Received: 2 May 2022 | Revised: 6 July 2022 | Accepted: 11 July 2022

DOI: 10.1111/dom.14815

ORIGINAL ARTICLE

WILEY

Lived experience of CamAPS FX closed loop system in youth with type 1 diabetes and their parents

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Abstract

Aim: To examine changes in the lived experience of type 1 diabetes after use of hybrid closed loop (CL), including the CamAPS FX CL system.

Materials and Methods: The primary study was conducted as an open-label, single-period, randomized, parallel design contrasting CL versus insulin pump (with or

Funding information
National Institute of Diabetes and Digestive and Kidney Diseases, Grant/Award Number: UC4 DK108520

without continuous glucose monitoring). Participants were asked to complete patient-reported outcomes before starting CL and 3 and 6 months later. Surveys assessed diabetes distress, hypoglycaemia concerns and quality of life. Qualitative focus group data were collected at the completion of the study.

Results: In this sample of 98 youth (age range 6-18, mean age 12.7 ± 2.8 years) and their parents, CL use was not associated with psychosocial benefits overall. However, the subgroup (n = 12) using the CamAPS FX system showed modest improvements in quality of life and parent distress, reinforced by both survey ($p < .05$) and focus group responses. There were no negative effects of CL use reported by study participants.

Conclusions: Closed loop use via the CamAPS FX system was associated with modest improvements in aspects of the lived experience of managing type 1 diabetes in youth and their families. Further refinements of the system may optimize the user experience.

1 | INTRODUCTION

Closed loop (CL) automated insulin delivery systems have led to substantial improvements in glycaemic outcomes in people with type 1 diabetes (see Forlenza and Lal reference 1 for recent review). CL systems automate insulin delivery via insulin pump and then base this on continuous glucose monitoring (CGM) results and an algorithm running on the device or smartphone. These 'smart' systems are intended to make insulin delivery more precise while reducing the decision-making burden that comes with type 1 diabetes management. In addition to glycaemic benefits of lowered haemoglobin A1c (HbA1c) and increased time in range,[2-4] several studies show broader benefits on the person's lived experience with diabetes (i.e. psychosocial benefits).[5-7]

Past reports in youth and their parents show great enthusiasm and high expectations in potential CL users.[8-10] Children tended to prefer that CL systems help with specific situations such as school or friend interactions, while adolescents preferred the systems to be discrete and manageable to wear; parents and other caregivers were much more focused on the safety and potential glycaemic benefits of the devices.[8] When evaluating the psychosocial benefits, patient-reported outcome surveys are often used to evaluate important areas such as quality of life[11,12] and diabetes-specific experiences such as emotional distress[13] and fear of hypoglycaemia.[14] In children and adolescents, the addition of the parent/caregiver perspective offers a unique view of the lived experience of these systems, given the variable demands on parents as the child ages. For example, a parent of a 6-year-old will be doing much of the management and operating the devices, while the parent of a 16-year-old may be remotely monitoring values from CGM and supervising insertions rather than doing them.

In addition to surveys, the lived experience of CL can also be obtained through focus groups and/or structured interviews. These experiences often draw out more context to daily use of a CL system and highlight situations that are more or less distressing as well as situations in which CL systems worked (or did not work) well.[8,9,15,16] The combination of the two methods results in a more complete picture of the lived experience of using CL systems in paediatric type 1 diabetes.

The primary objective of this study was to analyse survey and interview data from children and adolescents, and their parents, who participated in the CL trial and completed surveys. The primary article from the study has been published[17] showing improvement in HbA1c for CL versus control participants, and superiority of the CamAPS FX system compared with the FlorenceM system. For this study, planned analyses were carried out to document changes to survey responses across the study, and between groups, and provide additional context for CamAPS FX users through focus group analyses given the promise of this hybrid CL system.

2 | MATERIALS AND METHODS

This study was conducted as an open-label, single-period, randomized, parallel design contrasting CL versus a control condition.[17] The control condition involved insulin pump therapy with or without glucose sensor. The study duration was 6 months, and participants were recruited from diabetes outpatient clinics at seven UK and five US paediatric diabetes centres. Before initiating study procedures, approval was received from an independent research ethics committee in the UK (East of England-Cambridge East Research Ethics Committee), an independent review board in the United States (Jaeb Center for Health Research Institutional Review Board), regulatory authorities in the UK (Medicines and Healthcare products Regulatory Agency) and in the United States (Food and Drug Administration). Safety aspects were overseen by an independent data safety monitoring board. The study is registered with clinicaltrials.gov (NCT02925299).

2.1 | Study participants

Eligibility criteria were age between 6 and 18 years (inclusive), diagnosis of type 1 diabetes for ≥12 months, insulin pump therapy for ≥3 months and screening HbA1c between 53 and 86 mmol/mol

(7.0%-10.0%). Key exclusion criteria included current use of CL therapy, and more than one episode of severe hypoglycaemia or diabetic ketoacidosis during the preceding 6 months. Complete inclusion and exclusion criteria are noted elsewhere, along with full study procedures.[17]

2.2 | Procedures

Following randomization to either the CL or the control, those on CL were trained on the study insulin pump and glucose sensor and used this for 3-4 weeks in open loop mode before starting CL. The same Cambridge model predictive control algorithm (version 0.3.71) for insulin delivery was run on two different hardware iterations, FlorenceM and CamAPS FX. In the FlorenceM system, the translator/smartphone enclosure intermittently failed, limiting CL usage. To address the issue, different hardware, the CamAPS FX system superseded FlorenceM in July 2019 in the UK. In the United States, however, participants continued using FlorenceM until study completion, as the insulin pump for CamAPS FX did not have US regulatory clearance. For more detail on the difference between these two systems, please see the primary article and associated tables.[17]

Control participants continued using their usual insulin pump and, if applicable, CGM. Throughout the study, participants and/or their clinical team were free to adjust diabetes therapy, but no active treatment optimization was undertaken by the research team. All participants were provided with a 24-h telephone contact for the local study team. All participants wore a masked CGM (FreeStyle Libre Pro Flash Glucose Monitoring System) for 14 days at the study treatment initiation visit, and at 3 and 6 months. HbA1c was measured locally at enrolment, and centrally (Advanced Research and Diagnostic Laboratory University of Minnesota, MN, USA) at treatment initiation 3-5 weeks after randomization (baseline), and 3 and 6 months after treatment initiation. A Tosoh HPLC Glycohemoglobin Analyzer (Tosoh Medics, San Francisco, CA, USA) was used.

At the completion of 6 months of CL use, participants were offered participation in a focus group (or one-on-one interview). The uptake of this portion of the study procedures was low in FlorenceM users relative to CamAPS FX users. The focus groups were led by a psychologist, and questions included positives and negatives of CL use, system features and impact on quality of life and daily diabetes management. In the CamAPS FX subgroup we ran focus groups until no new ideas were reported (i.e. saturation had been reached).

2.3 | Questionnaires

Previously validated questionnaires were completed at baseline (before randomization) and at 3 and 6 months. All parents were offered the opportunity to complete surveys and those youth above the age of 11 years completed surveys, which included measures of the following.

2.3.1 | Parent depression

The Centre for Epidemiologic Studies-Depression (CES-D) provides a self-report of depressive symptoms. The CES-D is a 20-item measure.[18] Symptom frequency is rated 0-3 over a 1-week period. Higher scores indicate greater depressive symptoms.

2.3.2 | Diabetes-specific emotional distress

Parent diabetes distress was assessed by the Personal distress, Teen management distress and Parent-Teen relationship distress subscales of the Parent Diabetes Distress Scale.[19] Symptom severity was rated 0-4 over the past month. Scores are averaged, higher scores indicate greater diabetes distress. Youth diabetes distress was assessed with the 26-item measure Problem Areas in Diabetes-Teen (PAID-T).[20] Raters indicate on a 6-point scale how problematic each item was over the past month. Higher scores indicate greater diabetes distress.

2.3.3 | Hypoglycaemia concerns

Parents and youth above 11 years old completed the Hypoglycemia Confidence Scale,[21] which measures the degree to which the respondent feels able to stay safe from hypoglycaemia-related problems. They respond to eight situations (e.g. when exercising) and higher scores indicate greater confidence. Parents and youth above 11 years old also completed the Hypoglycemia Fear Survey, worry subscale.[22] Fear of hypoglycaemia, specifically the anxiety-provoking aspects of hypoglycaemia, was assessed by the 15-item Worry subscale where raters indicate on a 5-point scale how often they worry about low blood sugar over the past 6 months. Higher scores indicate worse fear of hypoglycaemia.

2.3.4 | Glucose monitoring satisfaction

The Glucose Monitoring Satisfaction Survey[23] evaluates satisfaction with glucose monitoring and results. Items focus on ease of use, hassle and perceived accuracy of monitoring devices. Higher scores on this 15-item scale indicate greater satisfaction. Parents completed one scale, the Emotional Burden subscale, and youth above 11 years completed all subscales.

2.3.5 | Technology attitudes

Attitudes about diabetes-specific technology were assessed[24] with this 5-item survey. Higher scores indicated more positive attitudes about devices and technology. Parents and youth above 11 years completed this survey.

2.3.6 | Pediatric Quality of Life

The Pediatric Quality of Life (PedsQL) scale[25] was used to provide an age-appropriate assessment of the youth's quality of life, and the parent report of their perceived quality of life of the youth. Analyses were conducted on the total score and subscales, and higher scores indicate better quality of life.

2.4 | Analytic plan

For the survey data, evaluation focused on potential interaction effects of group differences over time (group × time) between those in the CL arm versus the control arm (no CL) across three assessments (baseline, month 3, month 6). For each survey, repeated-measures ANOVAs using Type III Sums of Squares tested between-person differenced in treatment arm (group), within-person changes over time and interaction effects (group × time). Greenhouse-Geisser correction was used when sphericity could not be assumed. Significance was set to $p < .05$. Analyses were conducted with SPSS version 27.

Qualitative data were analysed using a thematic analysis approach.[26] First, three coders trained in qualitative data analysis independently read and open-coded a single transcript to develop an initial codebook that was then applied to additional transcripts and refined iteratively until no new codes emerged. Each transcript was coded by two coders, and the coding group met weekly to discuss codes, resolve discrepancies and refine the codebook.

3 | RESULTS

As reported in the primary article,[17] there were 133 participants randomly assigned to either treatment with CL (n = 65) or the control condition (n = 68). The sample was 44% ages 6-12 years and 56% ages 13-18 years; 57% female. At baseline, the mean HbA1c was 66 ± 8 (8.2% ± 0.07) in the CL group and 67 ± 8 (8.3% ± 0.08) in the no CL group; two-thirds of the participants were using CGM.

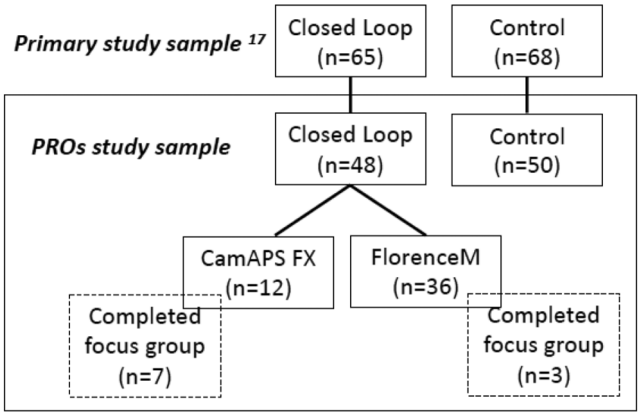

FIGURE 1 Study participants and flow-through study

TABLE 1 Youth survey responses and repeated-measures ANOVAs

	Baseline				3 months		6 months		p values		
	Closed loop		Control		Closed loop	Pump only	Closed loop	Pump only			
	n	Mean ± SD	n	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Time (within)	Group (between)	Time × group
Technology attitudes: diabetes specific	37	20.42 ± 3.35	33	20.33 ± 3.71	20.41 ± 2.95	20.61 ± 2.22	20.43 ± 3.76	20.61 ± 2.83	.93	.87	.92
Hypoglycemic confidence scale	37	26.51 ± 3.57	32	26.25 ± 4.55	26.32 ± 5.26	25.94 ± 5.71	26.05 ± 4.84	26.75 ± 4.26	.89	.98	.65
HFS-C worry subscale	25	26.04 ± 9.82	27	30.66 ± 10.99	27.76 ± 9.29	28.83 ± 8.82	26.43 ± 11.81	28.48 ± 8.57	.73	.28	.35
PAID-T	37	51.93 ± 19.92	34	47.65 ± 23.61	52.71 ± 21.17	48.56 ± 20.09	48.89 ± 17.33	44.22 ± 17.96	.16	.28	.99
Pediatric quality of life: diabetes module total	47	72.29 ± 11.99	48	71.37 ± 11.60	73.46 ± 12.19	71.64 ± 9.65	74.11 ± 12.25	72.61 ± 12.31	.24	.52	.88
PedsQL Comm. subscale	47	77.70 ± 20.89	48	82.42 ± 20.94	77.70 ± 21.37	81.12 ± 20.32	80.59 ± 18.37	85.07 ± 16.61	.14	.23	.91
PedsQL diabetes subscale	47	60.36 ± 14.09	48	56.97 ± 10.91	63.08 ± 15.26	58.47 ± 11.50	64.21 ± 14.63	59.35 ± 14.20	.02*	.08	.79
PedsQL treatment barriers subscale	47	79.47 ± 18.28	48	82.32 ± 18.64	81.06 ± 15.05	83.02 ± 15.09	80.24 ± 16.83	82.89 ± 17.64	.76	.41	.96
PedsQL treatment adherence subscale	47	86.28 ± 12.84	48	86.47 ± 14.08	86.25 ± 10.36	85.47 ± 13.27	85.02 ± 12.47	84.98 ± 13.83	.55	.92	.92
PedsQL worry subscale	47	74.82 ± 20.67	48	70.83 ± 20.56	72.70 ± 23.93	68.75 ± 22.77	76.42 ± 17.23	72.22 ± 22.70	.167	.291	.998

*$p < .05$.

TABLE 2 Youth CamAPS FX users

	Baseline				3 months		6 months		*p* values		
	Closed loop		Pump only		Closed loop	Pump only	Closed loop	Pump only			
	n	Mean ± SD	n	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Time (within)	Group (between)	Time × group
Technology attitudes: diabetes specific	9	20.22 ± 2.33	7	20.14 ± 3.76	20.89 ± 2.89	19.43 ± 1.81	22.22 ± 2.17	20.57 ± 3.91	.25	.33	.59
Hypoglycemic confidence scale	9	26.00 ± 4.09	7	23.71 ± 5.88	25.22 ± 3.73	25.29 ± 7.43	25.00 ± 3.81	24.86 ± 5.64	.94	.71	.59
PAID-T	9	52.22 ± 21.27	8	39.50 ± 15.85	50.22 ± 15.02	48.25 ± 26.70	44.00 ± 19.14	39.50 ± 18.85	.18	.46	.37
Pediatric quality of life: diabetes module	12	68.82 ± 7.96	12	75.45 ± 10.37	68.60 ± 9.11	71.80 ± 11.23	72.02 ± 9.20	73.59 ± 11.61	.24	.31	.27
PedsQL Comm. subscale	12	63.19 ± 18.96	12	89.58 ± 15.54	63.19 ± 17.57	73.61 ± 26.79	70.14 ± 11.49	82.64 ± 22.60	.04*	.03*	.05
PedsQL diabetes subscale	12	58.33 ± 11.44	12	55.87 ± 10.81	59.09 ± 12.26	56.63 ± 13.09	64.02 ± 12.37	57.20 ± 13.53	.21	.38	.47
PedsQL treatment barriers subscale	12	74.48 ± 14.22	12	89.06 ± 11.65	75.52 ± 15.18	83.33 ± 13.41	77.08 ± 12.31	84.38 ± 15.19	.74	.03*	.42
PedsQL treatment adherence subscale	12	80.65 ± 12.32	12	91.07 ± 13.66	82.74 ± 10.08	87.80 ± 12.13	81.25 ± 11.10	87.50 ± 14.16	.81	.10	.49
PedsQL worry subscale	12	77.78 ± 13.45	12	78.47 ± 16.84	66.67 ± 17.41	72.92 ± 23.87	75.00 ± 13.76	77.78 ± 19.57	.02*	.62	.62

*$p < .05$.

The analysis performed here included only those with questionnaire data, 98 of 133 participants (74% of the original sample). Figure 1 shows that the 98 analysed in this article included 48 in CL and 50 in the pump (with or without CGM). Of the 48 using CL, the majority were using FlorenceM (n = 36) compared using CamAPS FX (n = 12). Analyses comparing those who completed surveys from those who did not showed no significant differences on clinical and demographic characteristics (all $p > .05$). The 98 had a mean age of 12.7 ± 2.8 years and 85% of youth lived with both parents, 9% with one parent and 5% with one parent and another adult. Likewise, the FlorenceM and CamAPS FX subgroups had similar demographic characteristics as the larger sample of 133. While smaller sample sizes, the subgroups are representative of the primary study sample.

3.1 | Survey responses

Table 1 shows youth survey scores at baseline, 3 and 6 months and associated significance levels. There were no statistically significant effects. Of note, data reported in the tables represent fully completed surveys, thus sample sizes may vary by survey. Because the CamAPS FX system is the most advanced of the CL systems and achieved a use rate above 90%, additional analyses were run on those who received CamAPS FX (Table 2). Additional analyses were not run on the FlorenceM participants given the very low use rate (57%). Table 2 shows several statistically significant effects, highlighting improved quality of life (communication subscale) over time for the CamAPS FX CL group above the age of 11 compared with control ($p < .05$). Of note, the small sample sizes probably contributed to group differences as survey scores were different at baseline (e.g. PedsQL Communication subscale); the distributions were normal but with wider variances.

Table 3 depicts results for the parents and indicates that similar to youth, there were no statistically significant differences between groups over time. Subgroup analysis of the CamAPS FX users (Table 4) shows significant positive effects over time for parent diabetes distress (relationship subscale; $p < .001$) and fear of hypoglycaemia ($p < .05$). The group differences were probably influenced by differences present at baseline (e.g. hypoglycaemia confidence).

3.2 | Focus group findings

As families completed the study, those on CL were invited to participate in focus groups. There were just three FlorenceM families who participated fully in focus groups yet seven CamAPS FX families (of 12) participated. The FlorenceM qualitative data were not subjected to full analysis but did reveal common themes of hardware and connectivity issues, and less trust of the system compared with the previous treatment regimen. In the CamAPS FX focus groups, parents shared a range of ways that the CL system benefited their quality of life, noting significantly improved sleep for them because of not waking up from alarms or having to worry about their child's glucose levels overnight. Families described a reduced mental and emotional

TABLE 3 Parent survey scores and repeated-measures ANOVAs

	Baseline				3 months		6 months				
	Closed loop		Pump only		Closed loop	Pump only	Closed loop	Pump only	*p* values		
	n	Mean ± SD	n	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Time (within)	Group (between)	Time × group
Center for Epidemiologic Studies Depression scale	48	9.77 ± 8.45	50	10.32 ± 9.14	11.25 ± 11.21	11.86 ±11.19	10.90 ± 9.47	12.6 ± 10.89	.09	.59	.72
Parent diabetes distress: personal distress subscale	48	1.06 ± 0.94	46	1.01 ± 0.90	0.92 ± 0.85	1.13 ± 1.01	0.97 ± 0.79	1.22 ± 1.21	.50	.45	.07
Parent diabetes distress: parent-teen relationship distress subscale	48	1.01 ± 0.87	46	0.88 ± 0.76	1.08 ± 0.81	1.01 ± 0.90	1.22 ± 0.96	1.09 ± 1.02	.02*	.50	.87
Parent diabetes distress: teen management distress subscale	48	1.48 ± 0.87	46	1.64 ± 1.11	1.36 ± 0.81	1.80 ± 1.00	1.53 ± 0.86	1.79 ± 1.18	.43	.11	.22
Technology attitudes: diabetes specific	48	20.69 ± 2.49	46	20.57 ± 2.54	20.75 ± 3.5	20.21 ± 2.74	21.44 ± 2.48	20.67 ± 2.45	.18	.26	.58
GMSS emotional burden subscale	48	2.21 ± .76	46	2.20 ± .83	2.10 ± .65	2.22 ± 0.76	2.30 ± 0.92	2.21 ± 0.80	.42	.95	.33
Hypoglycemic confidence scale	47	22.91 ± 4.62	46	22.41 ± 5.22	23.13 ± 4.12	21.08 ± 5.24	23.34 ± 5.39	20.61 ± 5.27	.29	.05	.05
HFS-P worry subscale	47	31.95 ± 9.47	46	33.90 ± 9.75	30.28 ± 8.06	33.18 ± 11.21	30.82 ± 8.51	33.15 ± 10.30	.33	.17	.83
PedsQL communication subscale	48	75.04 ± 21.24	46	73.6 ± 24.13	75.48 ± 21.16	71.74 ± 2737	76.35 ± 19.7	72.69 ± 23.63	.88	.47	.80
PedsQL diabetes subscale	48	61.41 ± 15.68	46	60.39 ± 13.27	60.02 ± 14.84	58.54 ± 12.86	62.62 ± 15.11	59.65 ± 11.39	.18	.48	.64
PedsQL treatment barriers subscale	48	70.47 ± 18.87	46	72.99 ± 17.60	68.31 ± 17.61	70.14 ± 17.97	70.1 ± 17.34	71.03 ± 17.37	.27	.58	.87
PedsQL worry subscale	48	73.95 ± 19.87	46	69.38 ± 22.43	70.31 ± 19.14	64.40 ± 24.05	72.14 ± 18.78	71.01 ± 23.29	.06	.29	.49

*$p < .05$.

TABLE 4 Parents of CamAPS FX users' human factors descriptives and repeated-measures ANOVAs

	Baseline				3 months		6 months				
	Closed loop		Pump only		Closed loop	Pump only	Closed loop	Pump only	*p* values		
	n	Mean ± SD	n	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Time (within)	Group (between)	Time × group
Center for Epidemiologic Studies Depression Scale	12	12.17 ± 9.99	13	9.38 ± 7.19	11.92 ± 10.57	6.23 ± 5.95	11.92 ± 7.65	12.15 ± 7.17	.18	.32	.18
Parent diabetes distress: personal distress subscale	12	1.29 ± 1.09	10	1.00 ± 0.80	0.79 ± 0.76	0.95 ± 0.83	0.83 ± 0.74	0.93 ± 0.80	.13	.97	.25
Parent diabetes distress: parent-teen relationship distress subscale	12	1.20 ± 1.16	10	0.64 ± 0.61	1.04 ± 0.91	0.66 ± 0.62	0.88 ± 0.77	0.75 ± 0.64	.71	.28	.25
Parent diabetes distress: teen management distress subscale	12	1.94 ± 0.92	10	1.43 ± 0.99	1.17 ± 0.57	1.28 ± 0.79	1.27 ± 0.75	1.48 ± 1.03	.006**	.84	.03*
Technology attitudes: diabetes specific	12	20.75 ± 3.14	10	19.80 ± 2.39	20.92 ± 2.50	20.20 ± 2.86	21.92 ± 2.23	20.10 ± 3.07	.55	.19	.69
GMSS emotional burden subscale	12	2.48 ± 0.90	10	2.33 ± 0.44	2.08 ± 0.80	2.48 ± 0.76	2.19 ± 1.03	2.40 ± 0.69	.67	.59	.28
Hypoglycemic confidence scale	12	22.33 ± 4.66	10	19.70 ± 4.42	23.50 ± 2.94	19.40 ± 4.33	23.50 ± 4.60	19.90 ± 3.54	.75	.03*	.71
HFS-P worry subscale	12	34.67 ± 7.39	10	35.10 ± 11.05	33.42 ± 7.95	26.50 ± 7.89	31.50 ± 8.61	30.60 ± 7.26	.04*	.41	.12
PedsQL communication subscale	12	60.42 ± 16.71	10	78.33 ± 20.11	69.44 ± 21.71	74.17 ± 22.03	72.92 ± 22.79	73.33 ± 17.92	.62	.31	.07
PedsQL diabetes subscale	12	57.01 ± 11.77	10	53.18 ± 12.18	56.25 ± 11.35	55.00 ± 8.76	60.61 ± 14.02	56.60 ± 7.98	.22	.47	.77
PedsQL treatment barriers subscale	12	61.46 ± 16.61	10	67.50 ± 15.81	64.06 ± 20.84	75.00 ± 18.40	68.23 ± 19.12	68.75 ± 15.31	.35	.37	.37
PedsQL worry subscale	12	69.44 ± 15.62	10	65.00 ± 25.70	70.83 ± 16.48	68.33 ± 26.00	75.00 ± 19.14	60.00 ± 23.17	.81	.35	.26

*$p < .05$. **$p < 01$.

burden of diabetes while using the system, including less overall worry, and reduced concern about long-term complication risk. Some noted the reduced burden of diabetes management because of being in CL and the ability to get better glycaemic results with less management effort. In terms of benefits to the family and child/teen, several families mentioned that CL enabled the child to participate in sleepovers for the first time. The system enabled more freedom and independence for the child/teen and increased comfort for families to involve other caregivers in overseeing diabetes management (e.g. teachers and friends' parents).

Participants shared being overwhelmingly impressed by the improvement in glycaemic control when using the CamAPS FX system. Several noted reductions in low glucose concentrations and overall lower glucose variability as well as improvement in HbA1c. Participants shared specific situations in which they felt the system performed well, including reducing low glucose levels overnight, better handling of foods with higher glycaemic indices (e.g. pizza, pasta) and less worry when playing sports.

Parents and children/teens also experienced aspects of the system that were more burdensome. On the physical side, most families described additional burden of wearing and carrying multiple devices to keep the system running. Most families experienced some burden related to connectivity issues. They noted these issues could lead to delays in insulin boluses and that it could take time for the system to reconnect. Relatedly, several indicated that when their child was engaging in sports or certain activities, it was challenging to keep devices within physical range to stay connected or necessitated disconnecting from the system altogether.

4 | DISCUSSION

Results from this analysis showed that CL was not associated broadly with psychosocial benefits. However, one of the CL systems used in this study, CamAPS FX, which showed positive benefits on glycaemic metrics previously,[17] showed modest improvements. For example, parents experienced lower diabetes distress and improved quality of life centred around the relationship they have with their child/teen with type 1 diabetes. These reported improvements are encouraging given the complex and demanding nature of type 1 diabetes management and high likelihood of relationship conflict and communication problems.[27-29] While modest in their size, the effects suggest a dual effect on glycaemic and psychosocial outcomes for the CamAPS FX system.

While these findings are promising, interpretation of the results should consider four critical issues. First, the systems, FlorenceM and CamAPS FX, had differential use as reported in the primary article. Specifically, those on CamAPS FX stayed in CL for 93% of the time while those on FlorenceM stayed in CL just 57% of the time. Thus, the overall effects are influenced by differential use and overall satisfaction with the FlorenceM, which was poorer.[17] This led to the subgroup analyses with the CamAPS FX participants and their controls. Second, the small sample size in the CamAPS FX group caused large differences at baseline in survey scores, for several of the surveys. Thus, change over time was relative to where each group started and with limited participants who completed surveys; it was difficult to address the sample size limitations analytically. Further in-depth probing during focus groups provided additional context, and as noted, indicated that the CamAPS FX system was associated with quality-of-life benefits such as better sleep and reduced mental burden for parents. This provides some confirmation of results from surveys but needs further replication to increase confidence in these findings. Third, the CamAPS FX system was only approved for use in the UK thus there may be an unknown bias if there were cultural differences (UK and United States) not captured with study measures. Fourth, all participants had to be on an insulin pump for at least 3 months before starting the study, and nearly two-thirds of the sample were on CGM. Thus, this was a group that was relatively comfortable with diabetes devices, which may not fully represent participants in this age group with type 1 diabetes. Study participants also had access to clinical support through the study staff, which may be an additional service not available to most with type 1 diabetes. Again, further replication of these findings and testing in those in other settings, and on multiple daily injections would be beneficial.

These findings offer promise for the CamAPS FX system working well for children and adolescents with type 1 diabetes. Of note, focus groups revealed fewer worries overnight about hypoglycaemia and greater trust that the system was managing diabetes (often better than the family can), which also benefits parents and their quality of life. Families did note some frustrations with the number of devices needed for the system to work, and poor connectivity at times, but they noted this would not prevent them from using the system. Of note, the few FlorenceM families did note this was a barrier to continuing use of the system. System designs that would minimize the size of components and better reduce connectivity would probably improve the overall user experience for youth and parents, and probably sustain use beyond the study period. In sum, the CamAPS FX system shows modest quality of life benefits and is paired with high acceptability and satisfaction. Further research is needed to optimize the user experience, particularly for young people, and to continue to test acceptance and usability of the system over time. This can be aided by testing in various situations such as exercise and challenging situations away from parents (e.g. school trips, adolescent camps). Overall, the lived experience of participants improved and can be further advanced with future iterations of the system.

AUTHOR CONTRIBUTIONS

RH, MT, FC, RPW, BAB, LADM, SAW, CK, RWB, KKH and DSF co-designed the study. JMA, CKB, JW, MT, BAB, REJB, FC, ND, AG, LADM, NM, AT, SAW and RPW provided patient care and/or took samples. RWB was the medical monitor. KKH, SH and NG-W carried out or supported data analysis, including the statistical analyses. KKH was the primary writer of the manuscript. All authors critically reviewed the manuscript and contributed to the interpretation of the results. KKH takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors critically reviewed the article prior to publication.

ACKNOWLEDGMENTS

The study was funded by National Institutes of Diabetes, Digestive and Kidney Diseases (UC4 DK108520). Additional support for the Artificial Pancreas work by National Institute for Health Research Cambridge Biomedical Research Centre and Wellcome Strategic Award (100574/Z/12/Z). Abbott Diabetes Care supplied continuous CGM and receivers. Dexcom provided support for the development of the CamAPS FX system and supplied discounted CGM devices. Medtronic provided support for the development of the FlorenceM system and supplied discounted CGM devices, phone enclosures, pumps and consumables. The research was supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC), through funding of REJB. The views expressed are those of the author(s) and not necessarily those of the funders. We are grateful to study volunteers and their families for their participation and to the dedicated study coordinators that made the study possible at all sites. We acknowledge support by the staff at the Addenbrooke's Wellcome Trust Clinical Research Facility.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/dom.14815.

DATA AVAILABILITY STATEMENT

Deidentified data set will be made available on case-by-case basis on reasonable request for research purposes.

ROLE OF FUNDING SOURCE

NIDDK, Medtronic, and Dexcom representatives read the manuscript before submission. No sponsor had any role in the study design, data collection, data analysis, data interpretation, or writing of the report.

ADDITIONAL FINANCIAL DISCLOSURES

K. Hood reports consulting fees from Cecelia Health, Insulet, Lifescan Diabetes Institute, and Havas Health, outside the submitted work. J Ware reports speaker honoraria from Ypsomed. R.E.J. Besser reports receiving a speaking honorarium from Eli Lilly and Springer Healthcare, and sitting voluntarily on the Research selection committee for the NovoNordisk foundation. C.K.B. reports consulting fees from CamDiab.

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How to cite this article: Hood KK, Garcia-Willingham N, Hanes S, et al. Lived experience of CamAPS FX closed loop system in youth with type 1 diabetes and their parents. *Diabetes Obes Metab*. 2022;24(12):2309-2318. doi:10.1111/dom.14815