.01	0.04±0.04	-0.98
Feed	0.009±0.02	0.001±0.002	0.63

[†]Rate= frequency of the behavior per interval / number of intervals in the meal; families recorded one dinner meal at baseline and post-treatment, respectively.