

Project Title: Iterative Beta Testing of Videos for the DIPPer Academy

NCT Number: NCT03385265

Date: 9/27/2021

The incidence of type 1 diabetes mellitus (T1D) is increasing in young children (<6 years old).¹⁻⁴ Yet, the development of age-targeted behavioral interventions for this vulnerable patient group has been limited. Young children will face a lifetime with T1D, substantially increasing their overall risk for micro- and macrovascular complications.^{5, 6} In addition, young children have a higher risk of cognitive deficits than children diagnosed at an older age,⁷⁻¹⁰ suggesting the potential for greater impairment in education and job opportunities. Establishing good glycemic control early in the course of T1D can reduce the risk for complications (viz., metabolic memory),¹¹⁻¹³ thereby underscoring the importance of intervening with young children who are likely to benefit from the risk reduction into adolescence.^{5, 6, 11, 14}

Unfortunately, research shows that many young children with T1D exhibit blood glucose levels that exceed the current U.S. and international targets.¹⁵ They also can experience problems with high "glycemic variability,"^{16, 17} and hypoglycemia.^{5, 16-18} Within families, the research shows challenges parents face in managing their child's T1D including moderate to high rates of parenting stress and hypoglycemia fear,¹⁹⁻²¹ disrupted sleep schedules,¹⁸ difficulty in managing their child's disruptive behaviors,^{22, 23} depressive and anxiety symptoms,^{19, 24} and decreased quality of life.²⁴ Caring for a young child with T1D is uniquely challenging often because of the typical and developmentally appropriate behaviors exhibited by young children, who can be unpredictable, idiosyncratic, and contrary.^{5, 25-27} The young child's natural tendency to seek more independence may complicate daily T1D self-care; he or she may refuse to cooperate with insulin injections or pump site changes, glucose checks, or treatment for a low blood glucose level.⁵ Likewise, the tendency among young children to be unpredictable in their eating and activity patterns²⁶ can make it hard for parents to plan meals, administer insulin before meals, and effectively manage glucose levels between meals.^{5, 6}

Traditionally, young children have not been a focus of T1D education. Indeed, according to the American Diabetes Association (ADA) Recommendations for Daily Self-Care,^{5, 6} parents are encouraged to assume full responsibility of T1D self-care for their young child, making them the natural targets of existing T1D interventions. On its face this makes sense, but this exclusive focus on parents misses important opportunities to engage ever developing kids in their own T1D care. Young children are active learners, gaining new skills each year in personal self-care (e.g., toileting, dressing), language (e.g., following simple instructions, repeats information), social/emotional development (e.g., imitation, cooperative play, can recognize real versus make-believe, agrees with rules), and cognitive development (e.g., recognize familiar objects, starting to understand time, can remember parts of stories, can begin to predict what might come next in a story).²⁷ As parents, we inspire, teach, and encourage these new skills in our young children. Extending this to T1D understanding and self-care skills could establish a strong foundation for kids' ever evolving abilities that will likely increase understanding and cooperation during the early years and may even reduce well established struggles with self-care in later years²⁸ as they will have grown up with shared responsibility for and a greater sense of control over their T1D. Family-centered behavioral interventions exist for T1D pre-teens and teens and have been effective in improving glycemic control in kids and quality of life within families.^{29, 30} Thus, including young children as additional targets of self-management intervention is a logical next step in the development of innovative and developmentally-targeted interventions for families of young children with T1D

To date, four pilot studies have evaluated interventions exclusively designed for parents of young children with T1D, but only two have shown any impact on improving children's glycemic control.³¹⁻³⁴ Specifically, in one study, a multifamily in clinic group education program was trialed and the results demonstrated lower HbA1c levels among children for the 41% of parents who attended >3 groups versus the 59% of parents who attended fewer groups.³¹ However, the study was not randomized, the intervention was delivered during children's T1D clinic appointments, and the non-attenders also had a significantly lower attendance rate at their child's routine T1D clinic appointments making it difficult to solely ascribe changes in children's HbA1c levels to the intervention. The second study is part of our own preliminary work. In this study, we also piloted a multifamily group treatment program for parents. Nine families participated (M child age 5.0±1.2 years; see Preliminary Studies).³³ Our BEST MEALS intervention showed a 26 mg/dl decrease in children's average daily glucose levels (185±46 v 159±40 mg/dl, pre- to post-treatment, respectively, p<0.001) with virtually no change in children's rate of hypoglycemia, suggesting the intervention helped parents to safely improve their child's daily glycemic levels. We also found an improvement in mealtimes and parents reported a high level of treatment satisfaction. However, our pilot study was also not randomized, the treatment was parent-based and delivered face-to-face (limiting its scalability) and the content was highly focused on mealtimes. The treatment outcome literature for young children with T1D is limited, but preliminary studies and our own pilot work suggests: (1) families are interested in participating in behavioral interventions, (2) interventions focused on age-appropriate T1D education and reducing disruptive child behavior can lead to improved child glycemic levels. Additional work is needed to build on these preliminary studies to increase the generalizability and impact of these behavioral interventions.

One way to consider increasing the impact of existing interventions for families of young children is to modify their mode of treatment delivery from face-to-face encounters and in clinic visits to a more modern technology-based method using the internet or a cellular phone. Behavioral interventions are typically labor and time-intensive, which can limit their impact and feasibility.^{35, 36} But using technology to deliver a behavioral intervention, while not a short-cut to intervention, could enhance both its generalizability and scalability by minimizing traditional barriers to participation, including travel to the medical center, child care, and time off from work.³⁵ Also, for families of children with T1D, a technology-based intervention may be more feasible than an in clinic intervention because at most, youths are seen only quarterly and data suggest that the majority of families attend fewer than four diabetes clinic appointments per year.³⁷ There is growing evidence showing acceptability of internet interventions in adolescents with T1D³⁸⁻⁴¹ and their parents.⁴² In three of these studies,³⁹⁻⁴¹ the interventions resulted in improved T1D self-care. Two studies showed improvements in self-efficacy and quality of life,^{38, 42} while one study showed an effect for youths' HbA1c.⁴¹ Specific to mobile technology ("mHealth"), several studies have investigated the impact of using text messaging in adolescents and adults with T1D⁴³⁻⁴⁶ and one study compared text messages versus email.⁴³ In this study, both email and text message recipients experienced a short-term improvement in adherence, but the researchers noted a drop off in the use of these technologies after 3 months. It is possible that this drop off occurred because of the type of messages youths received which were only generic reminders to complete self-monitoring glucose checks versus more personalized feedback and reinforcement.⁴³ However, the emergence of more advanced communication technology now makes it very feasible to offer patients' personalized feedback to enhance intervention.⁴⁴ In short, using technology is a smart way to address the barriers to traditional face-to-face intervention that families articulate. Internet and mHealth interventions are feasible and acceptable in families of adolescents with T1D. Also, as packaged interventions for delivery via the internet or by cellular phone, these interventions would be easy to disseminate across centers.

Human Subjects Involvement, Characteristics, and Design

Aim 3 will involve a randomized pilot test (RPT) of DIPPer Academy. We propose to enroll up to 50 parents of young children with T1D into the RPT. Parents who participate will be randomized to either an immediate treatment or a control group. Parent will be recruited via letter, telephone call, or in clinic. Parents will be asked to give written informed consent for their participation and permission to obtain a measure of HbA1c level in their child. Parents will be asked to complete study assessments (online surveys) at Time 1 (baseline), Time 2 (post-treatment), and Time 3 (follow up). We will collect child HbA1c at Times 1, 2, and 3. We anticipate that parents may spend about 3 hours completing the DIPPer Academy curricula spread out across 14 weeks of treatment. We expect the surveys at Times 1, 2, and 3 will each time take about 20 minutes to complete.

All parents regardless of gender, race, ethnicity, and socioeconomic class will be considered potentially eligible to participate. Specific inclusion criteria for parents are:

1. Parents of a young child who is between 3-5 years old and at least 3 months post T1D diagnosis.
2. Parents who are English-speaking.

Parent exclusion criteria for are:

1. Young children with evidence of type 2 diabetes or monogenic diabetes.
2. Parents with evidence of severe psychiatric disorder.
3. Young children with a comorbid chronic illness (e.g., renal disease) that requires ongoing care beyond T1D.
4. Young children with a history of anemia or medication use that may interact with glycemic control (e.g., systemic steroids).
5. Young children with an HbA1c $\leq 7.5\%$ (which is the current ADA target).⁶

Sources of Materials

For all participating parents, we will collect demographic data and medical history data specific to T1D. We will also collect data via parent surveys and usage data collected during the intervention (i.e., website use statistics). Survey and parent usage data will be entered and stored in an electronic database (REDCap). This database will be located on a secured server maintained by the Department of Biostatistics at KUMC. No one outside of the research team will have access to data identifying the families who participated. We will obtain a measure of child HbA1c.

Potential Risks

The overall risks of participation in this project are no more than minimal.

1. Because the research requires the collection of personally identifying data, there is always a risk of breach of confidentiality.

2. Parents will be requested to disclose information about their child's diabetes adherence and about their values, sources of motivation, regimen knowledge, their psychosocial and behavioral functioning, their priorities for diabetes management, and their concerns about their child. Disclosing this information may potentially lead to emotional discomfort. Parents may also feel inconvenienced by the amount of time required to complete the study.
3. We will obtain a measure of children's HbA1c levels.
4. There is the potential risk that parents participating in the projects will find their participation time-consuming and inconvenient.

ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent

Potential subjects will be identified by a review of the clinic database and in consultation with the clinic director at CMH. Eligible parents will be notified of the project by a letter sent by the study team, by a telephone call placed by a member of the study team, or by in person solicitation. All parents will be explicitly told that they can continue to receive the same high quality of care from their child's diabetes team regardless of their decision to participate in the research projects. During the initial study contact, a member of the research team will describe the study and parents will have a chance to ask questions. During the informed consent process, parents will be explicitly told that their participation is voluntary and that they maintain the right to discontinue participation at any time. The research protocol and consent documents will be approved by the Institutional Review Board at CMH. (Note, KUMC and CMH already have an agreement in place which will allow the PI to seek a Request to Rely so that CMH will be the IRB of record for both CMH and KUMC should the project proceed). Consent forms will be filed in a confidential research file and copies will be given to parents/guardians. The consent forms will include contact information for the Principal Investigator and Co-Investigators should families have any questions or concerns regarding the research project. No study procedures will occur before written consent is obtained from parents.

Protection Against Risk

Before the project begins, Institutional Review Board approval will be obtained from the Institutional Review Board at CMH. In addition, all research team members will complete certification in topics related to the responsible conduct of research. Certification will involve passing an online competency in each of the following areas: Foundations of Responsible Research Conduct, Safe Handling of Blood Products, Research Administration, and Conflict of Interest.

Minimization of Risks:

1. We will use several procedures to ensure confidentiality of information collected throughout the project. Each participant will be assigned a unique subject ID number which will be used to identify/store all data collected from that participating family. When possible, all identifying information will be physically separate from the remainder of the data. Identifying information will be recorded only for the purpose of matching and merging databases and will be stored in a locked file cabinet or on a secured server separate from any corresponding data. All research data will be stored in a secure, password protected database and archived in a password-protected back up file. We will minimize risks to privacy during data collection by giving parents the option of home visits and using on-line survey completion.
2. During recruitment and the informed consent process, parents will be informed as to the time commitment necessary for participation, as well as the potential risk for emotional/social discomfort. Parents will be informed that they have the right to discontinue participation in the projects at any time. They also have the right to refuse to answer specific questions related to the projects. While the surveys proposed for this study are generally benign in nature and have been used in other pediatric diabetes research projects, should participation in this study unmask or exacerbate parents' feelings about diabetes, members of the research team will be clinically trained to provide a list of resources. Parents may be asked to complete a screener for depressive symptoms. These screeners will be reviewed by the post-doctoral fellow within 24 hours of completion and the results shared with the PI. If a screener suggests a parent may be experiencing symptoms of depression, the PI or fellow (under direct clinical supervision of the PI) will contact the parent to review the results and to provide a list of resources to the parent.
3. We propose to collect children's HbA1c levels at Times 1, 2, and 3 during the randomized pilot trial. The purpose of measuring children's HbA1c levels will be to explore the impact of DIPPer Academy on children's glycemic control even though children will not participate in the intervention.
4. Participating may inconvenience parents. We will minimize the potential risk of inconvenience by offering parents the opportunity to participate in a project from their home. If parents do not own a mobile device or would prefer not to use their personal mobile device to access DIPPer Academy, we will loan parents an iPad Mini with data plan for use during the study. Prior to informed consent, parents will be informed

of their ability to discontinue participation in a research project at any time without penalty. Discontinuation from a research project will not impact a child's care by their Diabetes Team. The PI will ensure that research staff is trained to explicitly inform parents of the purpose, procedures, and risk related to participating in one of these research projects.

5. We hypothesize that DIPPer Academy will be deemed feasible and acceptable by parents and will have a beneficial effect on children's HbA1c. We have attempted to minimize the potential risk of inconvenience to parents participating in DIPPer Academy by designing the intervention as a mHealth intervention. Parents will be able to access the DIPPer Academy website from their computer or any mobile device. From the website, they will be able to view the video microlectures at any time and as often as they wish.
6. Dr. Clements will be available to provide medical supervision.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

There is a chance parentss will perceive no direct benefit to study participation. In this case, parents who elect to participate have the opportunity to contribute to our evolving knowledge related to glycemic control in children with T1D and the development of preventative interventions to promote optimal glycemic control in young children with T1D.

IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

The proposed research project is part of a larger initiative to develop the infrastructure and research base to support the development of targeted behavioral interventions aimed at improving glycemic control in children with T1D. The knowledge gained from these projects will directly inform the development of a real-time and tailored technology-based intervention for parents of young children with T1D that will utilize educational, behavioral, and motivational strategies to improve glycemic control. Development of an effective intervention could significantly enhance care provided to these children and improve their health outcomes. Information obtained from these projects could lead to more efficacious health behavior interventions for children with T1D as well as other pediatric populations.

DATA AND SAFETY MONITORING PLAN

Before the proposed projects begin, we will obtain approval from the Institutional Review Board (IRB) at Children's Mercy Hospital (CMH). The PI will also secure approval from her home institution, the University of Kansas Medical Center, to Rely on the IRB at CMH as the IRB of record for the projects. In compliance with regulatory practices, the PI and Co-Investigators will secure "continuing approval" for the research projects each year from the CMH IRB and will notify the CMH and KUMC IRB's if any Adverse Events (AEs), Other Reportable Information and Occurrences (ORIOs), and Unanticipated Problems Involving Risks to Subjects or Others (UaPs) occur in the conduct of the projects. The PI (with the assistance of Co-Investigators, as needed) will assume primary responsibility for reporting AEs, ORIOs, UaPs, or unforeseen outcomes to the IRBs in a timely fashion and will promptly inform the study sponsor of any action taken by the IRB at CMH because of continuing review. The proposed research designs have been developed keeping in mind how to maximize specific data collection and minimize risk to parents (i.e., psychometrically sound and benign questionnaires, Dr. Clements' availability to provide medical supervision of patients). However, at the discretion of the CMH IRB, the PI will recruit a Data Safety and Monitoring Board (DSMB) to oversee and monitor the data collection and intervention delivery. We propose members of the DSMB will include an endocrinologist, a psychologist, and a certified diabetes educator. If a DSMB is requested by the CMH IRB, we propose that the DSMB will meet at least annually by teleconference. For each of these meetings, the PI and the biostatistician will jointly prepare a summary of the following topics:

Performance monitoring: A report of subject recruitment/retention, protocol adherence, and quality of data collection procedures.

Safety monitoring: A review of safety of the participants, including confidentiality and any adverse events or side effects related to the study procedures.

STATISTICAL ANALYSIS PLAN

Hypotheses:

Hypothesis 1: DIPPer Academy will result in better Time 2 HbA1c than standard of care controlling for Time 1 measurements.

Hypothesis 2: DIPPer Academy will result in improvements in HbA1c across time (a decreasing time trend for HbA1c).

Hypothesis 3:

Hypothesis 4: DIPPer Academy will result in greater reported Time 2 parent self-efficacy and lower reported post-treatment parenting stress, mealtime behavior problems and hypoglycemia fear than standard of care, controlling for Time 1 measurements on these variables.

Data Analyses. For the primary outcomes, we will conduct a sensitivity analysis to test for any effects due to attrition. We will also use an intent-to-treat strategy and imputation model to examine parent data even if they are lost to attrition. For all analyses, we will include parental depression as a covariate if determined to be correlated with our outcome variables. To test for between group differences in glycemic levels (Hypothesis 1), we will conduct an ANCOVA with Time 2 (post-treatment) score as the outcome, group (treatment vs. control) as focal predictor, and Time 1 (baseline) score as covariate. In addition, we will calculate within group standardized effect sizes (in SD units) and within-group changes for HbA1c based on Time 1 and Time 2 values. To estimate and test time trends in glycemic levels for DIPPer participants (Hypothesis 2) we will use appropriate generalized mixed models with a random parent intercept to account for clustering of repeated measures within parents. Finally, to test for post-treatment differences between groups in reported parent self-efficacy, parenting stress, mealtime behavior problems, and hypoglycemia fear (Hypothesis 3) we will calculate within group standardized effect sizes (in SD units) and within group changes for parents' PSESDM, PIP, BPFAS, and HFS-PYC scores using parents' Time 1 and Time 2 data. To test for statistical significance, we will conduct an ANOVA for each variable as described above for Hypothesis 1.

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