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An Intervention to Reduce Hypoglycemia Fear in Parents of Young Kids using Video-Based Telehealth (REDCHiP)

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Abstract

Introduction: To evaluate the efficacy of a new video-based telehealth intervention to reduce hypoglycemia fear in parents of young children with type 1 diabetes.

Methods: We randomized 42 parents to either immediate treatment (REDCHiP; n=22) or a waitlist control (WAITLIST; n=21) condition. REDCHiP parents completed a ten-session video-based telehealth intervention, while WAITLIST parents continued in usual care. After 14-weeks, WAITLIST parents completed the telehealth treatment. We examined for between group changes in parental hypoglycemia fear and parenting stress (n=18 per condition), three-month maintenance of treatment effects for parents randomized to REDCHiP (n=15), and pre-post changes for the entire sample (n=36).

Results: Mostly mothers participated (97.6%). They reported a mean age of 35.2±5.0 years at pre-treatment. Children were 4.4±1.4 years old and 59.5% boys. Between group comparisons showed a significant reduction in hypoglycemia fear (p=0.04) and a trend toward reduction in parenting stress-frequency (p=0.092) for REDCHiP parents compared to WAITLIST parents. After the three-month maintenance period, REDCHiP parents reported significant reductions in hypoglycemia fear, parenting stress-frequency, and parenting stress-difficulty (p's<0.01) compared to pre-treatment. When all parents received the telehealth treatment, we also observed significant reductions in hypoglycemia fear, parenting stress-frequency, and parenting stress-difficulty (p's<0.001), and sensitivity analyses revealed a significant reduction in child glycated hemoglobin for children who entered the treatment above target (p< 0.05).

Discussion: Our new video-based telehealth intervention appears to reduce hypoglycemia fear and parenting stress and may help parents of very young children with T1D to better achieve optimal child glycemic control when children are above target.

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Introduction

Hypoglycemia is the most common acute adverse event for children with type 1 diabetes.[1,2] Children experience higher rates of severe hypoglycemia than adults with type 1 diabetes[1] and very young children (<7 years) are particularly vulnerable to asymptomatic and nocturnal hypoglycemia because of their heightened insulin sensitivity, erratic eating and exercise behaviors, and inability to report hypoglycemia symptoms.[2–4] For parents who are the primary caregiver of a very young child with type 1 diabetes, these factors contribute to very high rates of parental fear of hypoglycemia (FH).[5] Up to 50–60% of parents report moderate FH and 20–30% report severe FH.[5–7] FH impairs quality of life and parents who experience FH often engage in hypoglycemia avoidance behaviors such as maintaining elevated blood glucose levels in their child.[8,9] Consistently high FH also relates to parenting stress, distress, and diabetes burn-out.[10–12] Interventions exist to address FH and teach blood glucose awareness in adult patients with type 1 diabetes.[13–15] There is also at least one intervention targeting FH and teaching blood glucose awareness in older children with type 1 diabetes.[16] However, to date, no interventions have specifically targeted FH in parents of young children with type 1 diabetes despite the high prevalence of FH in this patient group. Thus, to address this apparent gap in treatment, we developed a new video-based telehealth intervention to reduce FH in parents of very young children with type 1 diabetes: the Reducing Emotional Distress for Childhood Hypoglycemia in Parents (REDCHiP) intervention. The goal of this study was to test the initial efficacy of our telehealth intervention to reduce FH in parents of very young children with type 1 diabetes. We hypothesized a difference in FH and stress for parents who immediately received the intervention versus parents in a wait-list control group and we hypothesized that parents who immediately received the intervention would maintain reductions in FH and stress after three-months. Finally, we hypothesized that all parents receiving the intervention would experience significant reductions in FH, parenting stress, and diabetes distress and that children would experience improved glycemic control after parents received the intervention.

Methods

Participants and Procedures

We recruited families during a regularly scheduled diabetes clinic visit or via telephone contact from a single Pediatric Diabetes Center located in the Mid-Western United States. Eligible families had a child, between 1–6 years-old, with type 1 diabetes for at least six months, and on either multiple daily injections or an insulin pump. Parents had to be child's legal guardian and English-speaking to participate. Parents provided written informed consent for their own participation, as well as consent for data collection from their child. Researchers obtained approval for all study procedures by the local institutional review board prior to study initiation. We randomly assigned 43 families using block assignment by child sex to the immediate treatment (REDCHiP) or a waitlist control (WAITLIST) group (Figure 1). We stratified families by child sex to enable exploration of sex as a biological variable. All families completed a baseline assessment visit. Then, families randomized to REDCHiP began the weekly 10-session video-based telehealth intervention. Families

randomized to WAITLIST began the telehealth intervention after their 14-week assessment visit.

At baseline, all parents provided basic demographic and medical history information. We assessed outcome variables at baseline (or pre-treatment) and post-treatment. Parents randomized to REDCHiP also completed measures approximately 3 months after completing the intervention (e.g., maintenance). Families received compensation for completing each study assessment but parents did not receive compensation for attending intervention sessions.

Intervention

Our novel parent-focused intervention, called Reducing Emotional Distress for Childhood Hypoglycemia in Parents (REDCHiP), uses principles of cognitive behavioral therapy to help parents to reduce their FH and maladaptive avoidance behaviors, promote healthy coping, and reduce distress. Specifically, parents work with group leader(s) to recognize thoughts and behaviors related to their FH, develop a personalized fear hierarchy of T1D-related situations from least to most fearful (i.e., missing the symptoms of a hypoglycemic event, trusting another adult to safely treat a hypoglycemic event, checking blood glucose only one time during the night versus multiple times), develop and refine their coping strategies (i.e., relaxation exercises, self-care skills, finding support), and practice imagined and in-vivo exposures to challenge any maladaptive thoughts/behaviors related to their FH (i.e., use positive self-talk to challenge the fear that they will miss recognizing a hypoglycemic event). In addition, parents receive support from other parents and the group leader(s), review T1D management skills to build confidence for managing their child's T1D, and learn behavioral parenting strategies to manage general child behavior.

REDCHiP is a manualized intervention. It includes 10 telehealth treatment sessions (7 group-based and 3 individual sessions) delivered remotely via the HIPAA-compliant Zoom application. Treatment sessions were typically 30–60 minutes in duration. During sessions, the group leader(s) reviewed any homework from previous sessions, covered new treatment material and facilitated parent discussion, as well as explained any new homework assignments. While we invited all parents who have primary responsibility for their child's T1D management to participate, in most instances, only one parent from each family attended the groups. The group leader(s) (1–2 per group) were clinical psychology doctoral students and were supervised by a licensed clinical psychologist and certified diabetes educator.

Measures

Hypoglycemia Fear Survey for Parents of Young Children (HFS-PYC):

a 26-item self-report measure of FH conceptualized as worries and maladaptive behaviors.[5,17] Parents rate items on a 5-point Likert scale from 1 (Never) to 5 (Very Often). We summed items to compute the total score (range: 26–130) as well as two subscale scores reflecting parents' Worry (range: 16–80) about FH and use of Hypoglycemia Avoidance Behaviors (range: 10–50). For these scales, higher scores indicating greater FH.

Pediatric Inventory for Parents (PIP):

a 42-item measure of perceived stress related to parenting a child with a chronic illness.[12] Parents rate each item independently based on their perceptions of how often the item occurs (parenting stress-frequency) and how difficult the item is (parenting stress-difficulty). We scored the PIP separately for parenting stress-frequency and parenting stress-difficulty (range: 0–168 for both), with higher scores indicating greater perceived stress.

Problem Areas in Diabetes (PAID-PR):

an 18-item measure of diabetes-specific distress.[18] Parents rate each item using a 5-point Likert scale 0 (Not a problem) to 4 (Serious problem). A subset of parents completed the PAID-PR (n=25). We summed parent responses to compute a total perceived diabetes distress score (range: 0–72).

Child glycemic levels (HbA1c):

We used HbA1c level as a proxy measure of average glycemic levels at pre-treatment and post-treatment. We collected a finger-prick blood sample from children. We analyzed children's HbA1c levels in a single laboratory using automated high performance liquid chromatography, with measurement methods reliable to Diabetes Control and Complications Trial (DCCT) standards (Reference range 4.0–6.0%; Tosoh 2.2, Tosoh Corporation, San Francisco, CA).[19]

Data Analyses

We assessed between-group differences for parental FH and parenting stress using a repeated measure analysis of variance (ANOVA) factored by randomization group. We examined pre-post treatment outcomes for parental FH, parenting stress, diabetes distress, and child glycemic levels (e.g., HbA1c) for all treatment completers using paired-sample t-tests. Additionally, we examined for pre-post treatment outcomes in child HbA1c among children who entered treatment above the glycemic target of ≥7.5%, which was the standard at the time of the trial.[20] Finally, we examined treatment maintenance effects using paired samples t-tests for the subset of parents with long-term follow-up data. Where applicable, we report effect sizes for treatment outcomes using partial eta-squared (ηp^2), generally interpreted as small (0.01), medium (0.09), or large (0.25). Unless otherwise stated, we set alpha at 0.05 for two-tailed tests.

Results

At baseline, parents had a mean age of 35.2±5.0 years, 97.6% were mothers, 81.0% were married, and 78.6% reported a Hollingshead Socio-Economic index score of at least 4 (21). Children had a mean age of 4.4±1.4 years, 59.5% male, 95.2% Caucasian, and 5.1% Hispanic/Latino. Most children (78.6%) were on an insulin pump and 40.5% used a continuous glucose monitor. Average child HbA1c was 8.07±1.02% (Range = 5.20–10.10%) and 21.4% of children achieved glycemic targets of HbA1c <7.5% at baseline. Over half of parents (59.5%) reported that their child experienced a low blood glucose event at least 1–2 times per week and one family (2.4%) reported that their child had experienced a

hypoglycemic seizure (see Table 1). Families who enrolled in the study did not differ in age at time of enrollment (p=.91), but had a younger age at diagnosis [Population M=3.1±1.4 years; F(1, 189)=17.4, p=.002] and lower HbA1c [Population M=9.37±1.82%; F(1, 189)=19.7, p<.001] than the hospital mean for this age group. There were no significant differences between intervention completers (N=36) and those lost to attrition (N=6) in demographics or baseline variables, although there was a trend toward higher Hollingshead Socio-Economic indexes (p=.067) for intervention completers.[21] Parents who began treatment attended 94% of intervention sessions.

Between-Group Differences

Comparing parents in REDCHiP (n=18) versus WAITLIST (n=18) (see Figure 2), we observed significant reductions in parental FH (F(1,34)= 4.490, p=0.04, ηp^2=.117) and a statistical trend suggesting a reduction in parenting stress-frequency (F(1,34)= 3.013, p=0.09, ηp^2=.081). We did not observe reductions by group in parenting stress-difficulty (p=.628). We also did not observe differences by group for diabetes distress (PAID-PR Total p=0.41).

Maintenance of Treatment Outcomes

For the subset of parents randomized to REDCHiP and who completed the long-term follow-up assessment (n=15), we saw significant reductions from pre-treatment to follow-up for FH (t(14)=5.419, p<.001), parenting stress-frequency (t(14)=4.169, p=.001) and difficulty (t(14)=3.708, p=.002), and perceived diabetes distress (t(9)=3.286, p=.009). Within the domain of FH, parents noted significant reductions in both hypoglycemia avoidance behaviors (p<.001) and worry (p<.001).

Pre-Post Treatment Outcomes

Because all parents had the opportunity to receive the telehealth intervention at some point, we examined overall pre-post changes. Consistent with our hypothesis, after parents received the telehealth intervention they reported significant reductions in FH (t(34)=4.667, p<.001), parenting stress-frequency (t(34)=4.548, p<.001) and parenting stress-difficulty (t(34)=2.08, p=.045), and perceived diabetes distress (t(34)=4.667, p<.001). Within the FH domain, parents reported significant reductions in both hypoglycemic avoidance behaviors (p=.005) and worry (p<.001). We did not observe a reduction in child HbA1c (p=.12) among all completers, but when we re-examined and focused on children who entered the treatment with an HbA1c level above target, we did observe a significant reduction in child HbA1c (p<0.05) (see Table 2).

Discussion

Overall, our findings suggest initial efficacy for a novel video-based telehealth intervention tailored to reduce FH in parents of very young children with type 1 diabetes. We examined for efficacy based on between-group comparisons for REDCHiP versus WAITLIST parents, treatment maintenance effects for REDCHiP parents, and finally pre-post comparisons for all parents receiving our manualized telehealth intervention. Across our analyses, our intervention resulted in significant reductions in parent FH and at least a trending reduction

in parenting stress-frequency. Notably, in our pre-post comparisons, our intervention also resulted in significant reductions in parenting stress-difficulty, parent-reported diabetes distress, and child HbA1c for children who entered treatment above their glycemic target.

While past research has explored the prevalence of FH among parents of very young children with type 1 diabetes,[5,6,11,22,23] our intervention represents the first targeted intervention to reduce FH in this special population. To target our intervention for parents of young children, we included behavioral parenting strategies to help parents manage age-appropriate child problem behaviors such as unpredictable eating and physical activity patterns, tantrums, and non-cooperation.[24–29] We also adapted cognitive-behavior strategies, such as identifying cognitive distortions, cognitive reframing, exposure and response prevention, and coping to address the specific fears parents of young children may experience related to hypoglycemia (e.g., leaving their child in another adult's care, night time, mistreating a hypoglycemic event).[5–7] We believe these adaptations helped to make our treatment successful because they enabled parents/group leaders to focus on the unique concerns of parents of young children with type 1 diabetes. Of note, there are existing FH treatment programs for adults with type 1 diabetes.[14,15,30–35] For the most part, these treatment programs have also been multicomponent and included diabetes education as well as cognitive-behavioral strategies to reframe negative thoughts, emotions, and behaviors related to FH. However, unlike our results, treatment outcomes in adults suggest these programs may be more successful in reducing the frequency of hypoglycemia avoidance behaviors versus FH worry.[30–35] Moreover, the two exceptions to this, Blood Glucose Awareness Training and HypoCOMPaSS, only found reductions in worry among a subset of adults with a history of severe hypoglycemic events and hypoglycemia unawareness.[14,15] Therefore, our results provide novel outcome data from a targeted intervention showing preliminary efficacy for using cognitive-behavioral therapy to reduce FH in parents of very young children with type 1 diabetes regardless of the family's experience with hypoglycemia.[16]

We believe another innovation of our REDCHiP intervention is its use of a group-based telehealth approach. Other interventions have shown acceptability and preliminary efficacy for using individual telehealth to promote self-care engagement and reduce conflict in families of older youth with T1D,[36] but we believe this is the first example of a group-based telehealth approach targeting parent FH and child glycemic control. In our group-based approach, parents had the opportunity to seek support and learn from each other in addition to the group leader(s). In previous research, there is evidence supporting the efficacy of group treatment for anxiety disorders within the general population as well as a high level of patient satisfaction.[37,38] There is also evidence suggesting that group-based interventions have a benefit of being fairly cost-effective, which may promote larger dissemination.[38] Our results also suggest a high level of parent satisfaction and preliminary efficacy when applying a group-based approach to reduce parent FH. Our decision to design and deploy REDCHiP as a telehealth intervention has specific relevance to families with a very young child with T1D. While the incidence of T1D is high in very young children,[39,40] typically very young children comprise only a small number of youth with T1D in most diabetes centers. Therefore, if designed to be delivered in person, we were concerned that the relatively small number of families with a very young child with T1D within individual

centers and the distance many families need to travel to reach their child's diabetes clinic, might prevent future scalability of REDCHiP. However, by adopting a telehealth approach, we believed REDCHiP could be easy to deploy across multiple clinics thereby promoting greater family access to this behavioral health treatment.

As an exploratory outcome, we examined for changes in child HbA1c after parents received our intervention. In pre-post comparisons, we did not see a significant reduction in child HbA1c for all our intervention completers. However, we did see a significant 0.25% reduction in child HbA1c when we analyzed the data for children who had an HbA1c level that was above target at pre-treatment. Because our primary outcome was parental FH, in our pilot study, we did not exclude families based on child HbA1c at pre-treatment. We justified this because we thought it was possible that a parent could still experience significant FH and potentially benefit from our telehealth intervention even if their child had already achieved a HbA1c level <7.5%. In our sample, we had ten parents whose children had a pre-treatment HbA1c level of <7.5% and their mean FH was comparable to parents of children with a pre-treatment HbA1c level of ≥7.5% (73.60±16.53 versus 69.73±18.20, parents of children with HbA1c <7.5% and parents of children with a HbA1c ≥7.5%, respectively, p=0.562). Past research shows that psychosocial outcomes are generally more robust than glycemic outcomes following psychosocial and behavioral interventions in type 1 diabetes.[41] However, there is evidence of small-to-moderate reductions in child HbA1c (0.20–0.46%) resulting from a few self-management-based interventions.[36,42] Our observed HbA1c reductions in the subset of children with a pre-treatment HbA1c level of ≥7.5% mirror these small effects and suggest that it may also be effective to reduce child HbA1c by targeting parental FH.

This pilot efficacy trial has a several strengths including its randomized design, relatively low rate of family attrition (16%), use of a wait-list control group, use of psychometrically-sound outcome measures, and use of a single laboratory to analyze children's HbA1c levels. However, there are also some limitations. First, as a pilot efficacy trial, we recruited a small, generally homogeneous sample from a from a single Midwestern pediatric hospital system. Therefore, the next step is to conduct a confirmatory trial in a larger, multi-site trial to determine generalizability of our findings. Second, we recruited primarily mothers to participate in the intervention. In future trial, researchers will need to recruit fathers to determine if our telehealth intervention can successfully reduce FH in fathers as well as mother. Third, there are potential limits to our exploration of maintenance effects because we only tracked treatment outcomes for up to three-months post-treatment. In future examinations, researchers should consider assessing treatment maintenance up to six or twelve months post-treatment. Relatedly, it may prove interesting to assess for maintenance effects with the addition of periodic booster sessions in the post-treatment period to encourage parent engagement with treatment content. Fourth, there is the chance that we did not observe some differences in parent outcomes because of limited power. Again, it is possible that a future larger trial would have more power to detect between group differences in pediatric parenting stress-difficulty and diabetes distress because of our telehealth intervention. Alternatively, it may be possible in a larger trial to assess for any treatment differences between parents of young children who use a continuous glucose monitor versus parents of young children who do not.

We demonstrated initial efficacy of a novel video-based telehealth intervention to reduce FH in parents of young children with type 1 diabetes. We also observed reductions in parenting stress, diabetes distress, and a trend towards improvement in glycemic outcomes for those with HbA1c above target at baseline. A future larger trial is merited to confirm these findings. However, these results currently support the use of both cognitive behavioral techniques and group-based telehealth to address FH in parents of very young children with type 1 diabetes.

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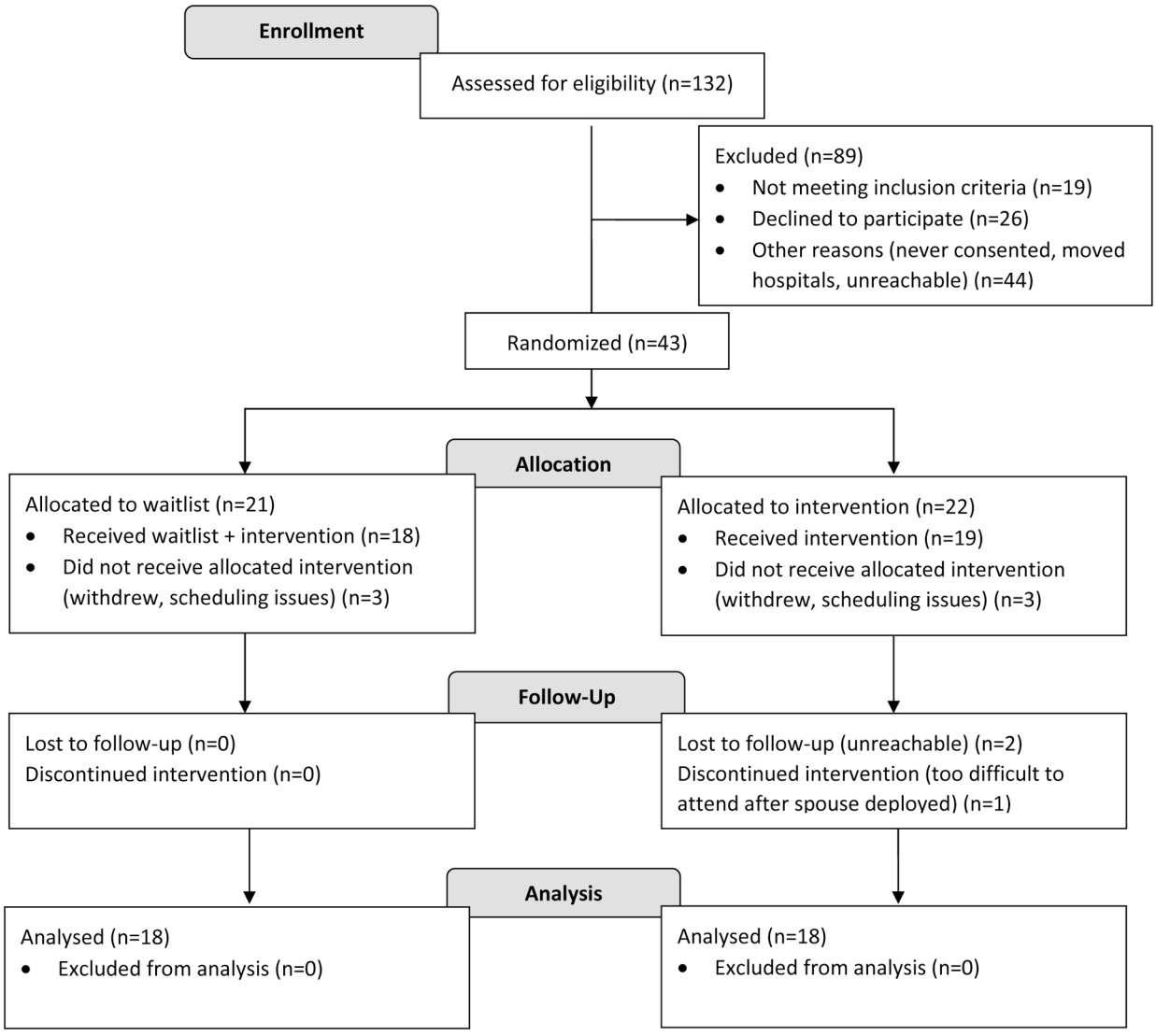

Figure 1.
CONSORT flow diagram of study participants.

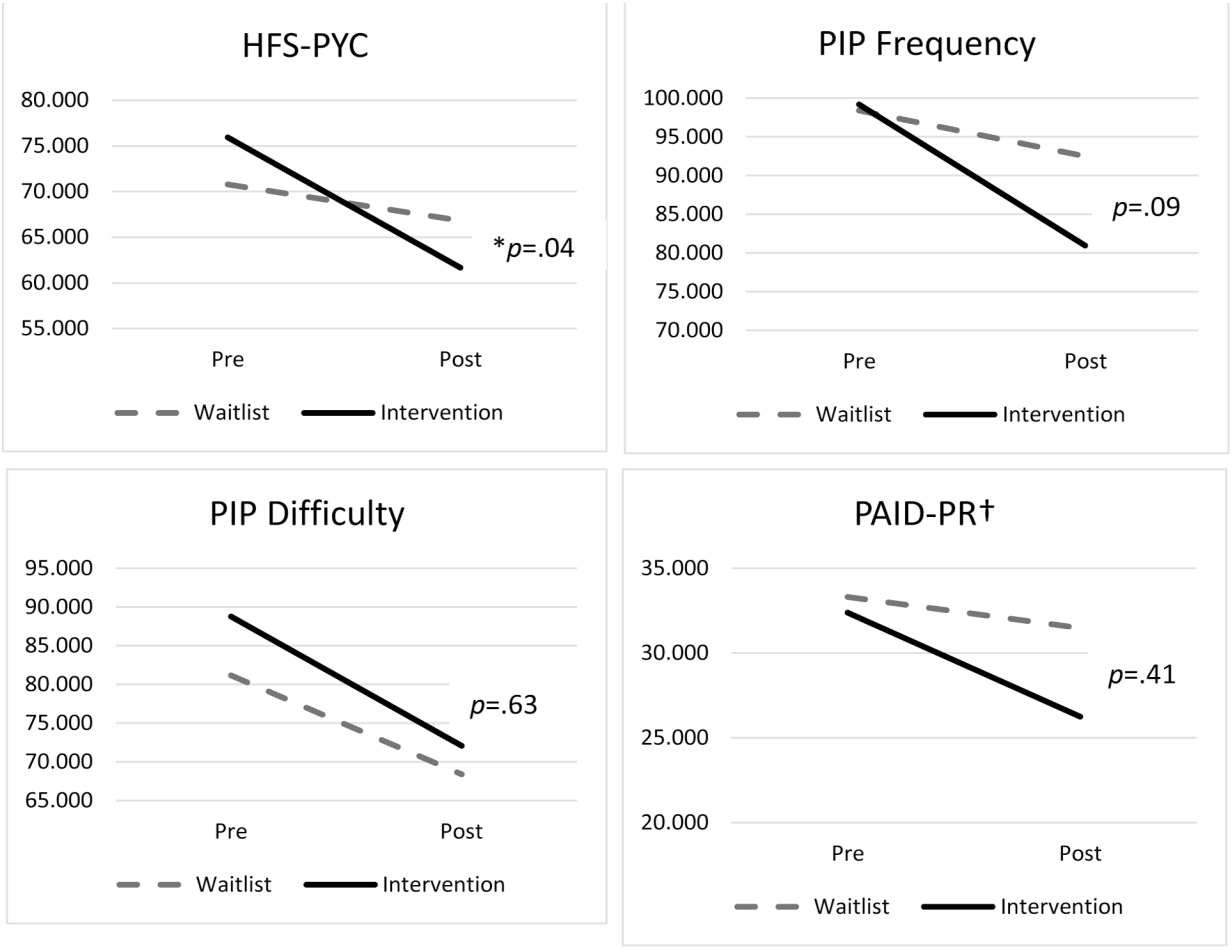

Figure 2.

Between groups comparison of primary outcome variables.

Note. *Indicates groups are significantly different at p<.05. N=36 except †indicates N=25.

Table 1.

Descriptive characteristics of the study sample at time of enrollment.

Variable	M (SD)	Range	N (%)
Parent			
Age (years)	36.0 (4.9)	25.0–45.0	
Mothers			40 (97)
Marital Status			37 (89)
Hollingshead Category			
1			2 (4.8)
2			2 (4.8)
3			4 (9.5)
4			17 (40.5)
5			16 (38.1)
Child			
Age (years)	4.4 (1.4)	1.0–6.99	
Age at diagnosis (years)	2.4 (1.2)	0–5.0	
HbA1c at baseline	8.01 (1.02)	5.20–10.10	
Boys			25 (59)
White			40 (95)
Hispanic/Latino			2 (4.8)
Insulin Pump			34 (80)
CGM			19 (46)

Table 2.

Pre- to post-treatment outcomes (paired sample t-tests).

Variable	Pre-Treatment (M+SD)	Post-treatment (M+SD)	95% Confidence Interval	P-value
Child HbA1c	8.01±1.02	7.89±1.03	−0.04 to 0.30	.120
Child HbA1c (>7.5% at baseline)†	8.62±0.79	8.39±0.80	0.01 to 0.44	.041
Parent HFS-Total (HFS-PYC)	71.5±16.5	59.9±15.7	6.53 to 16.61	<.001
Parent HFS-Behavior (HFS-PYC Behavior)	30.5±6.1	26.9±6.1	1.81 to 5.33	<.001
Parent HFS- Worry (HFS-PYC Worry)	40.9±11.9	33.9±10.2	3.34 to 9.99	<.001
Parenting Stress- Frequency (PIP- Frequency)	95.9±23.4	81.8±20.5	7.82 to 20.46	<.001
Parenting Stress- Difficulty (PIP- Difficulty)	79.0±30.6	70.6±28.2	0.19 to 16.66	.045
Parent Depressive Symptoms (CESD-R)	11.1±10.4	9.2±9.7	-0.83 to 4.54	.169
Parent Self-Efficacy (PSESDM)	32.9±5.2	33.7±4.8	-2.46 to 1.03	.411
Parent Diabetes Distress-Total (PAID-PR)‡	32.4±17.6	24.9±15.7	2.54 to 12.55	.005
Parent Diabetes Distress-Immediate (PAID-PR Immediate) ‡	9.6±7.0	7.3±6.8	0.03 to 4.57	.047
Parent Diabetes Distress-Theory (PAID-PR Theory) ‡	22.6±11.4	17.6±9.7	2.15 to 8.35	.002

Note. N=36;

† N=24, HbA1c >7.5% at baseline;

‡ survey added after cohorts 1 and 2, so N=25.