

## Development of the Diabetes Education, Counseling, Information Delivery and Evaluation (DECIDE) Program: A Health Promotion Intervention For Preadolescents with Type 1 Diabetes

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Careful attention to self-care behaviors is crucial to achieving good health outcomes in children and adolescents with type 1 diabetes. Despite the unequivocal research findings that adolescence is a time of poor metabolic control among affected individuals, there have been few *prevention* efforts geared toward health promotion in this age group. The diabetes education, counseling and information delivery, and evaluation (DECIDE) Program is intended to prevent the deterioration of self-care behaviors often evident during adolescence by intervening during the earlier, more stable time period of preadolescence. This paper describes the foundation for the DECIDE Program and outlines intervention development, current study recruitment, and preliminary program evaluation data. Findings indicate that enrollment into the program is feasible among children and their parents; early feedback suggests that parents and children are also satisfied with their participation. The challenges of conducting randomized controlled trials in health promotion for childhood diabetes are discussed, and ideas are offered for future research directions to improve the integration of child health psychology with public health approaches in this population.

**KEY WORDS:** diabetes; adherence; prevention.

Type 1 diabetes is the most common metabolic disorder of childhood, affecting nearly 1 in 400–500 children under the age of 20 (Centers for Disease Control and Prevention, 2004). In the United States alone, approximately 13,000 new cases of type 1 diabetes in children are diagnosed annually (Juvenile Diabetes Research Foundation, 2004) and the incidence is on the rise (Centers for Disease Control, 2005).

Type 1 diabetes affects both boys and girls and children from a wide range of socioeconomic and racial and ethnic backgrounds. While the onset of diabetes usually occurs in late school age or pre-

pubescent children, type 1 diabetes may be diagnosed in individuals from birth through adulthood (LaPorte & Cruickshanks, 1985). Thus, though it is often considered only a disease of childhood, this descriptor is not entirely accurate.

The management of type 1 diabetes involves adhering to a complex, medically prescribed self-care behavior regimen. Self-care behaviors are particularly important because diabetes is a lifelong illness that demands constant attention. In youngsters, proper diabetes management requires that they, along with their parents' assistance, perform tests of their blood glucose level, administer insulin, pay careful attention to food intake, and participate in regular exercise. If performed as recommended, the regimen can result in near-normal metabolic functioning. However, if the regimen is incorrectly or inconsistently performed, significant long-term adverse consequences may result. These consequences include poor metabolic control, retinopathy,

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nephropathy, and neuropathy. As the incidence of complications is largely inversely related to the intensity of the prophylactic insulin therapy regimen (DCCT Research Group, 1994), more and more children face performing increasingly complicated and difficult self-care regimens over time.

Adherence to the diabetes self-care treatment regimen has long been considered one of the most important determinants of achieving good metabolic control. An important construct in both the medical and child health psychology literatures, adherence has been defined in a number of different ways. Perhaps one of the most meaningful definitions of adherence for the current paper is the definition considering adherence as “self-care”—or the behaviors that an individual with diabetes performs on his/her own behalf, to maintain life, health, and well-being (Orem, 1985).

An individual’s self-care behavior is believed to change over time. While nonadherence or poor self-care is a significant problem in both youth and adults with diabetes (Johnson, 1992), adolescents have been found to be particularly vulnerable to developing a pattern of nonadherence or poor self-care behavior along with the resultant poor metabolic control. In fact, data from a number of sources clearly indicate that compared to younger children, adolescents with diabetes perform self-care behaviors less consistently (Christensen, Terry, Wyatt, Pichert, & Lorenz, 1983; Ingersoll, Orr, Herrold, & Golden, 1986; Johnson, Freund, Silverstein, Hansen, & Malone, 1990). In a study by Weissberg-Benchell et al. (1995), 144 adolescents (11–19-years-old) reported on the mismanagement of their diabetes. Specific mismanagement behaviors (and reported frequencies) found in this study included missing insulin injections (25%), fabricating blood glucose test results because testing was not performed (29%), administering extra insulin to adjust for inappropriate meals (34%), consuming inappropriate foods (81%), fabricating blood glucose test results because actual values were too high (29%), and tampering with blood glucose monitors to give lower readings (10%). Not surprisingly, parents and physicians alike underestimated the frequency with which these youngsters mismanaged their diabetes.

During adolescence, three main factors have been proposed as having an impact on developmental outcomes including primary developmental changes (e.g., puberty, cognitive, social), interpersonal contexts such as school, family, peers, and demographic and intrapersonal factors (e.g., ethnic-

ity, gender, family structure, socioeconomic factors; Williams, Holmbeck, & Greenley, 2002). Specifically related to adherence outcomes within diabetes, variables commonly hypothesized to impact upon adolescents’ adherence behaviors have fallen across all three domains and include disease knowledge (e.g., how to care for one’s diabetes), child social, cognitive, and psychological adjustment, family and peer relationships, and stress (e.g., Johnson, 1995). The construct or variable that has perhaps received the most focus in recent years is the family, and in particular, the role that parents play in the developmental and health outcomes of their children.

Within the family or parent–child relationship, the establishment of youth autonomy has been hypothesized as a challenge to maintaining adherence (Ingersoll et al., 1986). With an adolescent diagnosed with diabetes, this central developmental task is complicated by the presence of a chronic disease. Ingersoll et al. (1986) reported that parents often withdraw from the diabetes care process as children grow older, and usually discontinue their involvement by the time the child reaches age 15. However, it was also reported that this parental withdrawal is not always compensated for by greater adolescent involvement, especially among adolescents who are less mature. Thus, this transition often comes at the expense of metabolic control, suggesting that some less mature adolescents are given more responsibility than they are ready to assume.

It is not surprising that Ingersoll et al. (1986), as well as other researchers (Anderson, Ho, Brackett, Finkelstein, & Laffel, 1997; La Greca et al., 1995), have found that ongoing parent involvement in the child’s diabetes treatment, especially during adolescence, has been associated with better self-care behaviors and metabolic control. Remedying this potential barrier to adherence is not, however, as simple as encouraging parents to become or remain involved in their developing youth’s diabetes care. For example, the child’s cognitive development must be considered. Similarly, other research has stressed the importance of allowing for some independence from the parent in order to prevent dependency and low self-efficacy (Coyne & Anderson, 1988). For example, parents who are over involved or who are perceived as being overprotective may in fact also put their child at risk for poor self-care behaviors. Furthermore, increased parental involvement may come at the cost of increased family conflict. Taken together, and despite the inherent challenges, promoting continued parental involvement in

tandem with the child becoming increasingly involved in his or her diabetes management appears to be most appropriate.

In an attempt to remedy the deterioration of diabetes self-care or adherence as children transition into adolescence and early adulthood, multiple interventions have been conducted with this population (e.g., Anderson, Wolf, Burkhart, Cornell, & Bacon, 1989; Greco, Pendley, McDonnell, & Reeves, 2001; Grey, Boland, Davidson, Li, & Tamborlane, 2000; Wysocki et al., 2000). These studies targeting teenagers have largely focused on intervening with adherence difficulties after these problems have already begun. Interventions have varied with respect to focusing on adolescents already in poor metabolic control (Couper, Taylor, Fotheringham, & Sawyer, 1999), with high levels of parent-child conflict (Wysocki et al., 2000), or from high-risk populations (Harris, Mertlich, & Rothweiler, 2001). In addition, the modality and length of interventions have also varied, and have included individual (Couper et al., 1999), family (Wysocki et al., 2000), and group (Grey et al., 2000) sessions as well as single visits or multiple sessions. While most interventions have aimed to improve adolescents' overall metabolic control, improving self-monitoring of blood glucose (SMBG) levels has also been a key component of most interventions (e.g., Anderson et al., 1989; Delamater et al., 1990).

While intervention results suggest that aspects of diabetes management can be improved through behavioral intervention, there are shortcomings of these interventions. Most notably, studies targeting adolescents in poor metabolic control have shown limited improvement post-intervention (Boardway, Delamater, Tomakowsky, & Gutai, 1993), improvements that have not been maintained over time (Couper et al., 1999), and improvements in an intervention condition without comparison to an appropriate control (Ratner, Gross, Casas, & Castells, 1990; Rose, Firestone, Heick, & Faught, 1983). Additionally, while these studies have examined the efficacy of interventions to remediate nonadherence during adolescence, few attempts have been made to address this issue in preadolescence, and even fewer attempts to *promote* adherence, or *prevent deterioration in adherence behaviors* exist.

Because adolescence is a developmental period that is characterized by such significant biological, psychological, and social role changes (Williams, Holmbeck, & Greenley, 2002), it is likely that the limited success of these interventions is related to

the time period of intervention. Importantly, a successful intervention must attend to how developmental issues interact with health-related goals (Madsen, Roisman, & Collins, 2002). An intervention aimed at adolescents that is likely to be successful must thus take into account the many unique developmental challenges of this period. For example, during adolescence, as pubertal hormones are introduced, diabetes can be more challenging to manage due to increased insulin resistance and the attendant increased risk for poor glycemic control. Moreover, socially, due to cognitive changes associated with adolescence, it is likely that adolescents will think differently about adherence behaviors than they did during childhood. Specifically, because they are now able to consider the costs and benefits of remaining adherent, they may choose to be non-adherent to gain the benefit of full participation with their peer group (Holmbeck, 2002).

Taken together, trying to intervene during a developmental period that is not characterized by as many tasks may lead to more successful outcomes. Similarly, intervening before problems begin will minimize the challenge associated with changing engrained health habits (Williams, Holmbeck, & Greenley, 2002).

While much research has focused on adherence and control during the adolescent period of development, little is known about the precursors of nonadherence and poor control that may be present in the preadolescent stage—an earlier and potentially more effective point of intervention. Preadolescence is considered a more stable developmental stage that is generally characterized by fewer developmental changes, greater parental involvement with diabetes self-management tasks, and less individual and family stress. Further, preadolescence affords diabetes care professionals a window of opportunity to train and reinforce proper adherence behaviors that are associated with metabolic control at a time when receptivity to adult advice and guidance is higher. Greater attention to preadolescence could result in the prevention or minimization of nonadherence problems typically found during adolescence, thereby circumventing the need to intervene upon teenagers. Thus, the potential impact of this prevention and health promotion approach on children's health outcomes is high.

The remainder of this paper reports on a family-based behavioral intervention program to promote adherence to diabetes management in preadolescents with type 1 diabetes. Specifically, this paper

aims to: (a) describe the conceptual basis for the content of the intervention program, (b) outline the steps taken in the development of the intervention, (c) report on the recruitment process and participant characteristics, (d) present preliminary participant feedback on the process and content of the intervention program, (e) discuss attendant challenges of conducting a randomized controlled trial of behavioral outcomes among children with type 1 diabetes, and (f) propose areas of exploration for future research and health promotion in childhood diabetes in an effort to bridge the fields of child health psychology and public health.

## METHOD

### Conceptual Basis/Theory Guiding Intervention Development

In an effort to address the relative dearth of research in prevention and health promotion in the childhood diabetes literature, the diabetes education, counseling, information delivery and evaluation (DECIDE) Program was created. The DECIDE Program was specifically designed as a prevention program for preteens diagnosed with diabetes and their parents, regardless of previous adherence behavior or metabolic control history. The program aims to prevent or control deterioration in self-care behaviors typically occurring in early adolescence. A key goal of the DECIDE Program is to intervene *before* self-care behaviors begin to change and become increasingly erratic and problematic. Prevention or correction of daily self-care deterioration may best be directed at this age group because preadolescents are particularly vulnerable to secondary disease complications given the longer duration of their illness, and the generally poorer metabolic control which they experience even with intensive insulin therapy regimens (DCCT, 1994; Lestradet, 1981). Recent longitudinal evidence suggests a remarkable degree of consistency and tracking in metabolic control from adolescence to young adulthood and from young adulthood to middle adulthood (Bryden et al., 2001, 2003). Maintenance of adequate disease care may set the pattern for many years to come. Ultimately, by promoting adherence or self-care behaviors during the preadolescent period, it may be possible to prevent or control poor adherence typically evident during the adolescent period and improve health outcomes for these youngsters.

Development of the content of the intervention was largely guided by social cognitive theory (SCT), which addresses social and psychological factors influencing health behavior and prescribes methods of promoting behavioral change (Baranowski, Perry, & Parcel, 1997). The theory emphasizes that a person's behavior and cognitions affect future behavior. Health educators and behavioral scientists have often used SCT to develop interventions that address adherence to the diabetes regimen and other self-care behaviors, as well as to restructure the home/living environment so that positive gains seen during behavioral treatment can be maintained over time. Among the major concepts in SCT that have important implications for behavioral diabetes research are: (a) environmental factors that provide opportunities for social support for one's diabetes care (e.g., parental involvement), (b) behavioral capability, or the promotion of mastery learning through skills training (e.g., patient education), (c) self-control and reinforcements, which blood glucose levels provide as an immediate form of feedback, and (d) self-efficacy, which is the gradual building up of one's confidence over time that the diabetes regimen can be managed by breaking down components of self-care behaviors. Among all of these components, the self-efficacy component of SCT has been shown to be highly associated with adherence outcomes among patients with diabetes (Senecal, Nouwen, & White, 2000).

### Development of the Intervention

Intervention development progressed through several stages including: (1) identifying important topics of education modules based on relevant literature, (2) tailoring aspects of existing programs for preadolescents, and (3) development of a treatment manual. After the initial treatment manual was drafted, the intervention was delivered to (4) a pilot group of health care professionals, (5) a focus group of families, and finally (6) a second group of health care professionals. During each of these latter stages, refinements to the program were continuously made.

### Review of Existing Literature

The research team for the DECIDE Program consisted of a pediatric psychologist, pediatric endocrinologist, graduate student in psychology, and

dietitian. The group met as a whole and in smaller work groups to discuss the most salient clinical issues facing families of preadolescent- through adolescent-aged children with type 1 diabetes. Information gathered from these meetings was coupled with data from the existing literature on intervention research. With the overall goal of preventing nonadherence in mind, it was determined that the primary aim of the DECIDE Program intervention should be to teach families about the challenges inherent in managing diabetes during adolescence, and the importance of increasing or maintaining parental involvement in diabetes management as children grow older. These overarching points were emphasized through three components of diabetes self-care: blood glucose monitoring, nutrition, and exercise.

#### *Program Adaptation for Preadolescents*

Our research group identified an intervention manual published by the American Diabetes Association (2000) that focused on delivering the aforementioned modules to teenagers: *Teenagers with Type 1 Diabetes: A Curriculum for Adolescents, Families, and Health Professionals*. Several aspects of the existing intervention program were incorporated into the DECIDE Program, including teaching children a problem-solving strategy. Since young children were the target audience, we also adapted several of the concepts with new examples and reading materials geared toward younger ages.

#### *Treatment Manual and Piloting of Intervention Content*

After finalizing the intervention content, a treatment manual was developed that outlined general concepts to be covered, and also incorporated specific examples or activities. The first step in piloting the intervention was to deliver the program to a group of health care professionals working as part of a diabetes team, but not specifically involved in the DECIDE Program. This step proved invaluable, as it became clear that significant changes were necessary in order to make the intervention more widely applicable and not, for example, specific to children prescribed a certain number of insulin injections per day, or to those who used carbohydrate counting to manage nutrition. This was achieved by shifting the focus away from offering new health education information about diabetes management and onto as-

sisting families in negotiating how parents could be most helpful to their children in each area of diabetes management.

The treatment manual was subsequently revised, and now focused on the impact of puberty on diabetes management, the importance of blood glucose monitoring, healthy nutrition tips, and ways to promote regular exercise. Through all of these content areas, the focus was placed upon helping families identify barriers to parents working more closely with their children, and potential benefits of their doing so.

#### *Family and Health Care Team Focus Groups*

Next, several families were invited to participate in a pilot delivery of the intervention. Unfortunately, all but one family failed to attend this group; this single family was subsequently run through the intervention protocol in its entirety. Family members provided extensive feedback, and the treatment manual was revised based upon their suggestions to incorporate new activities for children and their parents. In the final step of intervention development, the program was delivered to a second group of health care professionals affiliated with diabetes team. The revised manual, activities, and handouts proved to be on target and only minimal changes were made following this session. Shortly afterwards, a formal program evaluation form based on the work of Kazak et al. (1999) and Patrick et al. (2001) was developed to be used at the conclusion of the randomized controlled trial.

#### *Mode and Content of Intervention*

During the early stages of the development of the intervention, all possible models of intervention delivery were considered. It was recognized that the format of the intervention could not be finalized until deciding on specific intervention goals or exercises, yet early on in the process the research team engaged in an ongoing discussion about the most practical yet effective means for administration of the intervention. It was clear that in order to achieve intervention goals, both children and parents would be included. At the same time, it was unclear if the intervention would be delivered in individual family sessions, group sessions, or a combination of the two. Ultimately, it was determined that a group format

was not highly feasible within the available clinical environment but that incorporating some aspect of group or peer and social support would be valuable. Thus, two individual family-based sessions and one group session where multiple families meet together was proposed. This design appeared to balance competing interests in maximizing intervention effectiveness (higher intensity) with the ability to translate the work into other clinical settings (low intensity).

In the DECIDE Program's randomized controlled trial, children randomly allocated to the intervention condition participate in three sessions; Sessions 1 and 3 occur with the individual family immediately prior to or following a child's regularly scheduled diabetes clinic visit. Sessions at clinic visits typically last for 30–45 min. For Session 2, which lasts 2 hours, families are invited to a clinic site during an evening or weekend to participate in a group with other families.

Consistent with the American Diabetes Association's intervention (2000), overall goals include helping youngsters better understand how they can problem-solve difficult diabetes related situations, use self-monitoring of blood glucose to better manage diabetes, and follow a nutrition and physical activity plan. In addition, parents are taught similar modules in order to increase their support of the preadolescents' diabetes management. Increasing parental involvement and family communication are achieved through: (1) having parents and preadolescents meet together for Sessions 1 and 3, and for the first and last portion of Session 2, (2) incorporating a parental diabetes simulation exercise (Satin, La Greca, Zigo, & Skyler, 1989), and (3) having parents and preadolescents set behavioral goals to work on together during each session.

*Session 1: The Ups and Downs of Blood Sugar:  
Keeping Your Diabetes on Track*

Preadolescents and their parents learn the effects of growth and puberty on diabetes management and the multiple causes of variable blood glucose levels during early adolescence. In addition, other influences on blood glucose levels are reviewed (i.e., insulin, nutrition, exercise, illness, and stress). The importance of checking blood glucose levels is also discussed. Parents and preadolescents are introduced to a problem-solving model, and problem-solving examples/role plays focus on conflicts with parents/teachers/peers about checking blood glucose

levels. At the end of the first and each subsequent intervention session, parent and child negotiate a behavioral contract that encourages parent–child sharing of one aspect of diabetes management.

*Session 2: Making Choices About Food and Getting Fit*

Families participate in Session 2 in between the child's first and second clinic visits (typically three to five months apart). There, two to five families come together on a weekend day or evening with parents and children spending the majority of the time in separate but concurrent parent and child groups, except for a joint meeting at the beginning of the session and again at the end. This session explores the benefits of eating healthy and leading an active lifestyle. In their separate groups, children and parents are asked to identify both benefits and barriers to having parents assist with diabetes self-care goals. All participants assist in identifying key ways that parents can be helpful to children with diabetes with respect to eating healthy and staying active. Group activities utilize problem-solving strategies, role-play, and negotiating parent–child management for diabetes tasks. Information is delivered in an easily digestible format, with many hands-on activities interspersed with didactic material. At the end of the session, parents and children come together and complete behavioral contracts for sharing responsibility related to eating healthy and maintaining an active lifestyle.

*Session 3: Parental Simulation and Putting it All Together*

During the final intervention session, parents and children again work with the interventionist prior to or following the child's diabetes clinic visit. In advance of this session, parents receive a diabetes simulation packet by mail with instructions for recording carbohydrates eaten and physical activity for one week. Parents are also asked to check their pulse and to record it four times daily. These behaviors were selected to simulate the time intensiveness, demandingness, and inconvenience of blood glucose monitoring and other diabetes self-care behaviors. The beginning of Session 3 is spent discussing the simulation exercise and parents and children are encouraged to describe their reactions, including parents reporting any difficulties they experienced in following their simulated regimen. Parents are also asked to reflect on how completion of the simulation

may impact their view of their child's diabetes management. Problem-solving steps are again reviewed, and families make a final behavioral contract for sharing an aspect of diabetes management. Parents and preadolescents are encouraged to choose a contract that they foresee as being able to be shared even as the youngster becomes a teenager.

Approximately 2 weeks after each of the three intervention sessions, families receive a 'booster' telephone call from the interventionist. The purpose of these 10–15 min calls is to review key intervention concepts, discuss the behavioral contract, problem-solve any "slips," adherence difficulties, or diabetes-related conflicts that may have occurred, and to provide positive feedback to participants for their accomplishments.

All intervention sessions are audiotaped in order to evaluate the performance of the interventionist, and to assist in the supervision of intervention leaders.

#### Procedure

As noted, the DECIDE Program includes an ongoing randomized controlled trial.

#### Inclusion and Exclusion Criteria

Participants are males and females (ages 9–11-years-old) with type 1 diabetes diagnosed for at least 1 year, who are seen through the outpatient diabetes clinics of a large metropolitan children's hospital and its satellite clinics. Eligibility requirements include the ability to speak and write in English and being free of developmental disabilities, psychotic disorders, or other serious medical conditions that might interfere with informed consent and participation in the intervention or completion of data collection. Given the focus on preadolescents, females who have reached menarche are also excluded.

#### Recruitment and Enrollment

To facilitate enrollment, the names and mailing addresses of preadolescents in the specified age range are generated by administrative clinic staff from the hospital's computerized appointment system approximately one month prior to scheduled clinic visits. Eligible subjects and their parents are then

mailed an introductory letter explaining the purpose of the project, followed by a telephone call from a trained research assistant in order to verify that children meet enrollment criteria, answer questions about the study, and determine if the family would like to participate. After verbally agreeing to participate in the project, parents are given the option of completing baseline questionnaires at their child's next clinic visit, over the telephone with a trained research assistant, or through the mail. Upon completion of the baseline assessment, participants are randomized to either the intervention or standard care condition. Importantly, families randomized to standard care are informed that they will have the opportunity to participate in the DECIDE Program's intervention after their follow-up data collection is complete.

#### Assessment

Data collection continues for up to two years, with families completing questionnaires and an interview at 1-, 6-, and 12-months post-intervention (or time equivalents for the standard care group). Families enrolled early in the trial are followed for up to 24 months. Data collection consists of a range of self-report questionnaires from both child and parent. Standardized measures of behavior and mood are administered, as well as diabetes-specific measures of quality of life, parent involvement, and parent-child conflict. Children and parents also complete a 24 hours recall interview (Johnson, Silverstein, Rosenbloom, Carter, & Cunningham, 1986) at each assessment point. The interview assesses all diabetes self-care behaviors that the child and/or parent engaged in over the previous 24 hours. Health outcome data are obtained through downloading blood glucose meters and conducting medical record reviews.

## RESULTS

#### Recruitment and Enrollment

To date, a total of 64 participants have been enrolled in the program. In order to enroll 64 participants, introductory invitation letters were mailed to 151 families. Forty families have been unreachable and 23 families have been ineligible. Sixty-four of the 85 eligible families contacted have agreed to

participate in the study, yielding a 73% rate of participation. Reasons for study refusal include lack of time and the preteen not being interested in participating.

#### Trial Subject Characteristics

At present, the study sample consists of 64 children ( $M$  age = 10.9 years,  $SD$  = .73; 51% female) and 64 primary parents ( $M$  age = 41.5 years,  $SD$  = 6.0; 93% female; 73% Caucasian). Primary parents self-identify themselves as being the primary caregiver with most responsibility for the child's diabetes management. When possible, a secondary parent also participates in both interventions and data collection. Seventy-nine percent of parents are married or living as married, with 22% reporting a mean family income of less than \$50,000 and 46% having completed college.

The majority of children in the DECIDE Program are being treated by an intensive diabetes therapy regimen: 56% are prescribed 2 or 3 subcutaneous insulin injections daily, and an additional 44% use a basal/bolus regimen with either Lantus insulin or continuous subcutaneous insulin infusion (insulin pump therapy). At baseline, 78% of children reported checking their blood glucose levels four or more times daily and, on average, had fair metabolic control ( $M$  hemoglobin A1C = 8.3%,  $SD$  = 1.2, range = 5.0–12.0%). Per study entry criteria, all children have been diagnosed with diabetes for at least 1 year ( $M$  = 4.0 years,  $SD$  = 2.6).

#### Assessment

Of the 64 preadolescents enrolled in the study, 57 have completed baseline questionnaires and have been randomized; 28 of the 57 randomized participants have been assigned to the intervention group, and 29 to the standard care control condition. Of the 28 randomized to treatment, 10 are in the midst of completing the intervention sessions: 24 have completed 1 intervention session, 21 have completed two sessions, and 16 have completed all three sessions. Several intervention sessions have been delayed for a variety of reasons including missed or cancelled clinic appointments and the child being brought to clinic by someone other than a parent. Rarely have intervention sessions been missed due to the family's inability to remain in clinic for additional time. While data col-

lection is ongoing, study retention is relatively high. Only one family in the standard care group withdrew participation before completing the first follow-up assessment. Several more families have been difficult to reach for follow-up.

#### Program Evaluation Data

As noted above, participants randomized to the intervention condition completed a program evaluation form. The evaluation form consists of 20 items assessing the format of intervention, convenience of delivery, quality of the interventionist, and intervention content area. Respondents were asked to rate each item from 1 (poor/strongly disagree) to 5 (excellent/strongly agree). Sample items include 'location of group session', 'the material was clear,' and 'the staff was tuned into my needs.'

Given that the program evaluation form was added into the study shortly after data collection had commenced, and initially was completed only by parents, data are currently available on the responses of 10 parents and five children. Overall, parents indicated being pleased with the intervention, with 18 out of the 20 items having a mean of 4 or higher. Highest rated items by parents included clarity of the material, importance of the topic, and group leaders. Parents appear to like the format, location, and interventionist for individual sessions, with 90% reporting good/agree or higher for each of these items. The format and convenience of the group sessions, which were located at the main hospital, were somewhat less highly rated, with 70% of respondents reporting good/agree. The content area of individual and group sessions also received high ratings, with 90% parents responding in the good to excellent range. Parents found the program to be helpful (90%), and were overall very satisfied with their participation (90%). Only 1 of 10 parents responded being uncertain if he/she would recommend the DECIDE Program to others.

In general, children's responses suggest a similar, yet slightly lower, evaluation to the overall program as compared to that of their parents. Individual sessions were seen as convenient with all children reporting good to excellent for location and timing of intervention sessions conducted at clinic. Furthermore, children reported greatest satisfaction with their individual interventionist. Items receiving the lowest ratings by children all related to the group session, including usefulness, location, and timing.



## DISCUSSION

The incidence of type 1 diabetes in childhood is increasing, and assisting families in their efforts to adhere to the required medical regimen is crucial to improving children's health outcomes. The majority of prior intervention research in the behavioral management of type 1 diabetes has focused on adolescents, or on intervening *after* adherence difficulties have already occurred. This paper reports on a novel intervention program designed to *prevent* nonadherence difficulties by targeting a younger age cohort of preadolescents, regardless of previous adherence behavior or metabolic control history. This paper describes the adherence promotion intervention and provides a first look at ongoing data collection efforts, including development of the intervention, preliminary feedback from participants, and challenges inherent in this work.

Randomized controlled trials represent a rigorous methodology requiring significant researcher and participant effort. The development of the DECIDE Program, and of the intervention in particular, took over 6 months and included careful study of the literature, meetings of health care experts, and focus groups of clinicians as well as family members. As indicated by the description of the stages of its development, intervention planning is intensive and requires multiple revisions prior to the start of the trial.

#### Challenges of Trials Involving Behavioral Outcomes in Childhood Diabetes

While the rate of participation for the DECIDE Program is somewhat higher than might be expected given the longitudinal nature of the study, intervention delivery and ongoing data collection efforts continue to pose many challenges. In an effort to include families most likely to continue their participation in the program, maximize retention, and reduce attrition, the study was purposefully designed to require completion of baseline data questionnaires and a recall interview prior to randomization (i.e., a behavioral run-in). Despite this strategy, several families have completed follow-up questionnaires on a delayed timetable. Further, several other families have missed their child's diabetes clinic visit and, therefore, have also missed scheduled intervention sessions. Although the diabetes treatment team at the trial site encourages children to be seen in clinic every few months, many families have gone longer (upwards of a year or more) in between clinic visits.

Other scheduling issues that have challenged the DECIDE Program include families losing medical insurance, moving out of the country, or having an ill parent. These obstacles to continued study participation are not unique to the DECIDE Program. Significant efforts are expended to accommodate families' schedules, and flexible participation options are exercised when possible. However, the net result is a somewhat unevenly distributed intensity of the intervention across participants, which could mediate or moderate impact.

Despite these challenges, feedback from parents and children has been generally positive, with families expressing their appreciation for the effort to maximize the convenience of intervention delivery, as well as the educational content of material presented. Positive feedback during this intervention is especially important given the randomized and preventative nature of the trial itself. Specifically, many of the participants initially report needing very little behavioral assistance and do not perceive themselves as trial-eligible. However, by the end of the third session, the majority of families report having acquired new and useful information.

Although the data presented herein are preliminary, limitations of this work should be noted. As described earlier, the program evaluation form was developed after the start of intervention delivery. Thus, data are not available on the first few participants completing the intervention. It is possible that feedback from the first few families would have differed, particularly prior to interventionists becoming more experienced. Furthermore, feedback from child participants is limited and may not be representative of the sample as a whole.

As noted by Elkins and Roberts (1988), intervention research accounts for a small portion of published reports in the field of pediatric psychology. *Prevention* intervention efforts account for an even smaller portion of these investigations and more are sorely needed (Black, 2002). Conducting methodologically sound trials is challenging work, yet the importance of these efforts in promoting good health outcomes for children with type 1 diabetes cannot be overstated.

#### Future Research

With regard to future directions for health promotion and prevention research in childhood diabetes, and intervention research in general, much

more is needed to support this type of work. In 2003, the National Institutes of Child Health and Development coordinated a call for contracts for a family based adherence intervention for early adolescents (National Institute of Child Health and Human Development, 2003). This multi-site, national investigation shares some aspects of the DECIDE Program and it is likely that results from this research will offer complementary findings. In addition to adherence promotion during the preteen and adolescent years, intervention development for the newly diagnosed period of diabetes, or for families with a very young child with diabetes, may prove valuable. The evaluation of prevention efforts in each of these age and illness trajectory cohorts is key to the translation of effective clinical strategies targeted at improving health outcomes for children. Researchers should be encouraged to move towards *prevention intervention* research. This may, in part, be facilitated by federal funding priorities that are preventative in nature, and by increased attention to the role of prevention by clinical psychologists and other health professionals working in medical settings, public health settings, and with children. While prevention of Type 1 diabetes itself is currently not scientifically possible, population based public health approaches may benefit those children and families living with diabetes. For example, public health programs that promote parents in taking an active role in assisting their children's development of healthy eating habits along with a physically active lifestyle would certainly work to complement the more illness-specific goals of working with families of children with Type 1 diabetes.

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