Project Title: Cognitive Adaptations to Reduce Emotional Stress Associated with Type 1 Diabetes

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**Study 2. Develop a preventative behavioral intervention for families of school-agers with T1DM.**

**Current Research Design.** We will recruit families to participate in a small pilot trial a video-based telehealth intervention to reduce diabetes distress, depressive symptoms, and hypoglycemia fear in parents of school-age children with type 1 diabetes. Diabetes distress comprises a constellation of negative psychological symptoms that may make it harder for children and parents to manage type 1 diabetes, leading to suboptimal health outcomes for children. There are promising examples of treatments to reduce diabetes distress for mothers of adolescents with type 1 diabetes and in adults with type 1 diabetes, but no interventions targeting parents of school-age children with type 1 diabetes specifically.

**Objective: To compete a pilot trial of a new video-based telehealth intervention to reduce diabetes distress, depressive symptoms, and hypoglycemia fear in parents of school-age children with type 1 diabetes.**

**Subjects.** We will recruit eligible families from the Diabetes Center at Children's Mercy-Kansas City (CMH). All families regardless of gender, race, ethnicity, and socioeconomic class will be considered potentially eligible to participate.

Family Inclusion Criteria are:

1. families with a child with T1DM between the ages of 5 and 12 years old,
2. T1DM diagnosis within 12 months of enrollment,
3. child using either basal/bolus or insulin pump therapy,

Family Exclusion Criteria are:

1. current involvement in foster care,
2. evidence of type 2 or monogenic diabetes,
3. the presence of severe psychiatric disorders or comorbid chronic conditions (e.g., renal disease) that require ongoing care beyond T1DM,
4. chronic use of medications that may impact glycemic control (i.e., systemic steroids),
5. a diagnosis of developmental delay,
6. non-English speaking families (the proposed study surveys are currently only available in English).

**Procedure.** Clinic staff will identify eligible families and research team members will recruit families. Once informed consent is obtained, parents will complete a demographic questionnaire. Families will complete a baseline assessment visit (viz., adherence measures and HbA1c kit) before the first treatment session. Following completion of treatment, families will complete a post-treatment assessment. Families will receive $40 each for completing the baseline and post-treatment assessments (total $80).

**Outcome Measures.** Primary outcome measures will be: parents' diabetes distress, depressive symptoms, and hypoglycemia fear. Secondary outcome measures will be the Feasibility and Acceptability the new treatment.

Diabetes Distress. We will use the Problem Areas in Diabetes-Parent Report (PAID-PR). This is a validated 18-item measure of diabetes distress with higher scores suggesting greater distress. Scores can range 0-72.

Depressive Symptoms. We will use the Center for Epidemiological Studies Depression Scale-Revised (CESD-R). This is a validated 20-item measure of depressive symptoms with higher scores suggesting more depressive symptoms occurring over the past 2 weeks. Scores can range 0-60.

Hypoglycemia Fear. We will use the Hypoglycemia Fear Survey for Parents (HFS-P). This is a validated 25-item measure of hypoglycemia fear with higher scores suggesting more fear. Scores can range 25-125.

Treatment Satisfaction. We will use a study specific 15-item survey to assess for treatment satisfaction. Survey scores can range from 15-75, with higher scores suggesting greater satisfaction/acceptability.

**Hypothesis.**

Hypothesis 1. Parents who participate in our new intervention will report lower diabetes distress post-treatment and at three-months follow-up.

Hypothesis 2. Parents who participate in our new intervention will report reduced depressive symptoms and hypoglycemia fear post-treatment and at three-months follow-up

Hypothesis 3. Our intervention will be feasible, meaning that it would exhibit an attrition rate of <25% of families and a group attendance rate of >85% of all telehealth sessions.

**Data Analysis***:* To test Hypothesis 1, we used a series of repeated measures analysis of variance (ANOVA) models with parent group (8- versus 12-sessions) as a between-subject variable, time as a within-subject variable, and parents' diabetes distress score as the dependent variable. We used separate models to test for treatment effects between parents' pre- and post-treatment diabetes distress scores and between parents' pre- and 3-months follow-up distress scores (maintenance effect). To test for treatment effects in Hypothesis 2 (i.e., parents' depressive symptoms and hypoglycemia fear scores), we used a similar analytical approach. We will use descriptive statistics to test for Hypothesis 3.

**Power Analysis***:* A sample of 12 families may not have sufficient power for the exploratory analyses. But this sample is sufficient to (1) obtain estimated effect sizes for the exploratory outcomes, which can be used to power a larger clinical trial; and (2) assess initial feasibility/acceptability of the intervention.