

REVIEW

Design of a family-based lifestyle intervention for youth with type 2 diabetes: the TODAY study

The TODAY Study Group

Type 2 diabetes is associated with obesity and is increasing at an alarming rate in youth. Although weight loss through lifestyle change is one of the primary treatment recommendations for adults with type 2 diabetes, the efficacy of this approach has not been tested with youth. This paper provides a summary of the reviews and meta-analyses of pediatric weight-loss interventions that informed the design and implementation of an intensive, family-based lifestyle weight management program for adolescents with type 2 diabetes and their families developed for the Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) study. A total of 1092 youth have been screened, and 704 families have been randomized for inclusion in this 15-center clinical trial sponsored by the National Institutes of Health. The TODAY study is designed to test three approaches (metformin, metformin plus rosiglitazone and metformin plus an intensive lifestyle intervention) to the treatment of a diverse cohort of youth, 10–17 years of age, within 2 years of their diagnosis. The principal goal of the TODAY Lifestyle Program (TLP) is to decrease baseline weight of youth by 7–10% (or the equivalent for children who are growing in height) through changes in eating and physical activity habits, and to sustain these changes through ongoing treatment contact. The TLP is implemented by interventionists called Personal Activity and Nutrition Leaders (PALs) and delivered to youth with type 2 diabetes, and at least one family support person. The TLP provides a model for taking a comprehensive, continuous care approach to the treatment of severe overweight in youth with comorbid medical conditions such as type 2 diabetes.

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Introduction

Type 2 diabetes, once considered an illness of older adults, is affecting more children and adolescents as population rates of obesity increase.¹ Estimates suggest that type 2 diabetes represents 20–25% of new-onset cases in children and that certain ethnic or racial groups are disproportionately affected.^{1,2} Type 2 diabetes shortens life expectancy and is associated with serious medical complications.³ Therefore, effective treatments are urgently needed for youth who face the possibility of experiencing these complications at an earlier age than their adult counterparts.^{4,5}

Weight management is recommended for the treatment of type 2 diabetes.⁶ Lifestyle weight management programs have been used successfully to prevent type 2 diabetes in

adults at risk,⁷ and are currently being evaluated in the treatment of overweight adults diagnosed with type 2 diabetes.⁸ However, the efficacy of lifestyle interventions to promote weight loss and improve metabolic control in children with type 2 diabetes is yet unknown.⁴

Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) is a 15-center clinical trial sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (start date, 2003; projected end date, 2012). The TODAY study examines the comparative efficacy of three approaches to the treatment of type 2 diabetes in youth ages 10–17 years. To date, 1092 youth (64% female) have been screened,⁹ and 704 of these youth have been randomized to one of the three treatment arms; metformin alone, metformin plus rosiglitazone or metformin plus an intensive lifestyle intervention called the TODAY Lifestyle Program (TLP). Although the overall design of the TODAY trial has been described elsewhere,¹⁰ the present paper details the development of the TLP, a family-based behavioral weight-loss program. To our knowledge, the TLP is the first program of its kind designed to take a comprehensive, continuous

Correspondence: Dr DE Wilfley, WUSM, Campus Box 8134, 660 S. Euclid, St. Louis, MO 63110, USA.

E-mail: wilfleyd@psychiatry.wustl.edu

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care approach to lifestyle modification with severely overweight youth with medical comorbidities (that is, the median BMI for the screening sample was 34.9 kg m^{-2} , and the median BMI percentile was 98.9, with duration from diagnosis of type 2 diabetes less than 2 years).⁹

Lifestyle modification and weight loss in the treatment of pediatric type 2 diabetes

Although family-based behavioral weight-loss treatments have shown efficacy in improving weight status in children in the short and long term,¹¹ the impact of family-based lifestyle interventions on weight and metabolic parameters in youth with type 2 diabetes has not been evaluated. However, family-based interventions targeting glycemic control have been successfully used with youth having type 1 diabetes.¹² Furthermore, lifestyle interventions have shown promise in facilitating positive changes in weight status and other indices of health in youth at risk for metabolic syndrome,^{13,14} and with other comorbidities.¹⁵ An extensive review of the literature on pediatric weight-loss programs resulted in the identification of a number of comprehensive reviews and meta-analyses of pediatric weight-loss interventions (see Table 1 for a summary of recent reviews and meta-analyses of pediatric weight-loss programs). The results of each of these reviews supported the application of multi-component lifestyle interventions to the problem of pediatric weight control, with family involvement identified as being particularly useful in the treatment of grade-school-age children.^{16–21} Drawing on this body of research, and the clinical experience of the TODAY investigators, we designed a lifestyle intervention adapted to the needs of youth with type 2 diabetes²² that is consistent

with expert consensus regarding best practices in the treatment of chronically ill children and children who are overweight.^{23–25}

Overview of the TLP

The TLP is designed to work with pharmacotherapy to improve diabetes control in youth of 10–17 years through sustained, moderate weight loss (7–10% of initial body weight or the equivalent for youth still growing in height). This weight-loss goal represents changes in weight status similar to those that have been found to be associated with significant physical health outcomes in previous studies.^{26,27} The TLP's family-based, behavioral approach to weight loss is grounded in social-learning theory and is modeled after the work of Epstein *et al.*¹¹ The TLP also uses features of weight-loss maintenance treatments developed and tested by Wilfley *et al.*²⁸ Lifestyle change programs such as the TLP are based on the assumption that knowledge alone is not sufficient to change behavior, and that individuals and families need intensive, ongoing support and training in the behavioral skills necessary to lose weight and to maintain weight loss.²⁶

Within the TLP, the primary behavior-change targets include energy balance behaviors (dietary and physical activity) and family involvement/support. There is substantial evidence for inclusion of these components in weight control programs for youth, and recent meta-analyses of pediatric weight-loss treatment trials document that behavioral programs that include parents have greater effect sizes than programs that do not involve families.^{17,21} The TLP promotes small, successive changes in participants' dietary and physical activity behaviors through the use of evidence-

Table 1 Recent reviews and meta-analyses of pediatric weight loss studies

Author	Type of review and number of studies	Target population	Conclusions
American Dietetic Association ¹⁶	Review of 29 RCTs and 15 other types of studies	Overweight children (ages 2 through 12 years) and adolescents (ages 13 through 18 years)	Positive effects for multi-component, family-based programs especially for children ages 5 through 12 years
McGovern <i>et al.</i> ¹⁷	Meta-analysis of 61 randomized trials	Overweight children and adolescents (ages 2–18 years)	Small-to-moderate treatment effects of combined lifestyle interventions on BMI
Snethen <i>et al.</i> ¹⁸	Meta-analysis of seven interventions	Overweight children (ages 6–16 years with an overall mean age not more than 12 years)	Multi-component lifestyle interventions that include parental involvement can be effective in assisting children to lose weight
Tsiros <i>et al.</i> ¹⁹	Review of 34 RCTs	Overweight or obese adolescents (ages 12–19 years)	Lifestyle interventions with behavior/cognitive-behavioral components are promising particularly for long-term maintenance
Wilfley <i>et al.</i> ²⁰	Meta-analysis of 14 RCTs	Overweight youth (ages 19 years or younger)	Lifestyle interventions produce significant changes in weight status in the short-term, with encouraging results for the persistence of effects
Young <i>et al.</i> ²¹	Meta-analysis of 16 studies	Overweight children (ages 5–12 years)	Family-based, behavioral weight loss programs produce large and reliable effects that are maintained across several months of follow-up

Abbreviations: BMI, body mass index; RCT, randomized controlled trial.

based behavior-change strategies such as self-monitoring (recording target behaviors on forms called 'Lifestyle Logs' and graphing weight changes),^{29,30} goal setting,^{31,32} reinforcement for goal achievement,^{33,34} stimulus control,³⁵ social support,²⁸ problem solving³⁶ and motivational techniques.³⁷

Specially trained interventionists called Personal Activity and Nutrition Leaders (PALs) provide the TLP. The TLP takes a calorie-deficit approach to decreasing energy intake by limiting the intake of high fat, high sugar foods. This is the approach that has been most often used in pediatric weight-loss programs.^{11,38} However, interventions targeting increased intake of vegetables, 'good' fats and high-fiber foods,³⁸⁻⁴¹ as well as interventions designed to improve portion control have also been associated with weight loss and/or improvements in other indices of health.⁴² Therefore, some aspects of these other dietary approaches have been incorporated into the TLP, as discussed below. The TLP addresses energy expenditure by setting goals to increase physical activity⁴³ and decrease time spent in sedentary pursuits,^{35,44} as described below. The TLP was also designed to be delivered to families over an extended period of time because interventions that provide weight-loss maintenance treatment after the initial weight-loss phase have been found to result in improved weight-loss outcomes over the long term.^{28,42} Figure 1 provides an illustration of the weight loss and weight maintenance phases of the TLP and their components.

Diet modification

The TLP uses a calorie-deficit diet, modified for use with youth having type 2 diabetes, called the Traffic Light Plan, which is an adaptation of the Traffic Light Diet.⁴⁵ In the Traffic Light Diet, foods are assigned colors of the traffic light depending on their nutritional quality. For example, foods containing 5 g or more of fat, sugary cereals, energy-dense, non-nutritious snacks and soft drinks are classified as RED (stop and think) foods.³⁵ The Traffic Light Plan for the TLP was designed in close collaboration with TODAY study dietitians and diabetes educators to help families make healthier food choices and decrease calorie consumption to within 1200-1500 calories, adjusted upward depending on baseline weight. Participants are encouraged to decrease the number of RED foods consumed daily and to increase the consumption of nutritious foods identified by the traffic light colors GREEN (go; highly nutritious, low calorie-dense foods) or YELLOW (good for you, but watch portion sizes; nutritious higher calorie foods or 'starchy' foods). A dietary resource called the Food Reference Guide is provided to TLP participants to assist families in modifying their dietary habits. The Food Reference Guide lists over 500 foods (with room for participants to add food items specific to their family) and classifies them according to the Diabetes Food Pyramid assigning each food a traffic light color. In addition to traffic light color and food group assignment, serving size and calories are listed for each food with a special notation for high-fiber foods.²²

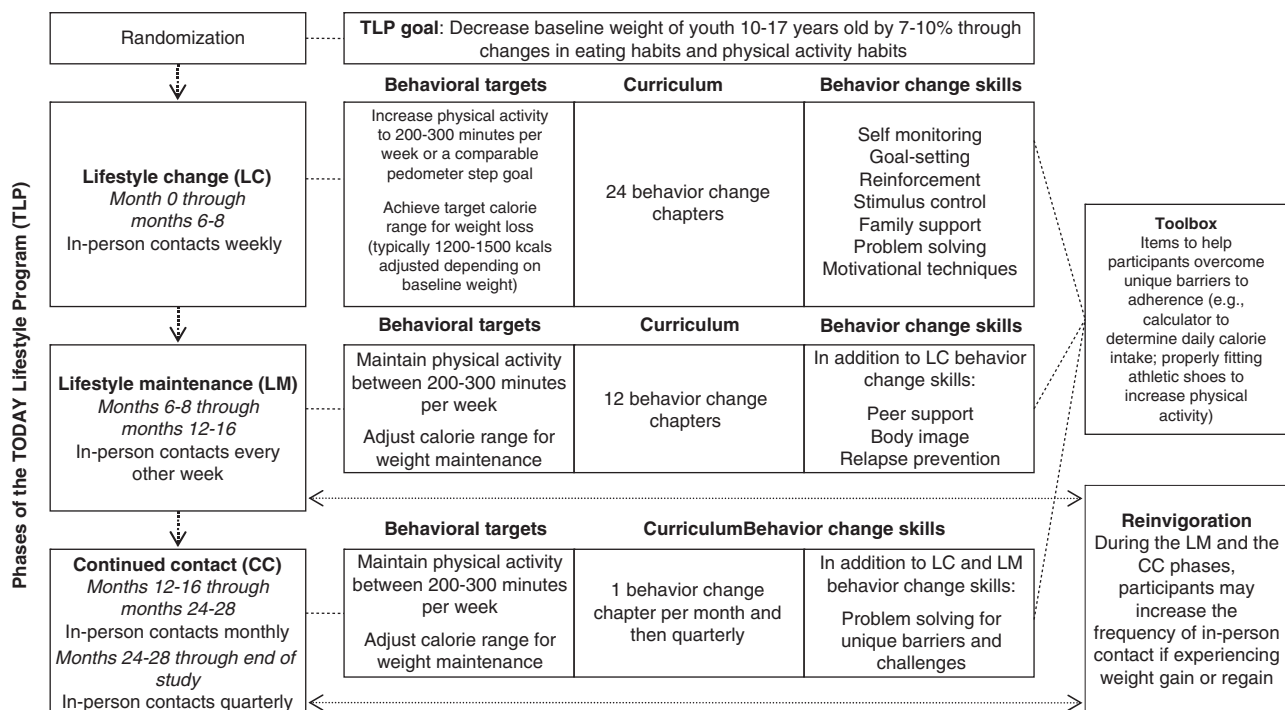


Figure 1 TODAY Lifestyle Program (TLP) intervention design.

Behavioral interventions such as the TLP that use a 'free-choice' approach to changing eating habits that build on existing preferences are particularly well-suited for application to individuals from a variety of cultural and ethnic backgrounds.⁴⁶ For example, rather than 'prescribing' particular foods, PALs listen to and learn from participants to determine preferences, traditions and beliefs that impact eating habits. Using this information, PALs are able to assist participants in making gradual adjustments to existing patterns of behavior to promote healthy lifestyle behaviors (for example, PALs can recommend cooking methods conducive to lowering the caloric values of traditional foods such as oven-baked, rather than fried, chicken).^{46,47}

Physical activity modification

The physical activity target for the TLP is 200 min per week of moderate-vigorous intensity activity for most participants and up to 300 min per week for those participants who enter the study already engaging in some regular, physical activity. These goals are consistent with physical activity targets for overweight youth but slightly lower than the goals set for children and adolescents on average.⁴⁸ Participants are encouraged to engage in more lifestyle activities such as walking pets, biking to school and using stairs instead of elevators, as well as to increase involvement in planned, moderate- to higher-intensity activities. Pedometers and the Activity Reference Guide are tools used to encourage spending less time in sedentary pursuits and to increase awareness of the levels of exertion of a variety of physical activities. In the Activity Reference Guide, activities are categorized using a traffic light color scheme similar to the one used to classify foods in the Traffic Light Plan. Moderate intensity activities such as brisk walking are categorized as GREEN activities ('go'); with higher-intensity activities such as jumping rope given the designation of 'fitness boosters'. Lifestyle activities such as light housekeeping or household chores are categorized as YELLOW ('keep moving'), and sedentary activities such as watching TV are RED ('use sparingly').²² Beyond the general focus on aerobic activity, strength training through the use of resistance bands is also introduced. Resistance bands are safe and acceptable to extremely overweight youth when more aerobic forms of exercise are perceived as too challenging. Also, there may be some benefits to glucose homeostasis related to the use of resistance strength training in overweight youth.³⁸

Family support

Research indicates that parental involvement in pediatric weight-loss treatment is related to better treatment outcomes,^{17,49} and the inclusion of family members in a weight-loss treatment for adolescents is supported by current developmental theory that acknowledges adolescents' desire

for adult involvement and closeness in their lives.⁵⁰ Furthermore, the influence of parents, adult authority figures and family functioning on adolescent health behavior choices has been well documented,^{51–55} and family support has been shown to enhance adherence and management of type 1 diabetes in youth.⁵⁶ The focus of TLP on the supportive role of family is also very appealing to family-centered ethnic groups.

In the TLP, a family support person (FSP), who may or may not be the child's parent, is expected to accompany the youth to TLP visits. At each visit, the FSP and the youth are given some time to work alone with their PAL. The amount of time devoted to working alone with the FSP and the youth at each visit may vary depending on family preference and developmental stage of the youth. PALs also may schedule events or activities with more than one family, such as cooking demonstrations or group walking activities to incorporate some of the social support advantages of group-based, weight-loss interventions.^{57,58}

The TLP families are taught to use praise and to develop a family-based reward system to shape and reinforce changes in dietary and physical activity behaviors.³⁵ During the first five TLP sessions, PALs model the use of contingent reinforcement by providing small 'prizes' (for example, stickers, pencils) to the youth for goal achievement (for example, for bringing all of his or her TLP materials to a session, for improvements in self-monitoring). Later in the program, the PAL, youth and FSP jointly develop a list of acceptable reward items and privileges.⁵⁹ Then participants are awarded points for meeting TLP program goals that can be exchanged for family-provided rewards from the list. In addition to supporting the youth's lifestyle behavior changes through positive reinforcement, the FSP is also encouraged to engineer a home environment that is conducive to healthy lifestyle behaviors and to involve all members of the household in support of the youth's behavior-change efforts. As there is often a history of diabetes in first-degree relatives of youth with type 2, this format allows for family members other than the participating youth to benefit from a home environment that promotes healthy lifestyle behaviors. Although overweight FSPs are encouraged to make personal efforts to lose weight (for example, self-monitoring their own weight, food choices, and physical activity habits and setting individual weight loss and behavioral change goals to improve their weight status after approval by their personal healthcare providers), they are not required to do so.

Treatment duration and dose

Although the typical pediatric weight-loss treatment is delivered in 18 sessions,²⁰ there is evidence from the adult weight control literature^{58,60} and preliminary evidence from pediatric weight control studies²⁰ that weight-loss outcomes improve with extended treatment contact. As a result, the TLP intervention takes a chronic care approach to weight

control,⁶¹ treating participants for a minimum of 2 years. This type of treatment schedule provides the frequency of contact (treatment dose) and length of treatment (duration) appropriate to the TODAY study's severely overweight, chronically ill adolescents.²⁵

The TLP is composed of three treatment phases that vary in terms of intensity of treatment contact and in terms of the types of educational materials used to support behavior-change targets. The first phase of the TLP is the Lifestyle Change phase (LC), which begins at randomization and lasts for 6–8 months. During the LC phase, participants attend weekly in-person TLP sessions. These visits last 60–90 min and include time for education regarding healthy eating, physical activity and family support, as well as the teaching and practice of behavior and cognitive-behavioral change techniques to facilitate weight loss. The Lifestyle Maintenance Phase (LM) follows LC and lasts another 6–8 months. The LM phase of the TLP is characterized by a decrease in the frequency of in-person contacts to bi-weekly, lasting about 60 min each. During the LM phase, education and behavior-change targets center on the introduction of weight maintenance skills such as self-monitoring of weight, relapse prevention and the enlistment of peer support in weight control efforts. The Continued Contact Phase (CC) begins at the end of the LM phase and lasts until the end of the TODAY trial. During the CC phase, in-person contacts, lasting 45–60 min each, occur monthly for the first 12 months and quarterly thereafter. During the CC phase, participants are encouraged to take an increasingly active role in identifying barriers to weight control and applying problem-solving skills within and between TLP visits to improve healthy lifestyle behaviors.

Educational materials

Educational materials were developed for the TODAY study to support the TLP treatment goals.²² Lesson titles for materials used during each phase of the TLP are provided in the Supplementary information that accompanies this paper (<http://www.nature.com/ijo>). New behavior-change lessons are provided to TLP participants each week during the LC phase, for a total of 24 lessons; twice per month in the LM phase (12 lessons); and once a month for 12 months followed by once every 3 months in the CC phase. The TLP materials are presented to families in a standard order in the LC and LM phases. However, in the CC phase, families choose TLP materials from a 'library' of topics depending on each family's needs. The TLP educational and self-monitoring materials are available in both English and Spanish, and the graphics used in the materials depict individuals of diverse backgrounds and body shapes.

To accommodate the developmental and cognitive differences between the youth and the FSP, there are two similar, yet slightly different, versions of TLP educational materials allowing FSPs to receive information specifically for adults (for example, positive parenting techniques, the importance

of being a role model for healthy lifestyle behaviors). The TLP materials also incorporate interactive exercises and quizzes to engage participants in the learning process and to assess mastery of the information. For lower literacy or time-pressed families, summaries of the materials in the form of 'Magnetic Memos' and 'Tip Sheets' are provided, and audio recordings of the Lifestyle Change chapters are available in English and Spanish.

Adjustments in treatment dose and addressing barriers to behavior change

Given naturally occurring disruptions such as vacation or illness, families are allowed up to 8 months in each of the first two phases of the TLP (Lifestyle Change and Lifestyle Maintenance) to receive the intended educational materials before moving on to the next phase. Transition between phases is determined by time from randomization, not mastery of material or attainment of behavioral goals. However, behavior-change information and the opportunity to practice the skills needed to acquire healthy lifestyle goals are introduced in novel ways during each phase of the TLP. Thus, participants who did not master a concept or acquire a dietary or physical activity goal during an earlier phase have opportunities to learn the necessary skills in later phases of the intervention. For participants who experience weight gain, or for those participants who are still overweight and request additional support to focus on further weight loss in the later phases of the TLP, the frequency of in-person visits can be temporarily increased for 4–8 weeks. This increase in the frequency of treatment contacts, 'reinvigoration,' can occur once in the LM phase and annually in the CC phase.

In addition to adjusting treatment dose as a means of overcoming barriers to the achievement of behavior-change goals, PALs may also use the TLP 'toolbox'. The term 'toolbox' was coined in the DPP (Diabetes Prevention Project) to describe strategies, equipment, services or goods needed for overcoming barriers to meeting treatment goals.⁶² In the Look AHEAD (Action for Health in Diabetes) trial, the toolbox was more narrowly defined as a set of weight-loss strategies for participants who did not achieve weight loss/weight maintenance targets.⁸ After taking a rigorous problem-solving approach to issues of treatment adherence, PALs are able to use 'toolbox' funds (a modest \$150.00 annually per TODAY family) to purchase goods, services or equipment that would allow participants with financial limitations to overcome adherence barriers. For example, a PAL and a TLP family may determine that a calculator is needed to help the youth and FSP add up daily calorie intake to promote accurate and effective self-monitoring. The PAL could then suggest the use of toolbox funds to purchase a calculator for the youth and FSP. Case examples are provided in Table 2, illustrating how the TLP, a standardized, behavior-change intervention, can be tailored to meet the needs of a diverse patient population.

Table 2 Clinical examples of TLP implementation

Example participant	Implementation of the TLP across phases		
	Phase 1: Lifestyle change	Phase 2: Lifestyle maintenance	Phase 3: Continued contact
Case 1	<p>Location of sessions: TLP sessions held in participant's community library.</p> <p>Behavior change skills and family/peer support: PAL used a 'grab bag'—a collection of small, tangible rewards such as stickers, nail polish and so on—to shape the youth's adherence to desired goals (for example, complete logging, coming to session prepared) and to model the use of contingent, positive reinforcement.</p> <p>Modeling of the use of positive reinforcement as a behavior change technique for this single mother resulted in her successful work with the PAL to develop a family-based reward system consistent with this family living on public assistance.</p> <p>Improved logging allowed for the identification of portion control as an area for intervention.</p> <p>Addressing barriers: The TLP 'toolbox' was used to purchase measuring cups/spoons and a steamer to assist family in meeting healthy eating goals (for example, better portion control and low-fat cooking methods).</p>	<p>Location of sessions: TLP sessions continue to be held in the community library.</p> <p>Behavior change skills and family/peer support: Family continued to effectively use the TLP reward system.</p> <p>FSP continued her support of healthy eating goals by serving appropriate portion sizes to youth and youth begins tracking her weight weekly on her abbreviated, maintenance lifestyle log.</p> <p>Addressing barriers: When youth did not make the middle school basketball team, PAL worked with the family to identify a recreational basketball league in the community in which the youth participated.</p>	<p>Location of sessions: TLP sessions moved from the community back to the clinic. Travel to the sessions was less of a burden for the family due to the decreased frequency of the in-person sessions in this phase of the TLP.</p> <p>Behavior change skills and family/peer support: Family no longer used formal reward system.</p> <p>In response to weight regain, the PAL recommended that the youth resumes the use of more complete self-monitoring forms and large portion sizes were again identified as the source of additional caloric intake contributing to weight gain.</p> <p>Behavior change goals for reducing portion sizes were reintroduced and more detailed logging was used until weight returned to the weight maintenance range.</p> <p>Addressing barriers: The TLP 'toolbox' was used to assist the family in the purchase of a uniform the youth needed to participate on the school's cheerleading squad.</p>
Case 2	<p>Location of sessions: TLP sessions occurred in the clinic.</p> <p>Behavior change skills and family/peer support: Self-monitoring identified school lunches and after-school snacks as an area for improvement; as a result, the youth began packing his lunch and taking it to school. The mother and the youth shopped together for healthy after-school snacks.</p> <p>Addressing barriers: To increase physical activity, the family turned the garage into a 'mini' gym using equipment purchased at yard sales.</p>	<p>Location of sessions: TLP sessions continued to take place in the clinic until mother's illness resulted in PAL's offer to meet the family in their home to reduce the burden of time spent traveling to the clinic.</p> <p>Behavior change skills and family/peer support: Youth successfully used abbreviated self-monitoring forms to track weight and maintenance of eating and physical activity goals.</p> <p>Addressing barriers: Mother, who had been the FSP, was diagnosed with cancer and father became the identified FSP. Location of TLP sessions moved to the home during the mother's treatments to decrease stress on the family related to travel back and forth to TLP sessions.</p>	<p>Location of sessions: TLP sessions returned to the clinic after the acute phase of the mother's illness.</p> <p>Behavior change skills and family/peer support: Youth began a strength-training program with the support of his brother-in-law and made increased use of the 'mini-gym' in his garage.</p> <p>As a result of learning more about the TLP goals and the benefits of adopting healthy eating and physical activity behaviors during his time as FSP, the father began taking healthy lunches to work just like his son did for school.</p> <p>Addressing barriers: Youth expressed feelings of anxiety and sadness related to his mother's illness, which resulted in episodes of emotional eating.</p> <p>With the assistance of the supervising psychologist, the PAL provided the family with recommendations for counseling services in the community.</p> <p>The PAL used TLP educational materials on emotional eating to help the youth set behavior change goals to regulate meals and to problem-solve ways to combat emotional stress other than through eating (for example, being physically active, talking to friends, family or his counselor).</p>

Abbreviations: FSP, family support person; PAL, personal activity and nutrition leader; TLP, TODAY lifestyle program.

Implications and future directions

The TLP represents a landmark opportunity to study the effectiveness of a long-term weight management program with a diverse, chronically ill population of adolescents and their families. For example, the median age of the youth screened for inclusion in the study was 14.0 years with 35% of this sample Hispanic, 37% non-Hispanic Black and 19% non-Hispanic White.⁹ In contrast, the majority of participants described in a recent meta-analytic review of multi-component lifestyle interventions for the treatment of pediatric overweight were identified as Caucasian,²⁰ and few studies of family-based weight-loss treatments have included children over the age of 12 years.

The extended care provided during the TODAY trial and the ability to deliver the program in the community removes many of the barriers that limit the participation of diverse or economically challenged families in weight control programs. Also, to offset the potential costs of travel to deliver the intervention off-site,^{63,64} distance telemedicine technologies can be used in the TLP.⁶⁵ For example, at the time of this writing, the clinical site at Oklahoma had provided nine TLP visits to four families (two Native American, one African American and one Asian American) using web cams (Logitech QuickCam Communicates and Orbit AF, Logitech, Fremont, CA, USA), videophones (Starview 500 TravelStar Pro XL, Starview VideoCom Corporation, Tucson, AZ, USA) or video conferencing systems (various Polycom systems, Polycom Corporation, Pleasanton, CA, USA). Providing TLP treatment through the use of distance medicine technology to these families has resulted in a total savings of 2364 miles (Personal Communication, Jeff Preske MA).

Although the TLP employs several adaptations that may result in enhanced recruitment and retention for the research trial, some adaptations may dilute the effectiveness of the weight-loss intervention, as it relates to diabetes symptom management. For example, the decision was made to separate the TLP from standard diabetes education and medical management received by the participants to maintain differences between the treatment arms. In clinical practice, integrating family-based weight-loss programs into existing diabetes care could be more beneficial to patients.⁶⁶ Further, given the diverse family constellations of TODAY participants, an effort was made to enhance the feasibility and acceptability of the TLP by not requiring (although supporting if requested) the identified FSP to engage in his or her own weight-loss efforts, despite extant research evidence indicating that parental weight loss is related to successful weight loss in children.⁴⁹ Finally, although interventionists with educational backgrounds and training similar to those of the TLP's PALs have successfully been employed in the delivery of lifestyle interventions in the past,⁶² it is possible that employing PALs without earlier experience conducting behavioral interventions may dilute TLP treatment effects.

Although the relative efficacy of adding lifestyle interventions for weight loss to the pharmacological treatment of

pediatric type 2 diabetes is yet to be determined, the extant literature suggests that such approaches are helpful for the prevention and treatment of type 2 diabetes in adults, and therefore supports investigation with youth. Developing effective treatments for youth with type 2 diabetes is especially important given the potential these children have for experiencing the medical complications of this disease at earlier ages and for longer periods of time than their adult counterparts. In this report, we describe a family-based, pediatric weight-loss approach to the management of type 2 diabetes that provides a model for taking a comprehensive, continuous care approach to the treatment of severely overweight youth who have comorbid medical concerns. Should the TLP be shown to be efficacious, an examination of the process by which this program can be disseminated to other health care or community settings would be warranted.

Conflict of interest

The authors declare no conflict of interest.

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Appendix

TODAY study group: The following individuals and institutions constitute the TODAY Study Group (* indicates principal investigator or director):

Clinical centers **Baylor College of Medicine:** M Haymond*, B Anderson, S Gunn, H Holden, M Jones, K Hwu, S McGirk, S McKay, B Schreiner **Case Western Reserve University:** L Cuttler*, E Abrams, T Casey, W Dahms, D Drotar, S Huestis, C Levers-Landis, P McGuigan, S Sundararajan **Childrens Hospital Los Angeles:** M Geffner*, N Chang, D Dreimane, M Halvorson, S Hernandez, F Kaufman (Study Chair), V Mansilla, R Ortiz, A Ward, K Wexler, P Yasuda **Children's Hospital of Philadelphia:** L Levitt Katz*, R Berkowitz, S Boyd, C Carchidi, J Kaplan, C Keating, S Kneeshaw-Price, C Lassiter, T Lipman, S Magge, G McGinley, B Schwartzman, S Willi **Children's Hospital of Pittsburgh:** S Arslanian*, F Bacha, S Foster, B Galvin, T Hannon, A Kriska, I Libman, M Marcus, K Porter, T Songer, E Venditti **Columbia University Medical Center:** R Goland*, R Cain, I Fennoy, D Gallagher, P Kringas, N Leibel, R Motaghedi, D Ng, M Ovalles, M Pellizzari, R Rapaport, K Robbins, D Seidman, L Siegel-Czakowski, P Speiser **Joslin Diabetes Center:** L Laffel*, A Goebel-Fabbri, L Higgins,

M Malloy, K Milaszewski, L Orkin, A Rodriguez-Ventura **Massachusetts General Hospital:** D Nathan*, L Bissett, K Blumenthal, L Delahanty, V Goldman, A Goseco, M Larkin, L Levitsky, R McEachern, K Milaszewski, D Norman, B Nwosu, S Park-Bennett, D Richards, N Sherry, B Steiner **Saint Louis University:** S Tollefsen*, S Carnes, D Dempsher, D Flomo, V Kociela, T Whelan, B Wolff **State University of New York Upstate Medical University:** R Weinstock*, D Bowerman, K Duncan, R Franklin, J Hartsig, R Izquierdo, J Kanaley, J Kearns, S Meyer, R Saletsky, P Trief **University of Colorado Health Sciences Center:** P Zeitler* (Steering Committee Chair), A Bradhurst, N Celona-Jacobs, J Glazner, J Higgins, F Hoe, G Klingensmith, K Nadeau, H Strike, N Walders, T Witten **University of Oklahoma Health Sciences Center:** K Copeland* (Steering Committee Vice-Chair), R Brown, J Chadwick, L Chalmers, C Macha, A Nordyke, T Poulsen, L Pratt, J Preske, J Schanuel, J Smith, S Sternlof, R Swisher **University of Texas Health Science Center at San Antonio:** D Hale*, N Amodei, R Barajas, C Cody, S Haffner, J Hernandez, J Lynch, E Morales, S Rivera, G Rupert, A Wauters **Washington University School of Medicine:** N White*, A Arbeláez, J Jones, T Jones, M Sadler,

M Tanner, R Welch **Yale University**: S Caprio*, M Grey, C Guandalini, S Laviates, P Rose, A Syme, W Tamborlane

Coordinating center George Washington University Biostatistics Center: K Hirst*, L Coombs, S Edelstein, N Grover, C Long, L Pyle

Project office National Institute of Diabetes and Digestive and Kidney Diseases: B Linder*

Central units Central Blood Laboratory (Northwest Lipid Research Laboratories, University of Washington): S Marcovina*, J Chmielewski, M Ramirez, G Styliwicz DEXA

Reading Center (University of California at San Francisco): J Shepherd*, B Fan, L Marquez, M Sherman, J Wang **Diet Assessment Center (University of South Carolina)**: E Mayer-Davis*, Y Liu, M Nichols **Lifestyle Program Core (Washington University)**: D Wilfley*, D Aldrich-Rasche, K Franklin, C Massmann, D O'Brien, J Patterson, T Tibbs, D Van Buren

Others: Centers for Disease Control: P Zhang, **Hospital for Sick Children, Toronto**: M Palmert, **State University of New York at Buffalo**: L Epstein, **University of Florida**: J Silverstein