

Study Title: Family Routines – Healthy Families

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Family Routines – Healthy Families

Specific Aims

Type 1 diabetes is one of the leading chronic diseases of childhood.¹ Families live meal to meal carefully adhering to a complex treatment plan that includes insulin injections, blood glucose monitoring, following a prescribed meal plan, and exercise. The American Diabetes Association (ADA) now recommends that children under 6 years old diagnosed with type 1 diabetes strive to maintain an A1C level lower than 7.5 percent.² Maintaining such tight glycemic control requires that parents carefully monitor blood glucose and eating behaviors so that they can accurately calculate insulin dosing. However, home life for families of young children can be unstructured, thus creating logistic problems related to glycemic control, especially during the evening hours. For example, if there is less than 2 hours between dinner and a bedtime snack, the bedtime blood glucose reading may be above the targeted range and parents are unsure of how to handle the blood glucose result. This can result in overnight hyperglycemia, and an elevated A1C. In addition, mothers report feelings of intense “constant vigilance” due to fear of hypoglycemia and this constant watchfulness has a negative effect on quality of life for parents.³

Even though parents of children with type 1 diabetes report that they (parents) are confident in their diabetes specific skills, e.g., blood glucose monitoring and insulin injection, within one year after diagnosis, in fact, diabetes specific self-efficacy has not been found to be correlated to child metabolic control.⁴ Because the consequences of hypoglycemia are dangerous, parents often err on the side of under-dosing with insulin to avoid these consequences. We propose that a structured evening routine would (a) reduce snacking after dinner and (b) ensure at least two hours between dinner and bedtime glucose readings which in turn would help parents in their decision making process at bedtime.

Researchers are now investigating the protective mechanisms of family routines and their influence on childhood chronic illness management such as asthma and type 1 diabetes.^{5,6} Family routines have been defined as the regularity of certain activities engaged in by a family.⁷ Evidence is mounting that family routines mediate behavioral problems and adherence in children with type 1 diabetes.⁶ In addition, authoritative parenting in which parents are able to set consistent, realistic limits on children's behavior in a warm and sensitive manner has been linked to better diabetes-specific regimen adherence and metabolic control in young children.⁸ A family based intervention that incorporates an educational and a behavioral component to improve both parenting skills and child evening routines is likely to improve metabolic control by improving both the bedtime blood glucose reading and the overnight glucose control.

The purpose of the proposed study, Family Routines – Healthy Families, is to examine the feasibility and acceptability of a parenting/family routine intervention program for parents of young children, ages 2-5, with type 1 diabetes. The intervention, Family Routines – Healthy Families, contains an established and effective parent skills training curriculum, *The Incredible Years*,⁹ uniquely integrated with a newly developed family evening routine component e.g., family dinner time and evening routine, to promote improved metabolic control. The evening routine component was developed by Dr. Marvicsin based on her more than 20 years of clinical experience in working with these families. The team includes Dr. Peter Gerrits MD, Section Head, Pediatric Endocrinology & Metabolism at Beaumont Children's Hospital and Dr. Ruth Anan PhD, BCBA-D, Licensed Psychologist and Board Certified Behavior Analyst. Dr. Anan is specifically trained to deliver *The Incredible Years* curriculum. We will assess outcomes during and at one week post intervention. Outcome measures will include family routine, specifically the time between the dinner and bedtime glucose check, parent bedtime decision making, and child overnight glucose control. In addition, parental quality of life and receptiveness to the intervention will be assessed.

The **Specific Aims** are:

Aim 1. Examine the feasibility of a six session parenting skills and family evening routine intervention delivered in a group format. Post intervention interviews and attendance will determine suitability/preferences for mode of delivery and realism of behavioral expectations.

Aim 2. To develop preliminary evidence regarding the impact of a six-session family intervention on child evening routine and glucose control as measured by four indicators:

- a) time between dinner and bedtime glucose readings
- b) difference between bedtime blood glucose reading and morning fasting blood glucose reading
- c) parent decision making and response to bedtime snack/insulin questionnaire
- d) difference between child A1C pre- and 3 months post- intervention through chart review

Aim 3. Determine impact of Family Routines – Healthy Families intervention on parental quality of life for parents of young children with type 1 diabetes.

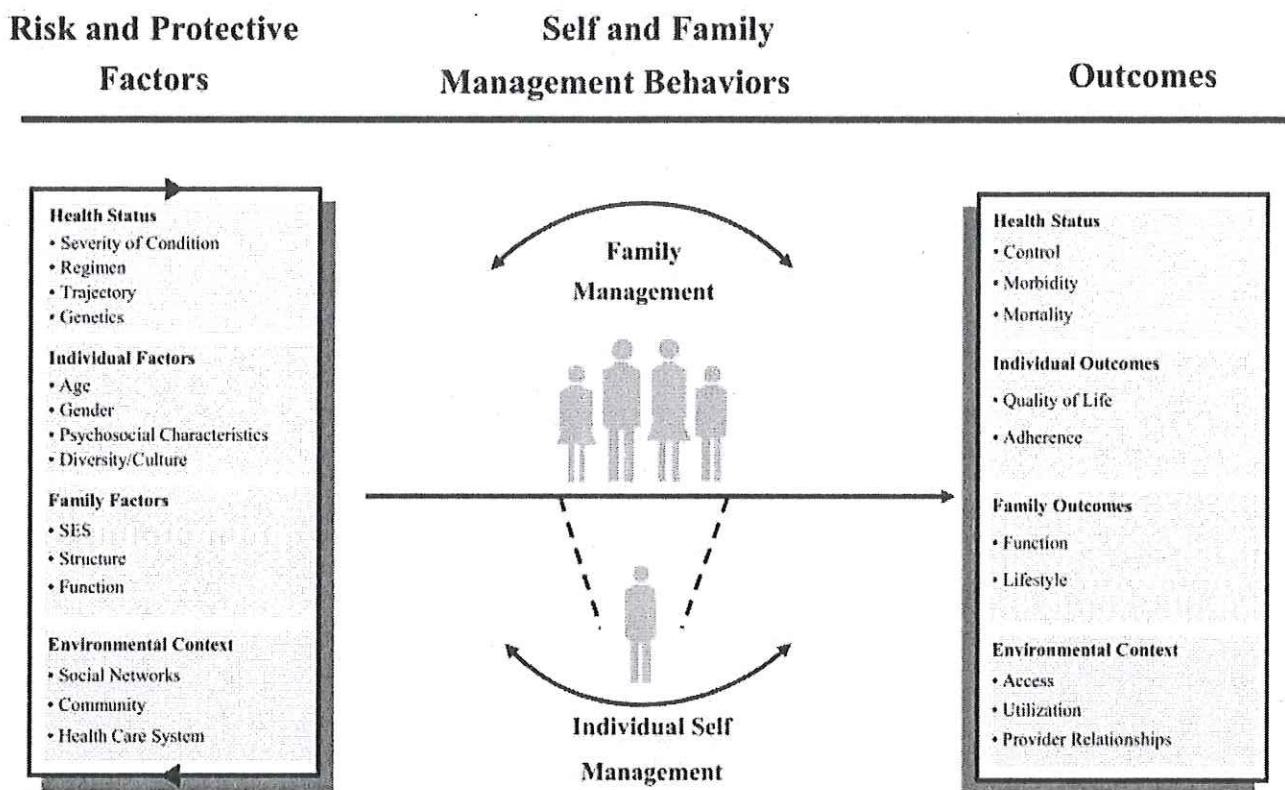
Background and Significance: Type 1 diabetes: Type 1 diabetes is one of the leading chronic diseases of childhood, affecting approximately 167,000 youth under the age of 20 years in the United States.¹ The incidence of type 1 diabetes is rising worldwide, particularly in young children under five years of age.^{10,11} It has been projected that the number of youth in the United States with type 1 diabetes could nearly triple by mid-century.¹² While much work is being done in immunology for the prevention of type 1 diabetes and in technology for a closed-loop artificial pancreas, the reality is that many families must still live meal to meal with the complex work of managing the disease. Recently, the American Diabetes Association (ADA) lowered its target recommendation for blood glucose levels for children with type 1 diabetes. The ADA now recommends that **all** children under the age of 19 diagnosed with type 1 diabetes strive to maintain an A1C level lower than 7.5 percent.² An A1C level of 7.5% corresponds to a three month average blood glucose concentration of approximately 170 mg/dl. This target concentration was lowered due to growing evidence of the potential risks of hyperglycemia and glucose variability on short term neurocognitive function. In addition, the ADA wanted to bring their recommendation in to alignment with those of the International Society for Pediatric and Adolescent Diabetes.

Grey and colleagues have developed a framework to organize the multiple concepts researchers need to attend to when studying self-and family management of chronic conditions.¹³ The framework attends to both risk and protective factors as well as specific outcomes. (See Figure 1) In the model, the health status (type 1 diabetes) and the individual factor (age) of a young child are risk factors. Parents are the managers of the condition in the preschool age population. Family factors such as family routine and parenting skills can be protective factors in the management of this condition. An intervention designed to improve these specific areas of family function is likely to improve outcomes such as metabolic control and parental quality of life.

Family Routines: Treatment regimens for tight glucose control in very young children are challenging due to variable eating, activity, and sleep patterns. In addition, young children have a limited ability to detect and communicate low blood sugar reactions. There is growing evidence of the protective mechanisms of family routines and their influence on childhood chronic illness management of conditions such as asthma and type 1 diabetes.^{5,6} Family routine has been defined as observable, repetitive behaviors which directly involve the child and at least one adult acting in an interactive or supervisory role, and which occur with predictable regularity in the daily or weekly life of the child.^{5,6} Experts in child development have emphasized the importance of family routines and parental consistency in fostering adaptive child behavior, family relationships, and medication adherence.¹⁴ Less is known about family routine and management of chronic conditions in the preschool age child. A family based intervention that incorporates both an educational and a behavioral component to improve

evening routines is likely to improve the variable activity and overnight glucose control in preschool children. This in turn will impact the child's long term metabolic control by maintaining the overnight blood glucose in the target range throughout the night.

Figure 1



Meals and snacks for pre-school age children tend to cluster during the day hours. It can be difficult for parents to obtain a true fasting blood glucose reading and adequately correct its level to target range. The new ADA guidelines highlight the need to have the overnight fasting blood glucose readings in target range for optimal metabolic control. An evening routine that decreases after dinner snacking and promotes an accurate bedtime glucose reading may contribute to improved glucose control over night. Having two hours between dinner and bedtime glucose check may help parents in their decision making process at bedtime.

Parenting: Although parents of children with type 1 diabetes report they are confident in their diabetes specific skills such as blood glucose monitoring and insulin injection, diabetes specific self-efficacy has not been found to be correlated to child metabolic control.⁴ Factors other than diabetes specific skills may be more relevant to metabolic control. General family functioning has an important role in maintaining the overall health of children with type 1 diabetes.¹⁵ Most research to date with families of children with diabetes has focused on school age children and adolescents.^{16,17} Families of young children, ages 2-8, with diabetes have demonstrated significantly poorer family functioning in communication, affect management, family role, and overall functioning when compared to the control group of families of healthy young children.¹⁸ Intervention studies for parents of young children have demonstrated improvement in parental stress and quality of life, but less impact on metabolic control.¹⁹⁻²² Of the four intervention studies we found that focused on families of young children with diabetes,

three focused on parental support such as: support groups, peer mentors for parents, and telephone support.¹⁹⁻²¹ The one study that did include parental skills training did not focus on family routine or overnight metabolic control.²²

Parents of very young children with diabetes indicated that the impact of diabetes on child behavior and family interactions was their highest priority.¹⁹ Davis et al found that "authoritative parenting" in which parents are able to set consistent, realistic limits on children's behavior in a warm and sensitive manner has been linked to better diabetes-specific regimen adherence and metabolic control in young children.⁸ Therefore, it has been recommended that family focused interventions for young children with type 1 diabetes should include components targeting family function in the areas of communication, affect management and family roles. This is the focus of the *Incredible Years Curriculum*, described in greater detail below.²³ It is important for parents to have the knowledge and skills to manage child behavior during the evening routine in order to have at least 2 hours between dinner and the bedtime glucose reading. An evening routine is likely to decrease variability in bedtime glucose readings which will in turn decrease parental fear of nocturnal hypoglycemia and improve parental quality of life.

Summary: The new ADA guidelines calling for lower A1C in young children makes it imperative that the health care community find ways to assist families in managing type 1 diabetes. The proposed study will examine the feasibility of delivering an intervention that includes positive parenting skills and establishment of evening routine that will promote less variability in evening snacking in young children. This in turn will improve the overnight blood glucose levels and A1C and assist parents in the management of their young child's type 1 diabetes. In addition, improved parental management during pre-school age years will provide a legacy of improved diabetes management throughout childhood and into young adulthood.

Methods

Design: This feasibility study will be a mixed methods non-randomized trial to examine the feasibility of combining a parent skill training intervention with a family evening routine intervention. Evidence of feasibility will include attendance, activities completed, and interviews. Families will be recruited from a suburban not-for-profit medical center. Initial set of patients to contact will be provided by data manager for all families who meet inclusion criteria. Patient list will be prioritized by Principal investigator and co-investigators. Study team will verify HbA1c meets criteria, then will call families to see if they are interested in study. If family is interested the consent will be sent to their home and then recalled to see if they want to be scheduled for the classes. If yes, they will be scheduled. Scheduling will stop once we have 12 families who wish to participate. Actual signed consents and interventions will happen at the first session.

Sample:

The sample will include 12 primary caregivers whose children have type 1 diabetes. Inclusion criteria will be (1) self-identification as primary caregiver (2) child aged 2-5 years (3) Child is newly diagnosed or Child's most recent HbA1c is ≥ 8.0 ; and (4) English fluency.

Intervention (See Table 1):

The Incredible Years parenting program is a well-established evidence based program that has been shown in randomized trials to promote positive parenting skills and reduce child behavior problems.²⁴ The program has proven effective in community settings with diverse populations.^{23,25,26} This curriculum targets the specific areas noted above: anger management, communication skills and positive parenting skills.

Family Routines-Healthy Families is a six week program that will assist parents in establishing consistent routines during the evening hours. This includes having dinner about the same time most nights, completing a transition to bedtime routine that should occur in the two hours after dinner and

before bedtime glucose check, and that may include activities such as bath time, story time, and brushing teeth.

Variables and Measures:

Demographics: Standard demographic items will be used to assess age of child, age of caregiver, socioeconomic status, employment status, marital status, level of education and race.

Feasibility: Feasibility of this intervention will be examined by documenting (a) attendance and (b) the extent to which caregivers carry out the required activities. In addition, feasibility will be examined by interviewing caregivers at the end of the intervention to obtain their perspectives about a) the intervention; b) their perception of the potential burden and benefits c) whether the intervention impacted their decision making or fear of overnight hypoglycemia, and d) any other information that is missing or needs to be addressed. The semi-structured interviews will last about 30 minutes, be audio-recorded, and transcribed verbatim. An Interview Guide will be used to ask open-ended questions about the measures' content and format, and to ask for any additional information participants may wish to share about their experience.

Child Evening Routine: Families will record time of dinner glucose reading and time of bedtime glucose reading. The time of the glucose readings will be verified with the information stored in the glucometer.

Child Overnight Glucose Control: Each child's bedtime and fasting morning blood glucose control will be documented and verified with information stored in the glucometer.

Parental Decision-making: A short survey will be given both pre and post intervention to determine parent perception of decision making at bedtime. See Attachment 1

Psychosocial Illness Impact: Parental quality of life will be measured with both positive and negative items from the PROMIS Psychosocial Impact item bank.

Child Metabolic Control: Most recent A1C will be retrieved from child's medical record.

Data Analysis Plan

Descriptive statistics and paired t-tests will be used to analyze the data. In addition qualitative methods will be used for Aim 1.

Aim 1. Examine the feasibility of a six session parenting/family routine intervention delivered at a suburban health care system site. Attendance and post intervention interviews will determine realism of behavioral expectations. Qualitative analyses will be performed by the PI using the constant comparative method (Glaser, 1992) to identify common themes, identify potential revisions, and modify instruments and procedures. Content analysis (Boyatzis, 1998) of the data will be performed to determine frequency and type of issues identified. Qualitative software, NVivo, will be used to facilitate management of the qualitative data.

Aim 2.a. Determine the degree to which a six-session parenting/family routine intervention will positively affect child evening routine. We will perform a paired t-test using the glucometer data for the times of dinner glucose reading and the bedtime glucose reading. Data will be gathered weekly at each educational session for analysis.

Aim 2.b. Determine the degree to which a six-session parenting/family routine intervention will affect the overnight glucose control of preschool age children with type 1 diabetes during the intervention. We will use descriptive statistics to describe the mean difference and absolute difference between the bedtime

glucose reading and fasting morning glucose reading. Data will be gathered weekly at each educational session for analysis.

Aim 2.c. Determine the degree to which a six-session parenting/family routine intervention impacts parental decision making at bedtime based on degree of change between pre and post response to bedtime snack/insulin questionnaire. We will use paired t-tests using the before and after scores on the questionnaire.

Aim 2.d. Determine change in child A1C pre and 3 month post intervention. Descriptive statistics will be used to describe the mean difference and absolute difference in A1C.

Aim 3. Compare PROMIS Psychosocial Illness Impact scores pre and post intervention.

Statement related to parental (self) management and complexity:

The new ADA guidelines for lower A1C in preschool age children makes it imperative that the health care community find ways to assist families of young children in their management of type 1 diabetes. Treatment regimens for tight glucose control in very young children can be very complex for their parents and caregivers. Parent management of diabetes is self-management in this young age group. This proposed study will examine the feasibility of delivering an intervention that includes positive parenting skills and establishment of evening routine that may improve overnight glucose control. This in turn may improve metabolic control. Preliminary data will be used to respond to a NIH/NIDDK FOA for improving diabetes management in children with type 1 diabetes (DP3), specifically to test the intervention in a larger trial and convert to a web-based approach that would be available to families in rural and underserved areas.

CSCD Services Requested: We plan to consult with the Center for Complexity and Self-management of Chronic Disease's co-director, Dr. Ivo Dinov, at the outset of the project and periodically as necessary throughout the two-year project for guidance with methodology.

Data Safety Management Plan (DSMP). We will follow the Center for Complexity and Self-management of Chronic Disease's approved DSMP, which is appended to this proposal.

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