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Patient Reported Outcomes (PROs) and User Experiences of Young Children with Type 1 Diabetes Using t:slim X2 Insulin Pump with Control-IQ Technology

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Abstract

Objective: Examine patient-reported outcomes (PROs) after the use of t:slim X2 insulin pump with Control-IQ technology (CIQ) in young children with type 1 diabetes.

Methods: Children with type 1 diabetes, ages 2 to <6 years (n=102), were randomly assigned 2:1 to either CIQ or standard care (SC) with pump or multiple daily injections (MDI) plus continuous glucose monitoring (CGM) for 13 weeks. Both groups were offered to use CIQ for an additional 13 weeks after the randomized control trial's (RCT) completion. Guardians completed PRO questionnaires at baseline, 13-, and 26-weeks examining hypoglycemia concerns, quality of life, parenting stress, and sleep. At 26 weeks, 28 families participated in user-experience interviews. Repeated measures analyses compared PRO scores between systems used.

Results: Comparing CIQ vs SC, responses on all 5 PRO surveys favored the CIQ group, showing that CIQ was superior to SC at 26 weeks (p values < 0.05). User-experience interviews indicated significant benefits in optimized glycemic control overall and nighttime control (28 of 28 families

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endorsed). All but 2/28 families noted substantial reduction in management burden resulting in less mental burden and all but 4 stated that they wanted their children to continue using CIQ.

Conclusions: Families utilizing CIQ experienced glycemic benefits coupled with substantial benefits in PROs, documented in surveys and interviews. Families utilizing CIQ had reduced hypoglycemia concerns and parenting stress, and improved quality of life and sleep. These findings demonstrate the benefit of CIQ in young children with type 1 diabetes that goes beyond documented glycemic benefit.

X/Twitter summary:

Families with young children with #T1D using Control-IQ experienced both glycemic benefits and had reduced hypoglycemia concerns, parenting stress, and improved quality of life and sleep.

Keywords

psychosocial; young children; type 1 diabetes; sleep; fear of hypoglycemia; automated insulin delivery

INTRODUCTION

Diabetes devices and advanced technologies offer substantial health and quality of life benefits for people with type 1 diabetes[1]. For example, automated insulin delivery (AID) systems demonstrate significant gains in time in range (TIR) and reduction of hypoglycemia[2,3]. A unique group within the larger type 1 diabetes population is young children below the age of 6 years because of their specific needs and challenges associated with their developmental stage. This group relies primarily on a guardian for management and safety and may have little awareness of symptoms of the extremes of the glucose range. Yet these children are the ones wearing the devices and navigating various activities with diabetes in the background. For these reasons, young children with type 1 diabetes need advanced tools and specific considerations in clinical trials.

In a recent study examining the use of the t:slim X2 insulin pump with Control-IQ technology (CIQ, Tandem Diabetes Care, San Diego CA) in this age group, we reported robust improvements in TIR, hemoglobin A1c (HbA1c), and hyperglycemia reduction[4]. During that clinical trial, an evaluation of the guardian (a person who is legally responsible for the youth such as a parent) user experience was also conducted. The focus of this analysis is on the user experience, defined as assessment of validated patient-reported outcome (PROs) measures completed by guardians and interviews about their experience in the trial and with the AID system. The primary objective is to quantify the guardian experience, and we hypothesized that they would experience benefits on PROs and report benefits beyond the improved glycemic outcomes of the children.

RESEARCH DESIGN & METHODS

Trial Overview

The Pediatric Artificial Pancreas (PEDAP) trial was a multicenter, randomized, unblinded, parallel-group trial designed to compare the CIQ system with standard care (SC).

Individuals were recruited to participate by three pediatric diabetes centers located in different areas of the United States, namely the University of Virginia (UVA), the Barbara Davis Center at the University of Colorado (BDC), and Stanford University.

An independent data and safety monitoring board oversaw the safety aspects of the trial. Funding was provided by the National Institute of Diabetes and Digestive and Kidney Diseases. The study is registered on clinicaltrials.gov (NCT04796779).

Study Participants

Inclusion criteria were people with type 1 diabetes ages 2 to <6 years old who were diagnosed at least 6 months prior to enrollment, took insulin for ≥6 months, took ≥5 units of insulin daily, had a body weight of >9.1kg (20lbs), and did not use an AID system. Guardians in the study were self-selected, living in the residence with the child, and considered the primary or joint caregiver. The full inclusion and exclusion criteria list can be found in the study protocol[4].

Procedures

Families were given the choice to onboard and complete study visits virtually or in a clinic, and over 90% of visits were completed virtually. All participants were randomly assigned in a 2:1 ratio to either the CIQ system or standard care (non-AID pump or multiple daily injections (MDI) with a continuous glucose monitor (CGM)) for 13 weeks. Randomization was assigned per trial site using a computer-generated sequence with a permuted block design. The randomization scheme, data validation, and monitoring were managed by the coordinating center, the Jaeb Center for Health Research. Both groups had the option to utilize CIQ during a subsequent 13-week period. At 26 weeks, families were given the opportunity to participate in user experience interviews to discuss their experiences with CIQ (Figure 1).

Families assigned to the standard care group continued to use their personal pump (23 participants: 11 using the Tandem t:slim X2 with Basal-IQ, 11 using the Omnipod DASH, and 1 using the Medtronic 670G in open-loop mode) or MDI (10 participants) during the randomized control trial (RCT) and were trained on how to use the study-provided CGM (Dexcom G6, Dexcom)[4]. Both groups had access to real-time updates of their glucose values through the CGM during the study. The guardians of participants assigned to use CIQ were trained on the study pump and the study CGM. After the completion of the RCT, both groups were invited to participate in the Extension Phase (study weeks 14 to 26). Standard care group participants received training on using CIQ on entering the Extension Phase upon completion of the RCT. Participants assigned to the CIQ group during the RCT continued use of CIQ for the same period. Clinical site personnel were allowed to adjust pump settings when needed throughout the study.

The families of all participants were given training on hypoglycemia treatment, hyperglycemia treatment, and carbohydrate counting. Additionally, they were provided with blood glucose meters and strips (Contour Next One, Ascensia Diabetes Care) and ketone meters and strips (Abbott Precision Xtra, Abbott Diabetes Care).

Patient Reported Outcomes

Validated patient-reported outcome questionnaires were completed by guardians at baseline, 13 weeks, and 26 weeks (for those who completed the study extension). They report on their perspective as the primary caregiver of a young child with type 1 diabetes on all PROs except the PedsQL in which they report on their perspective of the child's quality of life.

The Hypoglycemia Fear Survey (HFS-II) contains 26 questions and measures the worry and fear of hypoglycemia. The items focus on various aspects of fear of hypoglycemia: behavior, worry, avoidance, maintaining high blood glucose, helplessness, and social consequences. Higher scores indicate more fear around hypoglycemia[5].

The Hypoglycemia Confidence Survey is an 8-item questionnaire that asks about managing hypoglycemia in multiple scenarios. Guardians provided their perspectives on preventing and managing hypoglycemia with higher scores indicating more confidence[6].

The Pediatric Quality of Life (PedsQL) Diabetes Module contains 32 items and identifies the impact of diabetes on everyday activities and health under a guardian's proxy. The PedsQL diabetes module has items on treatment, impact on social and everyday activities, and perception of health. Higher scores are indicative of better child quality of life perceived by the guardian[7].

The Pediatric Inventory for Parents contains 42 items and identifies common parenting concerns (eg, making medical decisions, changing a child's medical routine) for children with serious medical conditions. The items measure the frequency and difficulty of emotional distress, medical care, communication, and role function. Higher scores indicate greater stress associated with managing their child's condition[8].

The Pittsburgh Sleep Quality Index (PSQI) is a 9-item questionnaire that measures sleep quality and patterns. Lower scores reveal fewer sleep disruptions and better sleep quality for the guardian[9].

PROs questionnaires were scored according to the instructions provided by their reference manuals.

Glycemic Outcomes

All participants wore a CGM (Dexcom G6) during the 13-week randomized trial period and the 26-week extension. The primary glycemic outcome was the percent of TIR 70-180 mg per deciliter (3.9-10.0 mmol per liter). Hemoglobin A1c (HbA1c) was measured at randomization, at 13 weeks, and at 26 weeks at the Advanced Research and Diagnostic Laboratory at the University of Minnesota.

User Experience Interviews

Once participants finished their 26-week study, their guardians had the option to participate in user experience interviews individually or in groups based on guardian availability. These were led by the Stanford study team and questions focused on expectations, how quality of life changed, likes and dislikes of CIQ, and future use.

Interviews were transcribed through a professional service, Landmark Associates (Phoenix, AZ, USA). Interviews were coded using a thematic analysis approach based on the frequency of answers to each question. All transcripts were analyzed by two authors (AKSU, KKH). The transcripts were analyzed and compiled into a single document containing the common responses, where each theme was represented by quotations from guardians.

Analytic Plan

A repeated measures regression model was run using data at baseline, 13 weeks, and 26 weeks. A comparison of CIQ versus SC was made by including a time dependent treatment group indicator variable. Significance was set to $p < 0.05$ after adjustment for multiple comparisons using the false discovery rate. Analyses were performed with the use of SAS software, version 9.4 (SAS Institute).

RESULTS

This sample of young children with type 1 diabetes ranged in age from 2 to 6 years (mean 4.17±1.23) with a HbA1c of 7.2% (55 mmol/mol) (±0.80) at the beginning of the trial's Extension Phase. The majority (98%) were on CGM prior to starting the trial. Full sample characteristics are shown in Table 1.

The mean (±SD) time that glucose was in the target range increased with the use of CIQ compared with SC. For the CIQ group, the mean TIR increased from 57% (±18) at baseline, to 70% (±11) at the end of 13 weeks and remained stable at 70% (±11) for those who completed the 13-week extension (at 26 weeks). In this group, the mean time below range (TBR, glucose level <70 mg/dl) remained constant from 3.0% (± 2.2) at baseline to 3.0% (±1.8) at the end of 13 weeks and decreased to 2.5% (±1.4) at the 26-week extension. In the SC group, TIR increased from 55% (±15) at baseline to 56% (±13) at the end of 13 weeks. TBR increased from 2.7% (±2.0) at baseline to 3.0% (±2.2) at the end of the 13 weeks. For nighttime control, TIR was 74% for the CIQ group and 56% for the SC group[4]. For those in SC who participated in the extension and used CIQ, TIR increased to 68% (±9) at 26 weeks[10].

Repeated measures analyses from PROs collected at baseline (SC n=33, CIQ n=63), 13 weeks (SC n=31, CIQ n=63), and 26 weeks (SC → CIQ n=30, CIQ → CIQ n=59) (see Table 2) indicated that parenting stress scores lowered (p=0.05), hypoglycemia fears scores decreased (p=0.02), hypoglycemia confidence scores increased (p=0.04), child quality of life scores increased (p=0.02), and sleep quality scores were reduced (p=0.005) for participants on CIQ versus standard care (based on the guardian's perspective).

User Experience Interviews

Of the 102 families enrolled in the study, 28 participated (6 from BDC, 11 from UVA, and 11 from Stanford) in the user experience interviews. These interviews were held virtually between December 2021 and July 2022. Full themes and associated quotes are included in Table 3. Overall, user experience interviews revealed that guardians were most pleased with nighttime glycemic control and the increase in TIR during the day. Guardians also

reported quality of life benefits, with 21 of 28 families noting a major reduction in diabetes management burden resulting in less mental burden. They attributed this to worrying less about out-of-range glucose values and were more confident letting their children go to school or other places outside of their care (Table 3).

Although all guardians provided some positive feedback, they also noted some areas that require improvement. Many noted that the system was not aggressive enough for treating highs (n=17). They mentioned the system was more “hands-off” than they had expected. However, the families expressing this had similar TBR averages as those who did not mention this. Five guardians noted that site changes were more painful and took longer to heal than their child’s former pump. Nevertheless, at the end of the interviews, all but four guardians stated they wanted their children to continue using CIQ (n=24/28), and three of those four indicated interest in an alternative AID system due to the tubing and lack of remote bolusing on the pump. As a result, most families (n=27/28) expressed a preference for continued use of an AID system.

DISCUSSION

Results show that the use of the t:slim X2 insulin pump with Control-IQ Technology in this young age group is associated with robust improvements in commonly used PROs, and user experience interviews highlight benefits beyond glycemic outcomes. Specifically, guardians endorsed fewer hypoglycemia fears while also gaining confidence in their ability to prevent and treat hypoglycemia. Guardians also reported improved quality of life regarding their child’s diabetes health and functioning and endorsed better sleep for themselves after using CIQ. Guardians noted in interviews that they felt less management burden and preferred to continue using AID. Overall, there are substantial benefits to using CIQ in young children with type 1 diabetes that go beyond glycemic improvements.

The combination of validated surveys and interviews provides a fuller snapshot of the experience of guardians of young children using CIQ. We can hypothesize, given the steadily improving scores with each subsequent time point (Table 2), that the improvement of time in range during the day and at night drove many of the associated benefits (e.g., sleep, less worry, better quality of life). Many guardians directly attributed their quality of life benefits to glycemic changes. Almost all felt safer on CIQ and preferred to stay on CIQ (or AID) after the trial ended.

The results obtained from the five PROs and user experience interviews revealed that the young age group experienced significant benefits from using this system. These findings are further supported by the fact that the SC group achieved 56% (±13%) TIR, while the group using CIQ achieved 70% (±11%) TIR[4]. The results for improved glycemic control using CIQ reflect the results of additional studies across different age groups. In a study with older children 6-13 years old, the mean TIR over 16 weeks was 67% (±10%) in the CIQ group compared to 55% (±13%) in the group using a sensor-augmented insulin pump[11]. In a study with participants ranging from 14-71 years old, TIR at the end of 6 months using CIQ was 71% (±12%) compared to those using a sensor-augmented insulin pump which remained

unchanged at 59% (±14%)[12]. An additional study is noteworthy in this young age group[13] with similarly robust improvements with a different AID system.

While overwhelmingly positive, it is worth noting that less than one-third of participants completed user experience interviews. It is possible the experiences provided by those who participated do not fully reflect the entire sample. The interview comments, however, are supported by the PROs scores, which are reliable, validated measures that were completed by almost all the study families. There are elements of the CIQ algorithm and the t:slim pump that are still viewed as needing improvements, such as more aggressive treatment of hyperglycemia, improved infusion sets, and smaller devices. Despite these concerns about the system, guardians overwhelmingly wanted to continue to use CIQ over their previous diabetes management.

In summary, although no AID system is specifically designed for young children, CIQ can achieve robust glycemic and quality of life benefits in young children with type 1 diabetes and their families. As AID systems evolve and are used more frequently in younger children, it is apparent that they can provide significant benefits to this age group and their families beyond glycemic improvements; however, some considerations specific to this unique population should be considered.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Author Conflict of Interest:

K. K. Hood has received consulting fees from Cecelia Health. B. A. Buckingham is on the Medtronic Scientific Advisory Board and has received research support from Tandem, Dexcom, Insulet, Medtronic, Beta Bionics, JDRF, and NIH. E. Cobry has been a speaker and advisory board member for Dexcom. M. D. DeBoer has received research support from Dexcom, Tandem and Medtronic. L. Ekhlaspour is funded by NIH 1K23DK121942. She has received consulting fees from Tandem Diabetes Care, and Ypsomed, Speaker fee from Insulet, and research support from Medtronic, Mannkind and JDRF through her institution. R. P. Wadwa has received research support from Dexcom, Eli Lilly & Co and Tandem Diabetes Care through his institution, received conference travel support from Dexcom and Eli Lilly & Co., and received speaking/ consulting honorarium from Dexcom and served on advisory boards for Eli Lilly & Co. and Provention Bio. M. D. Breton reports research funding and material support from Dexcom, Tandem, and Novo Nordisk, through by his institution. MDB reports consulting fees from Dexcom, Physiologic LLC, Roche, and Sanofi; MDB reports speaker fees and travel reimbursement from Sanofi and Tandem. A. K. Schneider-Utaka, Z. W. Reed, M. Schoelwer, J. Lum, C. Kollman, R. W. Beck, have no conflicts to report.

Data Availability Statement:

The study data will be made available at a later date at https://public.jaeb.org/datasets/diabetes.

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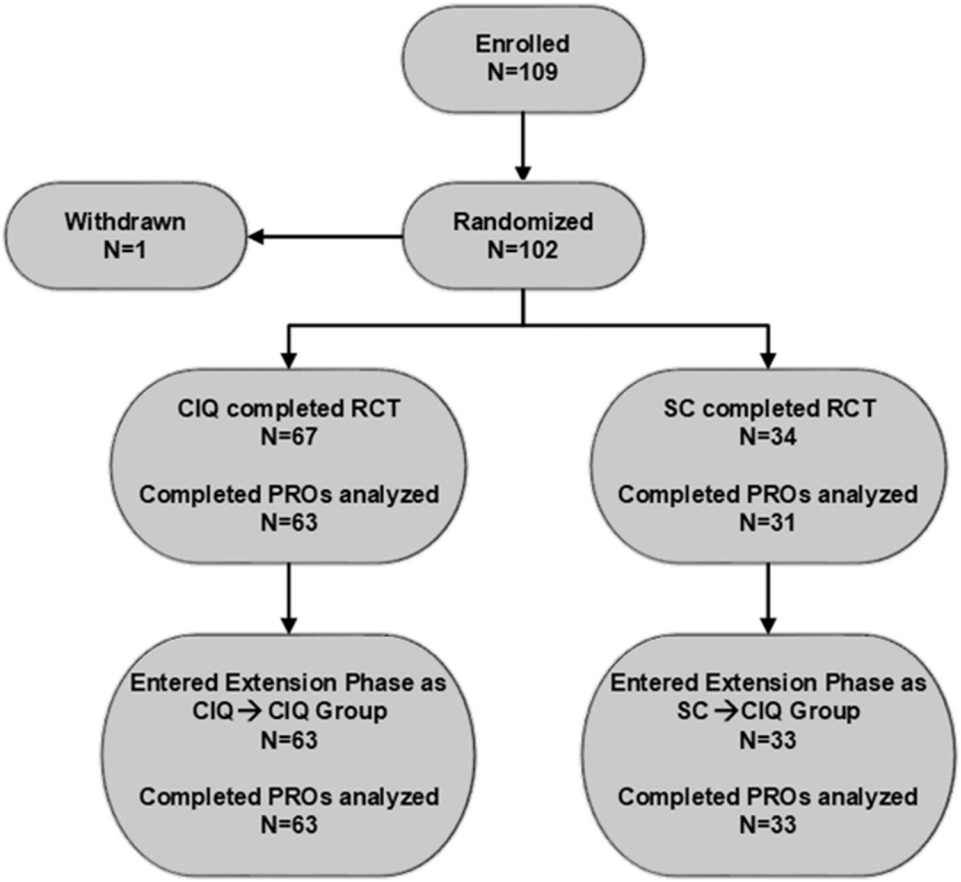

Figure 1: Study Flow by Treatment Group

Among the 96 participants enrolled in the 13-week extension, all but 4 completed it.

Table 1:

Baseline Participant Characteristics

	Overall N = 96	SC* N = 33	CIQ** N = 63
Age			
Mean (years) ± SD	4.17 ± 1.23	4.32 ±1.23	4.10 ± 1.23
Range (years)	2.30 – 6.33	2.35 – 6.22	2.30 – 6.33
Female – n (%)	51 (53)	19 (58)	32 (51)
Non-Hispanic White – (%)	81 (84)	28 (85)	53 (84)
T1D Duration at 13 Weeks*** – n (%)			
0.5 to <1 year	16 (17)	3 (9)	13 (21)
1 to <2 years	53 (55)	21 (64)	32 (51)
2 to <4 years	23 (24)	7 (21)	16 (25)
≥4 years	4 (4)	2 (6)	2 (3)
Range	0.77 to 5.32	0.84 to 5.32	0.77 to 4.30
Health Insurance at Baseline**** – n (%)			
Private Insurance†	74 (78)	25 (78)	49 (78)
Medicare	3 (3)	1 (3)	2 (3)
Medicaid‡	10 (11)	3 (9)	7 (11)
Other Government Insurance	8 (8)	3 (9)	5 (8)
HbA1c*			
<7% – n (%)	37 (41)	9 (28)	28 (48)
7% to <8% – n (%)	37 (41)	13 (41)	24 (41)
8% to <9% – n (%)	15 (17)	9 (28)	6 (10)
≥9% – n (%)	1 (1)	1 (3)	0 (0)
Mean ± SD	7.2 ± 0.8	7.0 ± 0.7	7.5 ± 0.9
Insulin Modality at Baseline – n (%)			
Insulin Pump	63 (66)	23 (70)	40 (63)
MDI	33 (34)	10 (30)	23 (37)

*SC: participants continued using their baseline insulin delivery modality while incorporating Dexcom CGM.

**CIQ: participants used the Tandem t:slim X2 pump with Control IQ and the Dexcom CGM.

***T1D Duration at 13 Weeks: the duration of T1D at the end of the initial period and before the extension.

****Missing data (SC/CIQ): annual household income (2/4), health insurance (1/0), and HbA1c (1/5).

†For participants with private insurance, 6 also had Medicaid, 1 participant also has Medicare, and 1 participant also had other government insurance.

‡For participants with Medicaid, 1 participant also had other government insurance.

Table 2:

PROs scores across the study timeline

	SC → CIQ			CIQ → CIQ			
	Participants on SC 13 weeks, then CIQ 13 weeks			Participants on CIQ all 26 weeks			
	Baseline (N=33)	13 weeks (N=31)	26 weeks (N=30)	Baseline (N=63)	13 weeks (N=63)	26 weeks (N=59)	P-value CIQ vs. SC*
Pediatric Inventory for Parents† (frequency score of how often common parenting concerns happen, eg, making medical decisions, changing child's medical routine)	91.2 ± 21.3	88.5 ± 24.1	80.6 ± 17.0	93.7 ± 24.7	88.4 ± 25.1	82.5 ± 26.8	0.05
Pittsburgh Sleep Quality Index† (quality of sleep in general, not specific to diabetes)	8.3 ± 3.2	8.0 ± 3.6	6.3 ± 2.9	7.8 ± 3.4	6.5 ± 3.4	5.8 ± 3.3	0.005
Fear of Hypoglycemia Total Score† (items about worry, fear about hypoglycemia)	41.9 ± 16.4	38.7 ± 15.3	35.6 ± 12.8	44.0 ± 17.5	37.5 ± 17.0	34.8 ± 16.9	0.02
Hypoglycemia Confidence Total Score (items about managing hypoglycemia in various situations)	64.8 ± 16.2	65.4 ± 16.5	68.8 ± 16.4	60.7 ± 17.8	72.9 ± 16.3	73.2 ± 14.9±	0.04
PedsQL Diabetes Module Total Score (items about the impact of diabetes on everyday activities, social areas, and health per the guardians)	74.4 ± 8.6	74.8 ± 9.9	77.3 ± 7.8	72.5 ± 11.8	77.3 ± 9.7	78.1 ± 10.2	0.02

*P-values from repeated measures analysis with False Discovery Rate correction and accounting for baseline values.

Mean (SD). † Lower score is better

Table 3:

Guardian Experiences of the CIQ System

Theme	Participant Examples
Expectations of CIQ	• "We expected it to kinda control her highs better than her previous system was doing. We expected it even to help with the lows 'cause it has more fine-tuning with that." • "I guess it was—our biggest thing was to prevent the lows at night."
Glycemic Control	• "I think he went from I think a 12 [% HbA1c] to a 7 [% HbA1c] on the pump." • "The nighttime part of it and it closing off when she doesn't need the insulin is impeccable." • "I would say it's also really helpful at daycare because I don't have to worry about these crashing lows."
Improved Quality of Life	• "I think she enjoyed it too 'cause she didn't have to wake up as much for the lows." • "With regard to the lows, he did spend a lot less time going to the nurse's office and being dosed by the nurse and just her management, it took a lot less time with him also, so that improved." • "I would say that we've probably gotten four more hours extra sleep."
Improved Mental Health	• "It was parallel to what I was doing before without the extra stress." • "I will say it's given us a lot more freedom and confidence to manage her diabetes." • "It's just been a huge improvement in our—my mental health is so much better, and stress level has gone down a lot since starting the study"
Shortcomings of the Algorithm	• "Highs, it doesn't correct s strongly as you would like it to." • "I kind of wish the algorithm was a little bit more aggressive because I know that it's not gonna correct until it's expecting to go over 180, 160. It'll start ramping up the basal, but, the majority of the time, if it's gonna correct going over 180, it's already too late." • "There was a lotta times that it didn't shut off when it would say it was supposed to shut off."
Physical	• "She wasn't a fan of the tubing, which was initially what we thought she wouldn't like. Yeah. She was okay wearing it for the study because we talked to her about what it was for. She wasn't a fan of long-term usage." • "I don't like those infusion sets; any of 'em. I don't like the cartridges and the—'cause I was only used to shots or pods and they're both so easy. I didn't like all the pieces and the long setup and take-down."
Trusting CIQ	• "It was like within a week or two I realized he was taking her solo places, and it was like I didn't have that anxiety around it, because I knew something else was helping out in the background." • "I guess maybe about a week or so, and then we saw how well it was starting to work." • "I wouldn't say that we "trust" the algorithm."