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ORIGINAL ARTICLE

Weight trajectory of youth with new-onset type 1 diabetes comparing standard and enhanced dietary education

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Abstract Youth with type 1 diabetes (T1DM) gain weight after insulin therapy initiation. We aimed to study the effects of Enhanced Dietary Counseling (EDC) compared to Standard of Care Dietary Counseling (SDC) on BMI trajectory in youth with new-onset T1DM. Youth with new-onset T1DM ($n = 47$; 8.9 + 4.2 years) were randomized 6 weeks post-diagnosis to either SDC per American Diabetes Association guidelines ($n = 25$) or EDC ($n = 22$: SDC plus monthly nutritional education and 3-day food records (FRs) at 6 and 24 weeks). Weights and heights were measured at diagnosis, 6 weeks, 3, 6, and 12 months post-diagnosis; pre-diagnosis BMI was obtained from pediatricians' records. BMI *Z* score was used to track BMI change. Knowledge of recommended daily energy intake (DEI) and daily carbohydrate intake was assessed at follow-up visits. Changes in BMI *Z* scores were similar in SDC versus EDC subjects from pre-diagnosis to 12 months post-diagnosis. BMI *Z* score at 12 months exceeded pre-diagnosis level in 58.5 % subjects (54.5 % EDC vs. 63.1 % SDC, $p = 0.75$). From 6 weeks to 6 months, percentage of subjects correctly recalling recommended DEI increased in EDC along with percentage of subjects meeting recommended daily fruit servings intake from 25 % (6 weeks) to 64 % (6 months), $p = 0.047$). EDC did not prevent BMI *Z* score increases in youth with new-onset T1DM, and BMI *Z* score exceeded pre-diagnosis levels in >50 % 12 months post-diagnosis. A family-based approach and/or additional intervention may be needed to prevent excessive weight gain.

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Introduction

Type 1 diabetes (T1DM) is one of the most common chronic diseases in children with a prevalence of 2 per 1,000 and an annual incidence of 23.6 per 100,000 [1]. Children with T1DM are traditionally considered to be lean. However, body mass index (BMI) distribution in youth with T1DM mirrors that observed in the general population and often children with T1DM are still overweight at diagnosis, despite having experienced some weight loss due to hypoinsulinemia [2]. The SEARCH study [3] and data from the Pediatric Diabetes Consortium [4] indicate that approximately 21 % of children aged 2–19 years with T1DM are overweight at diagnosis, comparable to the overall 32 % prevalence of overweight youth in the general population [5, 6]. Children with new-onset diabetes typically gain weight in the period immediately following insulin therapy initiation [7]. Part of this weight rebound is "physiologic" and can be attributed to correction of the hypoinsulinemic catabolic state. However, for children who were overweight prior to diagnosis, weight gain after diagnosis is likely to return the child to the unhealthy state of overweight or obesity.

In addition, further weight gain may occur as a "side effect" of intensive insulin therapy [8] and is associated with increased risk of metabolic syndrome in both adults and youth with Type 1 diabetes [7, 9, 10]. Youth with T1DM may be at risk for gaining excessive weight also due to an exclusive focus on carbohydrate counting, without accounting for the overall energy intake or distinguishing between simple and complex carbohydrates [11]. In the

absence of a specific medical nutrition therapy (MNT) for youth with T1DM, individualized carbohydrates, protein, and fat intake are prescribed by the nutritionist with an encouragement to increase the fruit and vegetable intake [12–14]. Yet, adherence to recommendations remains a problem [15]. Additionally, despite individualized MNT, flexible basal-bolus insulin therapy and carbohydrate counting allow many opportunities to consume unhealthful foods [16]. Data from glucose sensors demonstrate that exaggerated excursions in glycemic levels occur following simple carbohydrate consumption, despite appropriate insulin dosing based on carbohydrate count [17]. This in turn results in additional insulin boluses that may contribute to excessive weight gain. Coverage for excessive simple carbohydrate intake in the face of uncontrolled calorie intake contributes to excessive weight gain since insulin is an anabolic hormone [18].

Rapid weight gain in youth with T1DM may predispose them to the same complications that are seen in adults with T1DM who develop insulin resistance and metabolic syndrome [9, 19] secondary to excessive weight gain. Efforts should therefore be made to avoid weight re-gain in children whose BMI was above normal prior to T1DM diagnosis. Data comparing BMI of youth after initiation of insulin therapy to levels prior to the onset of T1DM is sparse. While compelling evidence is available for the efficacy of individualized MNT in care of adults with diabetes [14, 20], to the best of our knowledge, the literature is lacking on the effect of enhanced nutritional therapy on the BMI trajectory of overweight youth following T1DM diagnosis.

We hypothesized that enhanced dietary counseling (EDC) may prevent excessive weight gain in youth with new-onset T1DM in the first year after diagnosis. The aim of this prospective randomized interventional study was to evaluate the effect of EDC compared to standard dietary counseling (SDC) on BMI *Z* score and percentage over BMI (%OBMI) from pre-diagnosis to 12 months post-diagnosis. Secondary aims were to assess the effect of EDC compared to SDC on: 1. changes in knowledge of prescribed total daily energy and carbohydrate intakes from 6 weeks to 6 months; 2. changes in daily total energy, carbohydrate, fruit and vegetable servings from 6 weeks to 6 months; and 3. changes in HbA1c and insulin dose at 12 months post-diagnosis from diagnosis.

Materials and methods

Study population

Families of youth between ages 2–19 years with new-onset T1DM per American Diabetes Association criteria and at least one positive T1DM autoantibody marker (islet cell and/or glutamic acid decarboxylase-65 (GAD-65) autoantibodies) were approached at diagnosis between July 2011 and April 2012 at the Women and Children's Hospital of Buffalo (WCHOB) to participate in the trial. At diagnosis, all youth with new-onset diabetes were hospitalized briefly for initiation of insulin therapy, standard of care MNT and diabetes self-management education. We excluded youth with biopsy confirmed celiac disease, or taking chronic steroids therapy or attention deficit-hyperactivity disorder medications.

Methods

This study was approved by the University at Buffalo Children and Youth Institutional Review Board and was in accordance with the Helsinki Declaration of 1975. The subject's parent/guardian provided signed informed consent with assent provided by the subjects 7 years or older.

After receiving SDC at diagnosis, subjects were randomized 6 weeks after diagnosis (using a random number table) to continue SDC or start EDC. SDC subjects received standard MNT from the registered dietician (RD)/Certified Diabetes Educator (CDE) and included a discussion on individualized age- and gender- specific daily carbohydrate intake, daily energy intake, and recommendations on daily fruit and vegetable intake [12]. It is focused on accurate carbohydrate counting and appropriate insulin bolusing dose calculation. EDC received the same education as SDC and frequency of follow-up in person. Additionally, the EDC group was counseled monthly for the first 6 months (by I. Majumdar (IM)) on age-specific recommended daily energy intake, quality of carbohydrates, and fruit and vegetable servings. Families were given the option of face-to-face versus telephone counseling. All families chose telephone counseling. Each telephone counseling session lasted approximately 20 min. A parent/legal guardian recalled the food consumed by the youth over the previous 48 h. Food content was reviewed and compared to the recommended intake. Additionally, a comprehensive 3-day food record, developed in consultation with a RD/CDE, was used to assess the dietary habits of the EDC subjects at 6–8 weeks and 6 months after diagnosis. After the records were completed by parents (with assistance of the youth, when possible), they were reviewed with the parent and patient for accuracy and clarification. Food records were not completed by SDC subjects as youth with diabetes are not routinely advised to keep food records.

All subjects were followed at the outpatient diabetes clinic at 6 weeks, 3, 6, and 12 months where standard diabetes care was provided. The 12-month follow-up was

included to evaluate the residual effect of counseling on BMI trajectory, 6 months after completion of EDC.

To assess knowledge of daily energy intake and daily carbohydrate intake, we developed a questionnaire which was completed by all subjects at 6 weeks, 3- and 6-month clinic visits. The questionnaire, completed by patient when possible or parent/guardian, included a yes/no section inquiring whether they could recall the recommended daily energy and carbohydrate intake. One of the investigators (IM) also asked the reporter to verbalize the recommended daily carbohydrate and energy intake.

Pre-diabetes weights, heights, and BMI were obtained from primary care records within 6 months prior to diagnosis as most subjects were seen at least annually. At diagnosis, 6 weeks, 3, 6, and 12 months post-diagnosis, heights (nearest 0.1 cm) using a calibrated wall-mounted stadiometer, and weights (nearest 0.1 kg) using an electronic scale were measured. BMI was calculated as kg/m^2 and BMI *Z* score was calculated using software based on Center for Disease Control and Prevention (CDC) data [21]. Several measures have been proposed to follow weight changes in pediatric population [22, 23]. We are reporting %OBMI, similar to the TODAY study as well as BMI *Z* score [24]. %OBMI was calculated as BMI minus BMI at the 50th percentile for age and sex, divided by BMI at the 50th percentile × 100 [23–25]. Tanner stage, total insulin dose, and HbA1c were collected at the 6 weeks, 3, 6 and 12 months visits. Tanner stage was determined by the diabetologist who followed the child. HbA1c was measured using Bio-Rad Variant II (Bio-Rad Laboratories, Diagnostic Group, Hercules, CA) at diagnosis and with DCA Vantage® Analyzer (Siemens Corporation, Malvern, PA) at clinic visits. Parents' weight and height were measured and BMI calculated at study entry and at 4–6 months.

Statistical considerations

The sample size calculation was based on the results of an unpublished retrospective study at WCHOB in youth with T1DM, where standard deviation (SD) of BMI *Z* score was determined as 0.89 at diagnosis. We calculated that 40 subjects would give a power of 80 % with an alpha error of 0.05 to detect a difference in BMI *Z* score of 1 between groups. Data are expressed as mean $\pm$ SD for continuous variables and frequency for categorical data, respectively. ANOVA, Fisher's exact test, and Wilcoxon sign rank test were used for comparison. General linear model with repeated measures ANOVA was used for within-subjects and between-subjects BMI *Z* score and %OBMI data comparisons. Analyses were performed using SAS 9.3 (Cary, NC) and SPSS 16.0 (SPSS, Chicago, IL, USA). A p value <0.05 was considered statistically significant. Randomization of subjects and statistical analysis was done with assistance of a biostatistician, Chang-Xing Ma, PhD, Department of Biostatistics, University at Buffalo.

Table 1 Comparison of subjects: Standard Dietary Counseling versus Enhanced Dietary Counseling at diagnosis

	SDC ($n = 25$)	EDC ($n = 22$)	
Age (years)	9.7 ± 4.3	8.1 ± 4	$p = 0.21$
Male: Female	13:12	11:11	$p = 0.56$
Race (NHW: AA: Hispanic: Other)	18:2:1:4	19:3:0:0	
Tanner Stage	1 (1,4)	1 (1,4)	
%OBMI	19.3 ± 27.3	10.1 ± 24.1	$p = 0.23$
BMI *z*	0.8 ± 1.2	0.34 ± 1.2	$p = 0.19$
HbA1c (%)	11.2 ± 2	11 ± 2	$p = 0.8$
Insulin dose (units/kg/day)	0.58 ± 0.2	0.52 ± 0.2	$p = 0.29$

The data are expressed as Mean ± SD or median (25th, 75th percentile)

Conversion: HbA1c (m.mol/mol, IFCC) = 10.93 × HbA1c (%)−23.5

EDC Enhanced Dietary Counseling, *SDC* Standard Dietary Counseling, *AA* African American, *NHW* non-Hispanic whites, *BMI z* BMI *Z* score, *%OBMI* Percent over body mass index, calculated as described in the text

Results

Out of the 63 patients and families approached at diagnosis, only two refused to participate. Ten did not meet inclusion criteria due to negative auto-antibodies ($n = 2$) and biopsy confirmed celiac disease ($n = 8$). Additionally, four subjects who had signed informed consent failed to follow-up per protocol. Forty seven subjects (SDC ($n = 25$) and EDC ($n = 22$), age 8.9 ± 4.2 years, completed 6 months of the study (Table 1). Three SDC subjects were lost to follow-up between 6 and 12 months (Fig. 1, flow diagram). The subjects were mostly non-Hispanic white, with even gender distribution (Table 1). Pre-diagnosis BMI was available from the primary care providers in 43 subjects.

Subjects in the two study groups were comparable (Table 1). Overall, 46.5 % subjects (59.9 % SDC, 36.4 % EDC; $p = 0.11$) were overweight prior to diagnosis. At diagnosis, 37.7 % subjects (40 % SDC, 31.8 % EDC; $p = 0.41$) were overweight with 20.8 % subjects having a BMI $\geq$ 95th percentile (obese). At 6 months, 43 % (52 % SDC, 31.8 % EDC; $p = 0.11$) were overweight, including 30.4 % obese subjects. At 12 months, 40 % (47.8 % SDC, 31.8 % EDC; $p = 0.22$) were overweight, including 28.9 % obese subjects.

The mean %OBMI (BMI *Z* score) of all subjects decreased from 18.1 $\pm$ 24.6 (BMI *Z* score: 0.79 $\pm$ 1.2) pre-diagnosis, to 15 $\pm$ 26 (BMI *Z* score: 0.6 $\pm$ 1.2) at

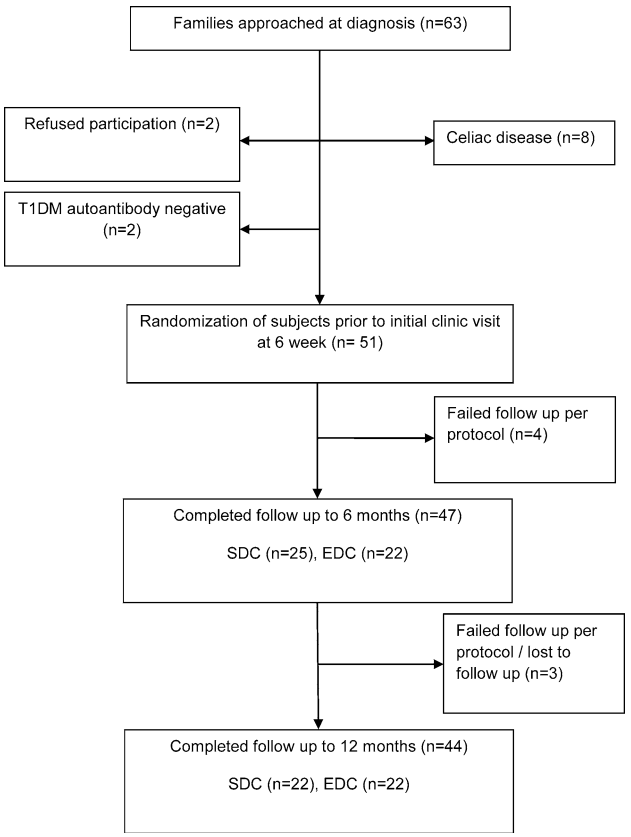

Fig. 1 Flow sheet for the follow-up of subjects enrolled in the trial. *SDC* Standard Dietary Counseling, *EDC* Enhanced Dietary Counseling

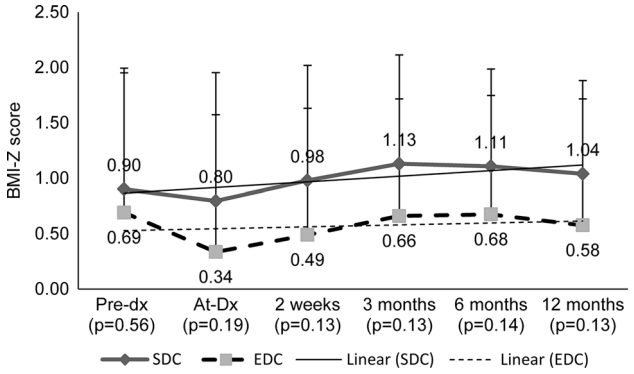

Fig. 2 Comparison of body mass index *Z* score trajectory in Standard Dietary Counseling and Enhanced Dietary Counseling subjects from pre-diagnosis to 12 months after diagnosis. *BMI Z Score* body mass index *Z* score, *SDC* Standard Dietary Counseling, *EDC* Enhanced Dietary Counseling, *dx* diagnosis

diagnosis (pre-diagnosis vs. at diagnosis; $p = 0.017$) and increased to 20.4 $\pm$ 24.4 (BMI *Z* score: 0.91 $\pm$ 1.03) at 3 months (3 months vs. at diagnosis; $p = 0.001$). Subsequently, %OBMI (BMI *Z* score) remained stable (20.6 $\pm$ 23.8 (BMI *Z* score: 0.9 $\pm$ 1)) at 6 months (6 vs. 3 months; $p = 0.21$) and at 12 months (19.4 $\pm$ 22.9 (BMI *Z* score: 0.8 $\pm$ 1)) (12 vs. 6 months; $p = 0.74$). Neither the %OBMI nor the BMI *Z* score was significantly different between SDC and EDC subjects at any time point (Fig. 2, %OBMI data not shown). The same trend persisted after adjustment of differences in pre-diagnosis %OBMI and BMI *Z* score, respectively, between groups. The changes in BMI *Z* score at 12 months from pre-diagnosis (SDC: 0.03 $\pm$ 0.64, EDC: $-$ 0.11 $\pm$ 0.82; $p = 0.53$), at diagnosis (SDC: 0.29 $\pm$ 0.43, EDC: 0.24 $\pm$ 0.66; $p = 0.79$), 3 months (SDC: 0.01 $\pm$ 0.34, EDC: -0.08 $\pm$ 0.40; $p = 0.41$) and 6 months (SDC: -0.04 $\pm$ 0.28, EDC: -0.1 $\pm$ 0.31; $p = 0.48$) after diagnosis did not differ significantly between groups. At 12 months, %OBMI (and BMI *Z* score) exceeded pre-diagnosis level in 58.5 % subjects and no significant differences were noted between groups (SDC: 63.1 %, EDC: 54.5 %; $p = 0.75$).

Parental BMI was available in 23 fathers (30.7 $\pm$ 5.6) and 39 mothers (31.1 $\pm$ 7.8). At least one parent was overweight in 85.1 % of families. In families with at least 1 overweight parent, 94.1 % subjects were overweight.

There were no significant differences in the total daily insulin doses and HbA1c levels between the two groups during the 12 months study period (Figs. 3, 4).

Analysis of questionnaires at 6 weeks and 6 months after diagnosis indicated that the percentage of participants correctly recalling daily energy intake did not change (16, 39 %, $p = 0.18$) among SDC subjects but nearly doubled in EDC subjects from 32 to 62 % ($p = 0.047$). Participants correctly recalling daily carbohydrate intake did not change significantly in either group (SDC: 84 to 72 % and EDC: 91 to 86 %).

EDC subjects completed 3-day food records at 6 weeks ($n = 20$) and at 6 months ($n = 11$) after diagnosis. Analysis of these food records indicated that there were no significant changes in the percentage of subjects exceeding daily energy intake, subjects exceeding daily carbohydrate intake and those meeting recommended daily portions of intake of vegetable, while those meeting recommended daily fruit serving increased (25–64 %, $p = 0.04$) from 6 weeks to 6 months after diagnosis (Fig. 5).

Discussion

This prospective randomized interventional trial demonstrates that a large percentage of youth aged 2–19 years diagnosed at a tertiary center in Western New York are overweight or obese at the time of T1DM diagnosis. Nearly 50 % subjects are overweight at the most recent pediatrician visit prior to onset of T1DM. Despite weight loss due to hypoinsulinemia, the rates of overweight and obesity at diagnosis were comparable to that in the general population

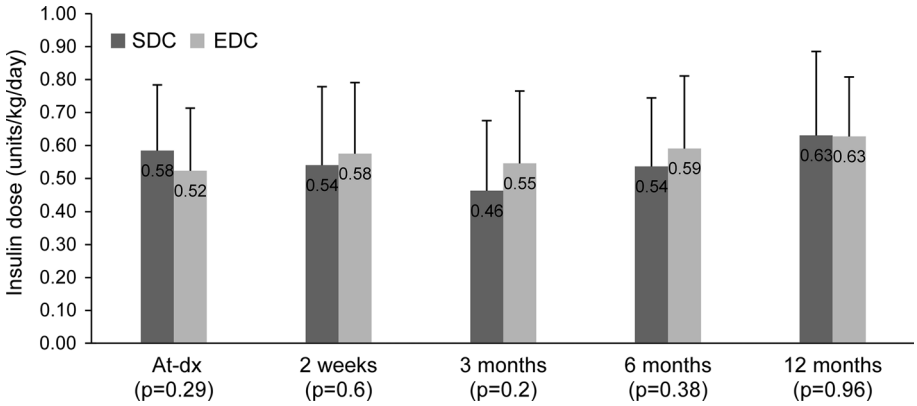

Fig. 3 Comparison of total daily insulin dose (units/kg/day): Standard Dietary Counseling versus Enhanced Dietary Counseling subjects from diagnosis to 12 months after diagnosis. *SDC* Standard Dietary Counseling, *EDC* Enhanced Dietary Counseling

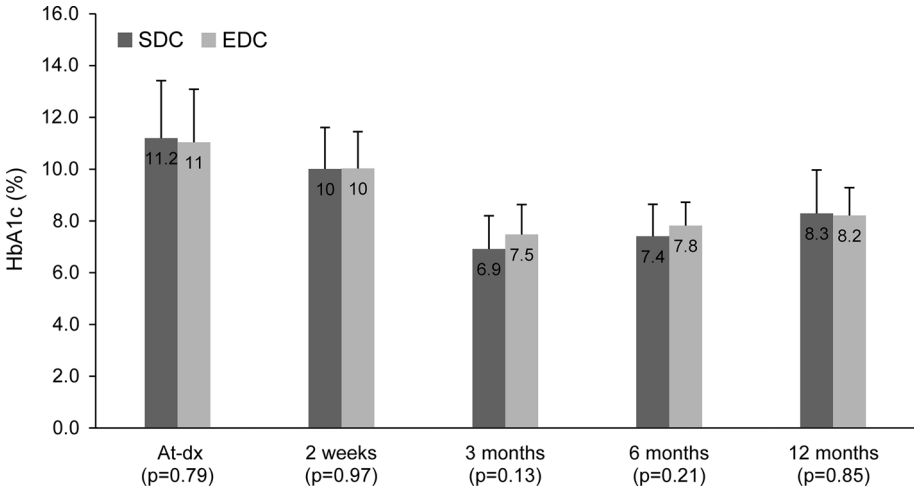

Fig. 4 Comparison of HbA1c (%): Standard Dietary Counseling versus Enhanced Dietary Counseling subjects from diagnosis to 12 months after diagnosis. Conversion: HbA1c (m.mol/mol, IFCC) = 10.93 × HbA1c (%)−23.5. *SDC* Standard Dietary Counseling, *EDC* Enhanced Dietary Counseling

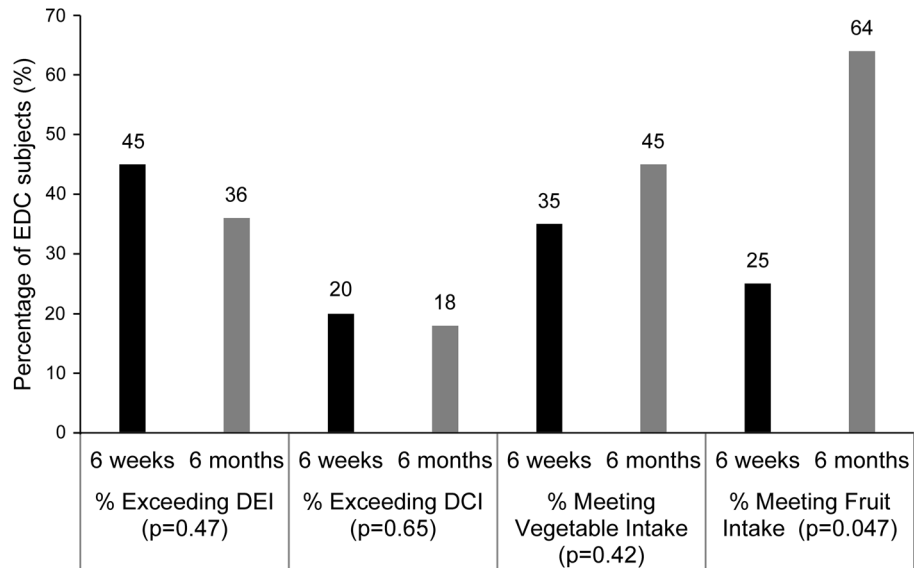

Fig. 5 Analysis of food records in Enhanced Dietary Counseling subjects at 6 weeks ($n = 20$) and 6 months ($n = 11$) after diagnosis, comparing percentage of subjects exceeding recommended daily energy intake, recommended daily carbohydrate intake, and those meeting daily recommended intake of fruit and vegetable portions. *EDC* Enhanced Dietary Counseling, *DEI* daily energy intake, *DCI* daily carbohydrate intake

where 32 and 17 % youth are overweight and obese, respectively [5, 6].

BMI of subjects did not differ between groups at randomization and weight gain continued similarly during the first 3 months after diagnosis in both groups, while %OBMI and BMI *Z* score did not change significantly between 3 and 12 months post-diagnosis.

Analysis of the questionnaires highlighted the poor knowledge of recommended daily energy intake among the youth and families recently diagnosed with T1DM. Overall, only a quarter of families recalled the recommended daily energy intake accurately at their 6 week visit despite recent education. There was a significant improvement in the percentage of EDC subjects correctly recalling daily energy intake by 6 months after diagnosis, unlike in the SDC subjects. In contrast, approximately 80 % families in both groups recalled daily carbohydrate intake at 6 weeks. This is not surprising as carbohydrate counting is a major change for families with individuals with newly diagnosed diabetes. The percentage fell slightly by 6 months in both the groups which may reflect the natural attrition of knowledge.

The 3-day food records in EDC subjects indicated that nearly 45 % subjects exceeded the recommended daily energy intake. Since food records typically under-estimate energy intake, it is possible, that a larger proportion of subjects may be exceeding daily energy intake [26, 27]. Despite enhanced counseling, the percentage of EDC subjects exceeding daily energy intake did not decrease significantly by 6 months. The food records additionally indicated that the subjects pay a closer attention to overall carbohydrate intake with only 20 % of EDC subjects exceeding daily carbohydrate intake. However, the percentage of youth meeting intake of daily recommended fruit and vegetable portions (a surrogate for intake of quality of carbohydrates [28]) was very low. Some improvement was noted by 6 months in the percentage of youth meeting intake of daily fruit portions, but not the intake of daily vegetable portions. Food records were not completed by SDC subjects as per the current MNT and diabetes care practice at our center.

The improvements in percentage of subjects correctly recalling daily energy intake and improvements in intake of quality carbohydrates on food records in EDC subjects did not translate to an improvement in the BMI trajectory of the EDC subjects during the 12-month follow-up period. %OBMI and BMI *Z* score were not significantly different between the EDC and SDC subjects either during the first 6 months after diagnosis with ongoing monthly counseling in EDC subjects or the subsequent 6-month follow-up period. Also, the enhanced education in the EDC group did not result in improved HbA1c despite demonstration of improvements in the percentage of youth meeting intake of daily fruit portions over 6 months. These results are contrary to the data from a cross-sectional study which showed association between higher fruit intake and lower HbA1c [29].

Strengths of the study include: a prospective design with randomization of subjects, enrollment of the majority of eligible subjects, and very small dropout rate with over 85 % subjects completing the study. However, we must acknowledge two limitations. The a priori sample size for the study was powered to detect BMI *Z* score difference of 1 presuming a standard deviation of BMI *Z* score of 0.89, as was seen in a previous study at our center. However, the standard deviation of BMI *Z* score was larger than anticipated in both groups leading to post-hoc power of 0.77 for the study. All subjects consented to participate in the study and were randomized before the first clinic visit, yet they failed to keep the scheduled appointment or changed their mind about participation. Additionally, children were diagnosed with celiac disease post-diagnosis. This may have led to unequal distribution of subjects. However, the changes in BMI *Z* score and %OBMI appeared very similar in subjects receiving either SDC or EDC, despite correction of the baseline differences. It is very unlikely that additional subjects would have resulted in statistical differences between the groups.

Time is often cited as a main barrier to participating in research studies and attending a weight control program [30]. It is for this reason that, while all families had the option of face-to-face counseling, they all opted for phone counseling. This approach was used successfully in other studies by our group [31, 32], but it is possible that in person sessions may have been more effective. Assessment of dietary intake is a very difficult task [25]. While the majority of subjects completed the food records at 6 weeks, less than 50 % of EDC subjects completed food records at 6 months, despite establishment of a close working relationship with the primary investigator. We have to consider that subjects completing food records at 6 months may be more motivated than those who did not, which may partially bias the results. We created a simple questionnaire to assess daily energy intake and daily carbohydrate intake recall which was user friendly and was very well received by the study participants. However, we acknowledge that it is not a validated instrument and further studies are required to validate this tool.

The present study supplements currently published data which have shown a concerning trend in the BMI trajectories after initiation of insulin therapy in youth with T1DM [4, 7]. In addition, this study compares %OBMI/BMI *Z* score after initiation of insulin therapy to pre-diagnosis %OBMI/BMI *Z* score and demonstrates that more than half of the subjects' %OBMI exceeded the pre-diabetes levels at 12 months after diagnosis. In a recent

longitudinal study in youth with T1DM, similar trend of rising BMI was noted and BMI *Z* score 6 years after diagnosis was significantly higher than the pre-illness BMI *Z* score [33]. The study underscores the importance of family history since weight available in a subset of parents indicates that more than 90 % of the youth with T1DM were overweight or obese at diagnosis if they had one or more overweight parents.

The results of our study indicate that enhanced phone counseling alone was not effective in preventing excessive weight re-gain in overweight youth with T1DM after the initiation of insulin therapy. Further, step would be to ascertain if in-person counseling maybe more effective if patients and parents could overcome the time barrier. Moreover, given the high prevalence of overweight among parents and the proven effectiveness of family-based interventions in youth without diabetes, this modality of therapy should be explored in this subset of pediatric population [34–36].

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Conflict of interest The authors declare that they have no conflict of interest.

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