Parents' experiences of using remote monitoring technology to manage type 1 diabetes in very young children during a clinical trial

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RESEARCH ARTICLE

Parents' experiences of using remote monitoring technology to manage type 1 diabetes in very young children during a clinical trial: Qualitative study

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Abstract

Aims: To explore parents' experiences of using remote monitoring technology when caring for a very young child with type 1 diabetes during a clinical trial.

Methods: Interviews were conducted with parents of 30 children (aged 1–7 years) participating in a trial (the KidsAP02 study) comparing hybrid closed-loop insulin delivery with sensor-augmented pump therapy. In both arms, parents had access to remote monitoring technology. Data analysis focused on identification of descriptive themes.

Results: Remote monitoring technology gave parents improved access to data which helped them pre-empt and manage glucose excursions. Parents observed how, when children were in their own care, they could be more *absent while present*, as their attention could shift to non-diabetes-related activities. Conversely, when children were others' care, remote monitoring enabled parents to be *present*

glucose monitoring devices. The views expressed here are those of the authors and not necessarily those of the funders.

while absent, by facilitating oversight and collaboration with caregivers. Parents described how remote monitoring made them feel more confident allowing others to care for their children. Parents' confidence increased when using a hybrid closed-loop system, as less work was required to keep glucose in range. Benefits to children were also highlighted, including being able to play and sleep uninterrupted and attend parties and sleepovers without their parents. While most parents welcomed the increased sense of control remote monitoring offered, some noted downsides, such as lack of respite from caregiving responsibilities.

Conclusions: Remote monitoring can offer manifold benefits to both parents and very young children with type 1 diabetes. Some parents, however, may profit from opportunities to take 'time out'.

KEYWORDS

closed-loop system, parents, qualitative research, remote monitoring, sensor-augmented pump therapy, type 1 diabetes, young children

1 | BACKGROUND

Type 1 diabetes is one of the most common chronic childhood conditions.[1] Achieving and maintaining clinically recommended glucose levels in very young children presents profound challenges, due to insulin sensitivity, rapid growth, childhood infections, difficulties predicting food consumption and activity levels and children being unable to detect and report hypoglycaemia and hyperglycaemia reliably.[2,3] Consequently, many young children spend significant periods of time with glucose levels outside their recommended range.[4]

The burden of care, which falls largely on parents, has been widely reported.[3,5–7] Many parents/caregivers experience high levels of anxiety, with fears about hypoglycaemia being especially prominent.[5,6] Such concerns may be heightened at night and when children are outside parents' direct supervision.[3,8] Parents often struggle to trust others with their child's care, or find people who are willing and able to look after their child.[3,6] The demands of care, and lack of respite, can affect parents' sleep, physical and mental health, personal and professional lives and finances.[7]

There is growing interest in whether, and how, new diabetes technologies can improve diabetes management and alleviate the burden of care.[7] Such technologies include continuous glucose monitors (CGMs); devices which stream glucose data from a subcutaneous sensor, worn on the body, to a display on a receiving device (often the insulin pump, though hand-held devices are also available).[9] Some receiving devices can be set to alarm if glucose levels breach specified ranges. More recent developments include the addition of remote monitoring (RM) capabilities, enabling relay of similar data and alerts to one or more other devices, for example, a parent's smartphone.

What's new

- Managing type 1 diabetes in very young children is extremely challenging.
- Limited research has explored parents' experiences of using remote monitoring (RM) to support the care of very young children with diabetes.
- RM offers manifold benefits to both very young children and their parents, and helps them lead more 'normal' lives.
- RM enables parents to monitor and manage diabetes without being physically present, thereby facilitating expansion of children's caregiver networks.
- Benefits of RM are enhanced by using a smartphone, having access to insulin as well as glucose data, and undertaking RM in conjunction with using a hybrid closed-loop system.

When studies have consulted parents about their experiences of undertaking RM in conjunction with a CGM, they have tended to focus on those of older/adolescent children[10] and/or involved a heterogeneous sample with minimal representation of parents of very young children.[11–15] This is an important limitation given the distinctive challenges parents experience managing type 1 diabetes in very young children.[7] A notable exception is Hilliard et al.'s study, which explored experiences of

TABLE 1 Details of the trial and technology used by participants

The KidsAP02 trial

The KidsAP02 trial was conducted at seven clinical sites across Europe (Cambridge, Leeds, Luxembourg, Leipzig, Vienna, Innsbruck and Graz). Seventy-four children were recruited: All were aged 1–7 years, had lived with type 1 diabetes for at least 6 months and used an insulin pump for at least 3 months. Children were randomised to use, initially, either a hybrid closed-loop system (the intervention arm) or sensor-augmented pump therapy (the control arm). After 16 weeks using the first system, and a 'wash-out' period, they began using the other. The same component devices (pump, CGM sensor and smartphone) and app were used by participants in both arms of the trial.

The CamAPS FX hybrid closed-loop system (CamDiab, Cambridge, UK)

The CamAPS FX is a 'hybrid' closed-loop system, calculating and delivering basal (background) insulin automatically, but requiring the user to administer boluses to cover meals/food. CamAPS FX comprises the following devices/components:

- **DANA RS insulin pump** (Sooil, Seoul, South Korea);
- **Dexcom G6 factory-calibrated real-time CGM sensor** (Dexcom, San Diego, CA, USA), with CGM transmitter;
- **An unlocked Android smartphone (Galaxy S8, Samsung, South Korea)** running Android 8 OS or above, hosting the **CamAPS FX app** incorporating the Cambridge model predictive control algorithm (CamDiab, Cambridge, UK). The smartphone/app communicates wirelessly with both the sensor and insulin pump, subject to being kept within 5–10 m of these devices.

The CamAPS FX App

In addition to being used to administer meal-time boluses, the app includes functions enabling (parents of) users to:

- view 'real-time' and retrospective graphs displaying glucose levels, rate of insulin delivery, meal-time boluses and carbohydrate intake, high/low glucose range, glucose trend arrows and indicators of whether the closed-loop is/was operational (Auto mode on) or interrupted/switched off (Auto mode off). [Note: In the sensor-augmented pump therapy, arm of the trial 'Auto mode' was not switched on; hence, the hybrid closed-loop system was not activated in this phase and rates/times of basal insulin delivery were instead preset.]
- view summary statistics for daily, weekly, monthly or 3-monthly periods, including: average glucose, estimated HbA_{1c}, time in/below/above target, number and average duration of hypoglycaemias, total daily dose/bolus/basal insulin; and percentage of time in Auto mode (for those using the hybrid closed-loop).
- personalise alarms triggered by high/low-glucose levels and signal loss with the sensor and/or pump. (Parents of) users can also adjust the threshold, repeat time, audio sound or vibration which accompanies an on-screen display, and turn on/off all alarms (except for the 'Urgent Low' glucose alarm).

Remote monitoring capabilities

The app automatically facilitates data upload to the cloud, thus enabling remote monitoring, that is, the sharing of data with parents/carers (and, moreover, health professionals—a practice we will discuss in a further/separate paper). Remote monitoring additionally requires the use of:

- One or more **other smartphones with the Diasend diabetes management system app** (Glooko/Diasend, Göteborg, Sweden) **installed**, via which parents/carers can view near 'real-time' glucose levels, rate of insulin delivery and meal-time bolus data.
- A **SIM card installed in the study smartphone**, enabling alarms activated on the CamAPS FX app and pump to be relayed to designated 'followers' (registered on the app) who receive SMS text alerts mirroring notifications of out-of-range glucose levels, signal loss etc. set on the app/pump.

CGM use amongst parents of children aged 1–7 years.[16] However, neither the specifics of the technology used by those parents nor the proportion with access to RM capabilities were reported. Moreover, whilst some parents reported technical difficulties and suboptimal experiences, these—the authors suggest—may have been due to the early generation devices available at that time.[16] Hence, further, more focused work reporting the perspectives of parents of very young children with experience of using newer iterations of CGM and RM technology is warranted.

To fill this gap, we drew on interviews with parents who undertook RM in conjunction with CGM use during a clinical trial (the KidsAP02 study) assessing the efficacy, safety and utility of hybrid closed-loop insulin delivery, as compared to sensor-augmented pump therapy, in children aged 1–7 years with type 1 diabetes.[17,18] Our aim was to explore parents' experiences of using RM technology in order to understand better how undertaking RM in conjunction with CGM affected their caregiving experiences and everyday family life.

2 | METHODS

2.1 | Overview

Our qualitative enquiry was underpinned by an understanding, informed by previous work, that personal and contextual factors may influence how people experience and make use of diabetes technologies.[19] It used an inductive design, involving in-depth, serial interviews and an iterative approach to data collection and analysis. Approval for the KidsAP02 trial and qualitative substudy was obtained from national regulatory authorities and relevant

ethics committees in participating sites/countries. In reporting our methods—and findings—we have been guided by the consolidated criteria for reporting qualitative studies (COREQ).[20]

2.2 | Setting/context

Parents taking part in the interview study were recruited from a multinational, multicentre, crossover trial, where their young child was randomised to 16-week use of a hybrid closed-loop (HCL) system (the CamAPS FX; CamDiab) followed by 16-week use of sensor-augmented pump therapy (SAPT) or vice versa.[17,18] See Table 1 for further information about the trial and technologies used. In both arms/phases, parents had access to RM technology. Parents could view their child's glucose levels, rate of insulin delivery and mealtime boluses, in near real-time (6–12 min lag) and retrospectively via their own smartphone(s) using the Diasend diabetes management app (Glooko/Diasend). They could also elect to receive SMS (text) notifications should their child's glucose level cross certain (largely user-specified) thresholds, or if there were technical issues such as sensor disconnection or low battery.

2.3 | Participants and recruitment

Parents were recruited to the interview study from seven sites in four countries: Austria, Germany, Luxembourg and the United Kingdom. They consented to take part in interviews alongside consenting to the KidsAP02 trial. Purposive sampling was used to encourage diversity with respect to countries and sites, children's age and gender. Recruitment continued until data saturation was reached (when new data generated no new findings).

TABLE 2 Topics explored in interview of relevance to this analysis

Background information and pretrial experiences
- Age of child with diabetes, parental occupations, whether parents lived together/separately, whether the child attended school/nursery.
- Devices (e.g. pump, CGM) used pretrial. Parents' experiences of and views about using these devices including how and what sensor data they accessed.
- Experiences of managing diabetes before the trial and views on their child's glucose control before the trial.
- Role of other people (e.g. informal caregivers, teachers) in diabetes management. Whether parents felt confident and able to entrust diabetes care to other people. Who and why (or why not).
- Impact of living with and managing diabetes on parents, the child with diabetes and others.

Experiences generally over the course of the trial
- Initial impressions, any concerns about using the devices/system used in the trial.
- Difficulties encountered with regard to using study devices, if any.
- Experiences of diabetes management over the course of the trial.
- Confidence/willingness to allow the child to be cared for by others (and other people's willingness to care for the child); whether and what aspects of the devices/system used in the trial made a difference to this.
- Parents' and children's quality of life, whilst using the study devices.

Perspectives on RM
- Thoughts and feelings about being able to access data on children's glucose levels, via their own phone, at all times.
- If, when, and how parents accessed data on their children's glucose levels, via their own phone (and if and how this changed, over time); which of the available data they scrutinised.
- How parents used the data they accessed and if/how data access affected how they managed their child's diabetes.
- Whether parents gave anyone else access to data (via the app or alerts); if so, who and why?

2.4 | Data collection

Parents were interviewed at the end of each trial arm (i.e. twice). Interviews were conducted by telephone, in English or German, by BK, an experienced (non-clinical) qualitative researcher fluent in both languages. Interviews took place between September 2019 and September 2020, and averaged 70 min. They were informed by topic guides which helped ensure discussions remained relevant to study aims, whilst affording parents flexibility to discuss issues they considered salient, including those unforeseen at the study outset. Rather than comprising standardised, highly structured questions, the guides contained a list of topics to be covered (see Table 2). Additional probes and tailored questions were used, in response to information shared during the interviews, to encourage fuller accounts. Between interviews and rounds, topic guides were revised to take account of emergent findings. Interviews were digitally recorded and transcribed verbatim for in-depth analysis. Those conducted in German were translated into English by professional translators, then checked for accuracy by BK.

2.5 | Data analysis

Analysis was guided by both a priori and emergent interests, including if, how and why experiences of RM varied when using the HCL system and SAPT respectively. It used the method of constant comparison[21] to

develop codes and identify and elaborate cross-cutting descriptive themes. Initially, two experienced qualitative researchers (JL and RIH) read all transcripts to identify and agree material relevant to the topic of RM. This material was extracted for detailed open coding by both researchers. The resulting codes, and associated data, were then collated to form provisional themes, documented in detailed analytical reports prepared independently by the two researchers. These reports were exchanged, discussed and developed, until consensus was reached on a framework of key codes and themes. RIH then reviewed the data (coded extracts and the wider data set) to assess how well those codes and themes worked, refine their definitions and names in consultation with JL and identify suitable illustrative quotations for use in reporting.[22] A qualitative data-indexing package, NVivo11 (QSR International), was used to support the process. The resulting analysis was critically reviewed and confirmed by DR and BK, who had familiarity with the entire data set.

3 | RESULTS

Round 1 interviews were conducted with 33 parents of 30 children (three interviews in each round involved both parents, at those parents' request). Round 2 interviews involved 29 parents of 26 children (one parent could not be recontacted; three second-round interviews were not pursued due to staffing difficulties arising from the Covid-19 pandemic and consensus that data saturation had been reached). The achieved sample is detailed in Table 3.

We begin our findings by detailing parents' perspectives on how improved access to data had helped them manage their child's diabetes more effectively. We then describe parents' experiences of RM in two distinct care scenarios: When children were under their own care and when they were in the care of others. We report how RM reshaped each of these care scenarios to the benefit of both parents and children. Finally, we highlight some potential psychological costs to parents.

While our analysis did not reveal variation in experience by country, site or child's gender, we note some differences relating to children's ages, and whether RM was used in conjunction with the HCL system or SAPT. Unless otherwise indicated, the parent quoted is a mother.

3.1 | Easier access to data enhancing management

Parents contextualised their experiences during the trial by highlighting the challenges they had previously faced keeping glucose within range, including difficulties accessing relevant data. Although almost all had a CGM prior to the trial (see Table 3), only a minority reported using a handheld receiver/display. The majority described having had to read glucose levels from the insulin pump attached to their child's body. Many noted how, when their child had been in the care of others (e.g. at nursery/school), they had been entirely 'in the dark' about their glucose levels, and reliant on other carers for information: only a small minority described having and using some sort of RM capabilities prior to the trial ('NightScout' or the Dexcom 'Follow' app).

Turning to their experiences during the trial, parents noted how RM had enabled them to ascertain and manage their child's glucose levels so much more easily and effectively. They emphasised how effortless it had been to access real-time glucose values and trends, and insulin data, due to having an app on their own mobile phone (see Table 4). Parents explained how this improved access to data had increased their awareness of actual and potential changes in their child's glucose levels and thus enhanced their ability to pre-empt and/or address glucose excursions promptly (see Table 4). Parents reported checking their child's data particularly frequently when using SAPT, since this system required more frequent manual/user adjustment (e.g. to basal rates) than the HCL (see Table 4).

In addition to using the app, many parents reported having activated optional text alerts. Parents explained how these equipped them to respond rapidly to changes in glucose levels and get these back in-range (see Table 4) and reassured them that they would not miss sudden and/or critical changes in glucose levels. Some saw such alerts as relieving them of the need to constantly check the app:

> 'It alerts me, it sends text messages to me if he's high or low, so... if I don't get any text messages, well I know he's 100 per cent in range.' (002-HCL)

3.2 | Enabling parents to be absent whilst present

When parents reflected upon situations when their child had been in their own care, they noted how use of the app and text alerts had allowed them to be *absent whilst present*, in the sense of being able to attend to other activities alongside caring for their child. Parents described how, as they no longer had to observe their child for signs/symptoms of hypo- or hyperglycaemia, undertake finger-prick tests or access a device on their child's body (see Table 4), RM gave them welcome

TABLE 3 Qualitative substudy participant (parent and child) characteristics

Characteristic	*n*	%[a]	Mean (range)
Parents[b]	33		
Mothers	25	75.8	
Fathers	8	24.2	
Married/co-habiting	32	97.0	
Country of residence			
Austria	10	30.3	
Germany[c]	1	3.0	
Luxembourg	9	27.8	
United Kingdom	10	30.3	
Employment			
Full-time	15	45.5	
Part-time	13	39.4	
Full-time carer	5	15.2	
Reduced hours/career break/quit employment due to diabetes care	9	27.3	
Occupation			
Professional	22	66.6	
Semi-skilled	5	15.1	
Unskilled	1	3.0	
Full-time carer	5	15.1	
Children	30		
Girls	13	43.3	
Boys	17	56.6	
Age at time of first interview; years			4.9 (2–8)
Age at time of diagnosis; years			2.2 (0.5–5)
Diabetes duration; years since diagnosis			2.7 (1–4.5)
Living with siblings	24	80.0	
Devices used before joining the trial			
Insulin pumps			
Medtronic MiniMed 640G	25	83.3	
AkkuCheck	4	13.3	
Animas	1	3.3	
Sensors			
Freestyle Libre	2	6.7	
Medtronic Enlite/Guardian CGM	21	70.0	
Dexcom 4/5 CGM	2	6.7	
Dexcom 6 CGM	5	16.7	

[a]Percentages may not add up to 100% due to rounding.

[b]Of a total of 30 first-round interviews, 22 were conducted with mothers, five with fathers and three were joint interviews with both parents. Of the 26 follow-up interviews, 19 were conducted with mothers, four with fathers and three were joint interviews with both parents.

[c]Only one parent could be recruited from Germany before recruitment into the interview study had to stop due to the German sites starting later on in the trial than other sites.

opportunities to do 'normal', that is, ordinary things that other adults took for granted. These activities included reading a book in the evening, or watching TV whilst their child played or slept. Many further remarked how RM helped them to switch off at night and sleep better, with fewer anxieties:

TABLE 4 Additional participant quotations

Themes and subthemes	Participant quotations
Easy access to data enhancing management	'When I want to know what his level is... I don't need to go to the pump, take the pump... I don't constantly need to run after my child.' (001-Dad-SAPT) 'You check how much active insulin there is, what is being discharged in the background, which micro bolus is running... (as) when (son) wants to go jump on the trampoline after lunch with a lot of active insulin, it's not so good.' (029-HCL) 'I can see now if she's on her way down... so when she's out in the garden, I can ... nip out with a biscuit.' (018-SAPT) Reviewing data frequently when using SAPT: 'With the open-loop (SAPT) system we must look more at the data, because we need to amend the pump settings regularly... (in) auto-mode (HCL) we didn't need to amend a lot of the settings.' (016-SAPT) Text alerts equipping parents to respond rapidly: 'I think it's very good that I get alerted when her glucose level is too low or too high, so that I can fix it immediately and get it back on track.' (021-HCL)
Enabling parents to be absent whilst present	'When he goes to bed... it is extremely helpful... we can quietly watch a film, or read, or do something else, and only look at our mobile from time to time and see, "OK, he is more or less OK," or, "We have to pop upstairs, and take action".' (012-SAPT)
Enabling parents to be present whilst absent	
Equipped to intervene, support and collaborate	'I can still see what she's doing... (and) if it got to a point where I needed to intervene... I could.' (006-SAPT) Features facilitating collaboration—access to insulin as well as glucose data: '(Post-trial) we can see the graph, but there no insulin and there's no carbs on it... For example, we don't know when she's had a snack now at school and they've bolused for it. We might be thinking, "Well, why is she going up?" [Whereas] on Diasend we could see exactly why it happened.' (026-Dad)
Increased openness to care	'It was a really great tool to have when we would have a babysitter... at any moment I could call it up on my phone, and... check and see how she was doing.' (025-HCL) 'We can trust people a bit more... we can just rely on those alerts and just talk people through what to do as and when they things happen, rather than giving them a massive list of things to think about.' (022-SAPT)
Psychological benefits outweighing costs	Feeling more in control: 'The fact that we can access all of this information from our mobile phones, it's, it really is life-changing... it's so less stressful and it's just peace of mind, that we can just pick up our phones and know instantly what his sugar readings are... it's comforting.' (004-SAPT) 'I think it's great, I find it positive. Of course, one could say it adds more stress, but for me it's not additional stress, more the opposite actually. That if I want to, I can take action immediately... I find it absolutely positive.' (030-HCL)

'It's been a lot better, 'cause we don't—we rely on the alarms now and we don't feel the need to get up and check her. Like even if I do get up in the night, I'll not feel the need to go into her room, 'cause I think, "Well, if she was high or low, it would have alarmed me. So I'm going to assume she's fine".' (018-SAPT)

3.2.1 | Making care less invasive for children

In addition to describing benefits to themselves arising from RM, parents highlighted important benefits to their child. They explained how the ability to access glucose data on their own phones meant they could monitor and manage children's glucose levels less disruptively and more discretely, and be *absent whilst present* in yet another sense. Previously, one father explained, it was always a case of: 'Come here for a moment, we have to check the pump!' (023-Dad-SAPT) In contrast, parents described how RM allowed their child to move around more freely, and reduced interruptions to play and sleep, thereby enabling them to experience a more normal childhood:

> 'That makes a big difference... that you don't always have to check on her body, because that really annoyed her sometimes, when you say: "(Name), come here, show me the pump!" ...Now she's no longer burdened by that.' (014-SAPT)

3.3 | Enabling parents to be present whilst absent

Parents further noted how, when children were in the care of other adults, RM enabled them, conversely, to be *present whilst absent*. In such care scenarios, many described closely monitoring their child's glucose levels (via the app and/or text alerts), especially at times of day when they expected glucose fluctuations (e.g. around lunchtime or when physical activity was scheduled). This was particularly common when using SAPT, as more active evaluation and management of insulin delivery were required. Parents also reported using RM more extensively where they felt uncertain about a carer's competence, as the following mother explained:

> 'With the parents-in-law... I have to admit I check Diasend more often. I'm nervous because they are not that skilful... I'm always on the phone when he's with them.' (015-SAPT)

3.3.1 | Equipped to intervene, support and collaborate

Parents noted how access to data (on insulin as well as glucose) could provide reassurance that rising (or falling) glucose levels had been acted upon:

> 'I don't need to sit and worry... is she now 270 (mg/dl)? I just log-on and see, "Okay, fine, everything is cool, they (school) have got it under control—I can see when she got insulin..." (and) I feel cool.' (017-Dad-SAPT)

However, parents emphasised that the value of RM lay, substantially, in the potential it offered them for intervention (see Table 4). Parents, for instance, recounted how RM had enabled them to pick up on glucose issues overlooked by carers and offer timely, informed advice and/or direction:

> 'One time... I had received a text message with a low value... nobody had reacted to it, so I called them. She was playing and the teachers hadn't heard her phone.' (005- HCL)

A few noted how anomalous RM data (e.g. glucose levels rising when they would expect them to be falling) had led them to suspect equipment issues, such as catheter disconnection, which they knew carers would need help to resolve.

When offering instructions and management advice to other caregivers, such as nursery/school staff, many parents noted how their own input had been enhanced (and made more efficient) by their instant access to real-time and retrospective data:

> 'As we are constantly in the loop, we don't base our instructions on assumptions... we base our instructions... on facts... (and) the length of communications are shorter, because we don't need to ask, "How has her morning been?"—we know.' (017-Dad-SAPT)

Some highlighted particular features of the RM technology as facilitating collaboration, including the access it provided to insulin as well as glucose data (see Table 4). Several noted how collaborative work was made markedly easier by the control device being a smartphone. Not only could they text or call carers but carers could also consult them very easily:

> 'Having the phone with the trial has been fantastic, because if they (nursery) have got any... queries, that aren't urgent, they can just text us, and we can have a look (at the data) and text back.' (022-SAPT)

Parents of older children (6–7 years) additionally noted how they and their child would use this phone to communicate; for example, to discuss food choices and direct or confirm management activity.

3.3.2 | Increased openness to care

Parents noted how being able to oversee and direct diabetes management had made them feel more comfortable entrusting their child's care to other people, including babysitters (see Table 4). Parents also reported that RM made other adults, such as grandparents, more comfortable about—and willing to provide—care, as it reassured them that responsibility for identifying and dealing with out-of-range glucose levels was shared:

> 'My mum has them on a Monday... (and) she feels more confident now, (with) me being able to see the information as well. She knows that... I'm alerted too if she's going hypo. And... mum can... check with me, for reassurance that's she's doing the right thing.' (006-HCL)

Parents further remarked how, since they could now direct care from a distance, they had been able to expand their caregiver network to include people without special training (see Table 4). This, as some parents noted, was made easier still when RM was used in conjunction with the HCL system, due to the reduced management demands on users/carers:

> 'There were so many more decisions to make before closed loop, and there just isn't—it (the HCL) simplifies everything for them (carers) really.' (002-HCL)

3.3.3 | Allowing children to experience a more normal childhood

Parents noted how, in turn, expanding the pool of people trusted and willing to provide care had enabled their child to participate in more leisure activities unaccompanied. This included joining clubs/groups and going to playdates, parties and sleepovers. Parents welcomed these experiences as an important part of a 'normal' childhood:

> 'That's given her a lot more independence than what she would have ... that's been the main thing... we feel like she's having more of a normal time now, because I'm happy for her to go off and do her own thing.' (018-SAPT)

> 'For the first time (child) had a sleep not at home but with a friend... just one weekend, but he's very, very, very happy (about it)!' (016-HCL)

3.4 | Psychological benefits outweighing costs

Predominantly, parents highlighted psychological benefits to undertaking RM. Specifically, parents described feeling more in control, due to their instant access to data and associated confidence that they could react rapidly and effectively, if required (see Table 4). Some, however, noted that the continual availability/stream of data (via the app and text alerts) could have psychological costs. Such parents drew attention to the potential to feel stressed and overwhelmed by constant prompts to scrutinise glucose data:

> 'I had the texts, the SMS, at the beginning, and I was overwhelmed.' (015-SAPT).

Others acknowledged that the ability to monitor when their child was in the care of others could be a mixed blessing, as they then had no respite from caring responsibilities:

> 'It... means that we don't really get a break, because we're... checking once he's not with us.' (022-SAPT)

Parents noted the importance of establishing considered and sustainable RM practices; for example, thinking carefully about which and when alerts were activated, as well as their settings (threshold, repeat intervals). To secure 'time-out', some described deactivating alerts altogether when their child was with the other parent or trusted carers.

4 | DISCUSSION

Parents described RM as a powerful tool which helped them pre-empt and/or manage glucose excursions promptly and allowed both them and their child to lead more 'normal' lives. Recounting their experiences, parents focused on two care scenarios—where their child was under their own care and where they were in the care of others. Parents observed how, in the former, RM enabled them to be more *absent whilst present*, as they no longer needed to access a device attached to their child and/or watch them so closely for signs of hypo- and hyperglycaemia. When children were in the care of others, RM conversely enabled parents to be more *present whilst absent*, because it permitted active oversight and supported collaboration with carers.

In keeping with findings of a study which employed psychosocial measures,[14] parents reported multiple quality-of-life benefits to using RM. As with parents of (mostly) older children,[10–15] these benefits included

decreased stress and worry about their child, and improved sleep. Parents also described feeling more able to get on with their own lives, since RM allowed them to undertake other activities whilst caring for their child, and increased their openness to entrusting their child's care to others, a benefit other researchers have similarly reported.[12,16] Importantly, parents highlighted manifold quality-of-life benefits for their child: care became physically less invasive; sleep, play and other activities did not need to be disrupted for glucose to be checked; and children could attend parties, sleepovers and playdates without direct parental supervision.

One of the reasons parents viewed themselves and their and children as able to lead more normal lives was that RM enabled caregiving networks to be strengthened and expanded. As parents noted, since RM enabled them to provide diabetes management support at one remove, it was easier to delegate care and find people who felt confident and willing to take on caregiving responsibilities. Moreover, it was possible for parents to involve caregivers who lacked the skills and/or confidence to manage their child's diabetes independently. This is a notable improvement on situations where a CGM is used without RM, when parents not only need to identify individuals willing to take on responsibility for diabetes management but also then train them up to understand and respond appropriately to CGM data/alerts.[23]

In a recent review of evidence on young people's and caregivers' use of diabetes technologies, Brew-Sam[24] noted how the *specifics* of technologies influence user experience. Our findings suggest that parents' RM experiences were enhanced by distinct aspects of the technology investigated during the trial. This included use of a smartphone and app (hosting the HCL control algorithm) to receive and upload data to the cloud, as that smartphone facilitated communication between parents and caregivers (and sometimes children). Delivery of automated text alerts/notifications and use of the study phone for communication with carers were, however, contingent on a SIM card being installed. Whilst none of the participants in the current study raised the cost of SIM cards as a problem for them, such costs might be prohibitive for other, lower income families.

Another feature that some parents suggested enhanced their ability to provide remote diabetes management support was access to insulin (not solely glucose) data. This gave them insights into actions undertaken (or not) by caregivers to pre-empt or address glucose excursions and possible problems with equipment (e.g. catheter disconnection). Finally, parents noted how their—and caregivers'—confidence was greatest when RM was used in conjunction with the HCL system, since less work and effort was then needed to keep glucose within target range. This perception is consistent with the main trial results, which have demonstrated that use of the HCL system increases time-in-range in very young children.[18]

While parents were mostly very positive about their experiences of using RM, in line with previous research,[16] some (actual or potential) psychological costs were also noted. Ironically, whilst RM increased opportunities to spend time apart from their child, it also reduced opportunities for respite, as the technology enabled parents to monitor and manage diabetes care at a distance. Other research, exploring school nurses' perspectives, has similarly reported (nurses' concerns) that RM may fuel parental anxiety.[25] These findings suggest the potential for 'burnout' over time. To address this, parents' own suggestions could be considered, including encouragement to take 'time-out' periods where monitoring responsibilities can be shared with a co-parent or other trusted caregiver.

A key study strength is the inclusion of parents of very young children of different ages and from different countries, as this increases the transferability of findings. However, as parents were recruited from a clinical trial investigating a new diabetes technology (the KidsAP02 trial), they may have been particularly motivated and/or technology enthusiasts. As is typical in studies of diabetes technologies, the sample was skewed towards White, educated, relatively affluent parents. Moreover, parents used RM for a relatively short time period (approximately 8 months) and, as other studies have found, use of diabetes technology may attenuate over time.[26] Given the importance of ensuring equitable and sustainable access to diabetes technologies, future work should consider the perspectives of people from other socio-economic and minority ethnic groups, and those who use RM for longer time periods and outside trial settings.

5 | CONCLUSION

Use of RM in the management and care of very young children with type 1 diabetes can offer divers benefits for both parents and children. Typically, these benefits considerably outweigh any psychological costs arising from the ability to access data continually. Some parents, however, may benefit from encouragement and opportunities to take 'time out'.

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CONFLICT OF INTERESTS

RH reports having received speaker honoraria from Eli Lilly and Novo Nordisk, serving on advisory panel for Eli Lilly and Novo Nordisk and receiving licence fees from BBraun and Medtronic. RH also reports patents, patent applications, shareholding and directorship at CamDiab. FC has attended Advisory Boards and obtained speaking fees for Abbott, Medtronic, Lilly and NovoNordisk. CdB has contributed to the Medtronic e-learning tools. EFR reports having received speaker honoraria from Eli Lilly and Novo Nordisk, and serving on advisory boards for Eli Lilly and Sanofi. SH declares having received speaker honoraria from Eli Lilly, Sanofi and Pfizer. TMK has received speaking honoraria from Eli Lilly and MerckSerono and consulted Sanofi for a transition brochure. BRM has received speaker honoraria from Abbott Diabetes Care, Eli Lilly, Medtronic, Novo Nordisk, Roche Diabetes Care, Sanofi and Menarini, and has been on the advisory boards of Roche Diabetes Care and Abbott Diabetes Care. The authors RIH, BK, DR, CKB, JW, JMA, AT and JL have no conflicts of interest to declare.

AUTHORS' CONTRIBUTIONS

JL conceived and designed this substudy. BK collected the data, which was then analysed by JL, RIH, DR and BK. RIH wrote the first draft of the manuscript. All authors reviewed, edited and approved the final version of the manuscript.

CONSENT TO PARTICIPATE AND FOR PUBLICATION

All research participants provided written informed consent including for anonymised information to be published in this article.

DATA AVAILABILITY STATEMENT

The data sets generated and analysed in the course of this study are not publicly available due to risks to individual privacy. However, they are available, via the corresponding author, on reasonable request.

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