Parents' experiences of using a hybrid closed-loop system (CamAPS FX) to care for a very young child with type 1 diabetes:

Parents' experiences of using a hybrid closed-loop system (CamAPS FX) to care for a very young child with type 1 diabetes: qualitative study

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ABSTRACT

Aims: To explore parents' experiences of using a hybrid closed-loop system (CamAPS FX) when caring for a very young child (aged 1-7 years) with type 1 diabetes.

Methods: Interviews with n=33 parents of 30 children who used the system during a randomised controlled trial. Data analysis used a descriptive thematic approach.

Results: While some parents were initially reticent about handing control to the system, all reported clinical benefits to using the technology, having to do less diabetes-related work and needing less clinical input over time. Parents welcomed opportunities to enhance the system's efficacy (using Ease-off and Boost functions) as required. Parents described how the system's automated glucose control facilitated more normality, including sleeping better, worrying less about their child, and feeling more confident and able to outsource care. Parents also described more normality for the child (alongside better sleep, mood and concentration, and lessened distress) and siblings. Parents liked being able to administer insulin using a smartphone, but suggested refinements to device size and functionality.

Conclusions: Using a hybrid closed-loop system in very young children can facilitate greater normality and may result in a lessened demand for health professionals' input. Systems may need to be customised for very young children.

Keywords: closed-loop system; type 1 diabetes; parents; young children; qualitative.

1. BACKGROUND

Hybrid closed-loop systems comprise a continuous glucose monitor (CGM), an insulin pump and an algorithm which translates, in real time, information from the CGM and directs the amount of insulin delivered by the pump [1]. Several systems are licensed for use in the USA and Europe and others are under development [1]. To optimise usability and efficacy, user input and feedback are essential [2,3]. To date, interview and survey studies have mostly consulted individuals with no or limited (≤ 5 days) direct experience of using the technology [4-9] and/or have sought the opinions of adolescent and adult users [10-19]. Limited (survey) research has explored perspectives of parents with very young children who have direct experience of using a closed-loop system in real-world settings [20]. Further in-depth research is needed, because young children are considered a priority group for this technology [21,22], and their diabetes care and technology needs may be very different to those of older individuals [8,23].

A recent synthesis of qualitative evidence highlighted distinctive challenges experienced by parents caring for a young child with type 1 diabetes [24]. Parents described constantly worrying and needing to be in a state of perpetual watchfulness in order to detect and address hypoglycaemia and hyperglycaemia. Parents also described feeling anxious when other people cared for their child and highlighted detrimental impacts upon their own physical and mental health and wider family life. Some reported quitting work or reducing their working hours so they could be available to care for their child. The review suggested that diabetes technologies, such as insulin pumps and CGM devices, could help alleviate some of the problems parents experienced. It also recommended that parents' experiences of using newer diabetes technologies, such as closed-loop systems, be investigated to see whether such technologies further ameliorate parental difficulties and concerns [24].

Here, we report findings from interviews with parents who used a hybrid closed-loop system (CamAPS FX) during a randomised controlled trial (KidsAP02 study) assessing the efficacy, safety and utility of closed-loop insulin delivery compared to sensor-augmented pump therapy in children aged 1-7 years with type 1 diabetes. Key aims of the interview study were to explore parents' experiences of using the CamAPS FX system, the benefits and

challenges arising from using the system, and their views about how using this technology affected themselves, their child and everyday life. Objectives were to inform further potential (age-appropriate) refinements to closed-loop systems and decision-making about using this technology in young children within routine clinical care.

2. METHODS

We interviewed parents of young children who took part in KidsAP02, which was a multinational, multicentre, crossover trial involving 74 children [25]. In this trial, participants were randomised to 16-week use of a hybrid closed-loop system (CamAPS FX; CamDiab, Cambridge, UK) or 16-week use of sensor-augmented pump (SAP) therapy before crossing over to the other arm. The CamAPS FX system comprised a control algorithm hosted within an app on an unlocked Android smartphone receiving sensor glucose data from a factory-calibrated Dexcom G6 CGM (Dexcom, San Diego, USA) and directing insulin delivery by a Dana RS insulin pump (Sooil, Seoul, South Korea). The CamAPS FX app included functions enabling users to input mealtime boluses and change glucose targets. The app also contained functions that increased ('Boost') or reduced ('Ease-off') basal insulin delivery by around 30%. Users were able to initiate and specify a start time and duration (up to 12 hours) for a 'Boost' mode of operation when they felt more insulin was needed (e.g., during periods of inactivity, increased food intake, or during illness or stress) or an 'Ease-off' mode when less insulin was needed (e.g., during exercise or when glucose levels tend to be low). Boost was automatically suspended when a user's personal glucose target was reached, and both functions were automatically suspended when the pre-set time period had elapsed. Further details about trial eligibility criteria and the CamAPS FX system are provided elsewhere [25] and in Table 1.

<<Table 1 here>>

In line with other studies that have consulted closed-loop system users [14-16,19], a qualitative approach was employed comprising in-depth interviews informed by topic guides. This approach ensured that the discussion remained relevant to addressing the study aims, while affording flexibility for participants to raise issues they perceived as

salient, including those unforeseen at the study outset. Topic guides, using open-ended questions and probes, were informed by literature reviews and input from parent representatives and clinical co-investigators, and revised in light of emerging findings (see Table 2 for information about the main areas explored). The interview study was conducted by an independent team of qualitative researchers at the University of Edinburgh.

<<Table 2 here>>

2.1 Sampling and recruitment

Participants were recruited and consented into the interview study when they were consented into the KidsAP02 trial. Recruitment took place at seven clinical sites in four countries: Austria, Germany, Luxembourg and the UK. Approval was received from relevant Ethics Committees in participating sites/countries and national regulatory authorities. Purposive sampling was used to encourage diversity in the final sample with respect to participating countries and sites, and the age and gender of the child. Recruitment continued until no new findings were identified in new data collected.

2.2 Data collection

Parents were interviewed at the end of the first study period (i.e., after 4 months of using closed-loop or SAP therapy) and, again, at the end of the second study period (i.e., after 4 months of using the other regimen). Parents were interviewed by telephone in English or German by BK (an experienced non-clinical, qualitative researcher fluent in both languages) between September 2019 and September 2020. Participants had no prior relationship with BK, were informed of her status as an independent, non-clinical researcher and reassured of complete confidentiality to encourage the sharing of any negative experiences as relevant. Interviews averaged 70 minutes and were digitally recorded and transcribed in full. Interviews conducted in German were translated and transcribed into English using a professional agency. To ensure accuracy, BK checked all transcripts against their original interview audio files.

2.3 Data analysis

To reduce bias and enhance rigour, the interviews were analysed by four experienced qualitative researchers (JL, BK, DR and RIH) using a qualitative descriptive approach, which produces rich, low-inference descriptions of an event or experience [26,27]. This involved: (1) repeatedly reading and cross-comparing transcripts; (2) recording initial analytical reflections on the data; (3) discussing these interpretations to achieve agreement on the main areas of relevance (discrepancies were minimal and resolved through discussion without need for third-party arbitration); (4) developing a coding frame which captured these main areas of relevance; and (5) undertaking in-depth analysis of coded datasets to develop more nuanced interpretations of the data. A qualitative data-indexing package, NVivo 11 (QSR International, Doncaster, Australia), was used to facilitate data coding and retrieval.

Our reporting follows the Standards for Reporting Qualitative Research (SRQR) [28].

3. RESULTS

Single/joint (i.e. involving both parents, as per their preference) interviews were undertaken with 33 parents of 30 children after the first study period, and 29 parents of 26 children after the second. One parent could not be re-contacted and three second-round interviews were not done due to staffing issues resulting from the Covid-19 pandemic. Further information about the sample, including demographic characteristics and the devices used pre-trial, are provided in Table 3.

<<Table 3 here>>

Our findings are structured according to the four main themes emerging from our analysis: adjusting to the system; better control, less work; facilitating normality; and, refining the technology for very young children. As findings did not vary according to parents' country of residence or the child's gender, our reporting is not separated out according to these variables. Key quotes are presented below, with additional quotes included in Table 4 (M=mother, F=father).

3.1 Adjusting to the system

Some parents noted benefits as soon as closed-loop system use commenced: “almost instantly we saw an improvement in her blood glucose control. It reacted if she was going high, you could see the app acknowledging that and giving her more insulin” (006M_child_6yrs). However, the majority described a transitory period, typically lasting several weeks, during which the algorithm calibrated itself to their child’s routines and insulin requirements, while they developed confidence and trust in the system. Parents often described this transition period as stressful and anxiety-provoking, because they had been used to closely monitoring and managing their child’s glucose levels and, hence, found adopting more passive caregiving roles hard: “I found that a little bit difficult, because I didn’t feel like I had enough control over it” (027F_child_3yrs); “it makes me feel a bit neglectful” (018M_child_7yrs). Indeed, some noted how their own anxieties and concerns had initially led to them stepping in and correcting glucose as soon as it started to go high or low, with some further describing having felt that the system had been “a little too slow” (030M_child_8yrs) in responding to high glucose. Some such parents also questioned whether, in hindsight, their interventions might have “confus[ed] the system” (028M_child_6yrs) and adversely affected their child’s glucose levels:

> “We did sometimes intervene ourselves… in hindsight unfortunately, we should not have done that. The system would have done it… sometimes we meant too well and messed the system up a bit and sent him into a low… this was our mistake.” (030M_child_8yrs)

Parents further noted how being able to closely scrutinise the algorithm’s actions on the child’s smartphone via the CamAPS FX app, or on their own smart device using the Diasend app, had been vital to developing confidence in the system and, hence, allowing it to operate without frequent interference:

> “We needed to get a feeling for the system obviously, and the advantage which I see with this closed loop is that we could follow constantly how much additional basal,

for example, the system would give [child's name]… And suddenly you realise that the system works." (017F_child_7yrs)

3.2 Better control, less work

After an initial calibration period, all parents noted how their child had experienced more time within target range and fewer extreme highs and/or lows: "I mean, overall he's an awful lot less high… and an awful lot less low" (002M_child_6yrs); "we've seen less aggressive swings. It definitely keeps him more in range" (022F_child_2yrs). Parents particularly valued the system's ability to keep their child's glucose levels more in range after meals (Table 4) and lessen glucose fluctuations arising from inaccurate carbohydrate counting, snacking or the child eating larger/smaller meals than planned (Table 4). In doing so, parents praised the system for being able to offer a level of input extending beyond their own capabilities (Table 4). Parents also highlighted the benefits of the system being able to offer a safety net when they and other caregivers made mistakes, such as forgetting to administer a mealtime bolus dose:

> "The real benefit of the auto-system is that something was looking at [child's name]'s readings the whole time… Therefore we have a lot more confidence that, should we forget something- because the other day I forgot to bolus something, she was sort of low-ish, I forgot to bolus it- but of course as the levels rise the Automode would put more insulin in… So you have taken a little bit of human fallibility out of it." (026F_child_6yrs)

3.2.1 Less work for caregivers and health professionals

As well as highlighting clinical benefits, parents noted how the time and effort involved in delivering diabetes care had been reduced by virtue of the system automatically correcting glucose and, hence, as this parent noted, "just hav[ing] to worry about what she's eating and making sure I've given her insulin to cover the food" (006M_child_6yrs). As another similarly observed:

> "I think that just not having to think about corrections and when to give them, I think that's definitely helped… It takes [away] a lot of that thinking of: do I need to tweak his basal? Do I need to change his ratios? Because it will be working in the background to do all that for you." (022M_child_2yrs)

Indeed, parents noted how, over time, they had experienced a lessened need to check and review their child's glucose data, "because we've been happy to let the [closed-loop] sort itself out" (018M_child_7yrs), with some further reflecting on how:

> "I no longer needed to every week think about his basal, how it had been during the week and if it needed any tweaking or changes." (028M_child_6yrs).

Once initial training had been received, parents also reported needing less health professional input than when using SAP therapy or other pre-trial regimens, as basal rates and/or mealtime ratios no longer needed frequent alteration:

> "We've had a lot less phone calls and emails to the diabetes team, because we've not had to tweak his basal every other week like we were doing before. So that's helped… We changed his ratios maybe once on the closed-loop system." (022M_child_2yrs)

> "We're not having to do the data uploads all the time, to the team, and then have another hour's appointment where we're reviewing- putting some context around those numbers, trying to understand them to get her settings right, which we would probably do once or twice a week. We don't need to do that now with this system." (020M_child_4yrs)

3.2.2 Enhancing control using Ease-off and Boost

While most parents welcomed being able to step back from glucose management tasks, virtually all highlighted situations where they were able to offer insight and knowledge that had resulted in them using the Boost and Ease-off functions to enhance the closed-loop

system's efficacy: "I think the Boost and Ease-off are necessary things for any user to put their knowledge in to help the system out" (026F_child_6yrs). This included situations where their child was doing planned physical activity, was unwell, or was about to consume foods (e.g., pizza, ice-cream) which, based on their own knowledge and experience, parents knew would lead to out-of-range glucose levels despite using the system (Table 4). Parents praised Boost or Ease-off for being "a very easy function, just pressing the button" (006M_child_6yrs) and highlighted the benefits to not having to calculate temporary basal rates (Table 4).

However, some parents felt that they had not always been able to use the Boost feature optimally. Several parents, for instance, described how this function could at times be too slow to regulate high glucose levels, "[be]cause he's having such small amounts that 30% is barely anything for him unless you have it on for a few hours" (011M_child_3yrs). Other parents, especially those of very young children, reported that they had used the Boost function only sporadically as they felt it could at times be too aggressive, which had caused their child's glucose to drop too quickly:

> "I don't know if it's 'cause he's only small, the Boost sometimes is a little bit too aggressive for him… I generally don't use it that often and if I do I don't use it for very long… because it starts bringing him down and then… he ends up sort of plummeting down and then going too low." (008M_child_2yrs)

3.3 Facilitating normality

3.3.1 Parental benefits

Alongside clinical benefits and reduced workloads, parents noted how using the closed-loop system had helped to make their lives feel more normal. This included experiencing less anxiety and worry about their child's safety when in their own and other people's care, less disruption from alarms going off, and improved sleep due to parents' confidence that the system would help keep glucose in range:

> "I think for me, just the fact that I could trust it… to take care of my daughter and it wasn't going to hurt her or make it worse, or that it wasn't something… I needed to constantly be checking on… it totally eased my mind." (025M_child_6yrs)

> "I'd say night-time is probably the most dramatic difference, because… we probably are only woken by alarms now, like, twice a week. And we never set an alarm to test [child's name] now. And we trust it. Like, honestly, the line is deadly straight overnight." (002M_child_6yrs)

Indeed, parents described how using the closed-loop system "has given us part of our lives back [because] we are not constantly that worried if school can cope or whoever can cope" (017F_child_5yrs). Some also reported feeling able to resume activities, such as going out for dinner together or contemplating a return to full-time employment, because they felt more confident outsourcing care to others, including those with limited diabetes management experience:

> "I'd feel more confident, you know, if he ever needed to go on a sleepover or play date, I'd feel just so much better about it, because it's like a little guardian angel, you know, looking over him. Whereas before… I don't think I could let him go without someone who is fully trained." (002M_child_6yrs)

3.3.2 Benefits to the child

Parents also noted how their child's own life had improved due to them experiencing more stable glucose levels and, hence, improved mood and concentration and less disrupted sleep:

> "It's like her temperament has changed… She's been so much calmer in herself… She's just generally much more able to get along with her peers when she's playing, she's able to compromise better, problem-solve better." (020M_child_4yrs)

> "So being more steady, it must make her feel better. Obviously not going hypo through the night, she's getting better sleep, because I'm not having to keep interrupting her to treat a hypo." (006M_child_6yrs)

Parents particularly emphasised how using the closed-loop system had enabled their child to feel more normal, in part because conversations and activities no longer needed to focus on glucose management, and parents having more time and energy to dedicate to everyday family life:

> "We had to talk numbers a lot around her. You're handing over and you're talking about: oh, she's got a temp basal at the moment, it's maybe lasting for two hours to do this. And then she's hearing this conversation… Now… we just have normal discussions, so it must feel so nice for her… we've had more time just to be her parents and do play and fun things." (020M_child_4yrs)

By virtue of diabetes having a lessened impact on everyday family life, parents also highlighted benefits to siblings:

> "Sometimes the other two say we favour [child's name], but then I think it's 'cause we have to spend more time with her, with the diabetes care. But that has got less since she's been on this system, we're not having to do as much as we used to." (006M_child_6yrs)

Parents further noted how using the closed-loop system permitted a more normal childhood experience, because other people were more willing to invite their child to parties, playdates and sleepovers due to diabetes management tasks being made simpler and lessened concerns about the child experiencing hypoglycaemia and hyperglycaemia:

> "If, like, my mum or someone else was having him, rather than having to give him a correction when she's a bit worried about not knowing how much to give or if it's right or whatever, it would have sort of corrected itself, so she wouldn't really have to do that much for him." (008M_child_2yrs)

This benefit was reinforced by parents' ability to remotely monitor their child's glucose levels on their own smartphone, which facilitated oversight and collaboration with other caregivers as required; a finding described in more detail in a companion paper [29].

Parents also described how being able to administer insulin via the smartphone facilitated a more normal childhood experience (albeit this benefit was also reported when in the SAP arm of the trial). Parents, for instance, observed how their child had experienced lessened distress and increased dignity as clothing no longer needed to be lifted/removed to access the pump (Table 4). They also noted how, when the child attended parties, played or was at school, it was possible for them or another caregiver (e.g., teacher) to administer insulin surreptitiously without the child (or other children) being aware of what was happening:

> "Like, she can be playing in the garden outside and I can just kind of hang out of the window and give her [insulin]… I don't have to get her to stop what she's doing." (018M_child_7yrs)

3.4 Refining the technology for very young children

Parents, especially those of infants and toddlers, reported some aspects of the technology, such as the smartphone's size and weight, as not being appropriate for very young children. Parents described how, to keep it in range of the other devices to maintain connectivity, they or another caregiver (e.g., teaching assistant) needed to monitor the child closely and/or follow them around (e.g., in the playground) while carrying the smartphone (Table 4), an approach which was not always feasible. Indeed, some parents raised concerns that their child had not gained optimal benefit from the closed-loop system due to them being very active and the difficulties of keeping them under sufficiently close supervision to ensure they were always in range of the smartphone:

> "Our garden backs onto a cricket pitch. And she jumps over our wall and goes running on the cricket pitch. And she doesn't always stay near her phone. And so obviously when she's not near her phone, then the Auto[mode] bit isn't working." (018M_child_7yrs)

To address this concern, parents recommended using a smaller smart device (e.g., a smartwatch), which would be easier to keep on the child's body (Table 4). However, given the benefits of being able to administer insulin remotely, parents emphasised how they would also like to retain the ability to administer insulin via a separate handheld device (Table 4).

In light of their mixed experiences of using the Boost function, and drawing on their experiences of using temporary basal settings to regulate their child's glucose levels in various situations, some parents also recommended that future iterations of closed-loop technology could offer either fully-customisable or a selection of pre-set insulin delivery rates, because, as this parent noted, "simply 'plus 30%'… is not necessarily what the situation demands" (023F_child_4yrs).

<<Table 4 here>>

4. DISCUSSION

This, to our knowledge, is the first qualitative study to explore parents' experiences of using a hybrid closed-loop system in a real-world setting when caring for a very young child with type 1 diabetes. Parents described the CamAPS FX system as offering wide-ranging benefits. These included the child spending more time in range and experiencing less frequent and/or significant hypoglycaemia and hyperglycaemia. The closed-loop system was also praised for providing better management of mealtime excursions and offering a safety net if the child consumed more/less food than planned or errors in carbohydrate counting occurred; this benefit has also been highlighted by adult and adolescent users [16].

Main trial results confirm the clinical benefits which parents reported [30]; however, trial data do not adequately capture the wider benefits which parents also shared. Notably, parents described the closed-loop system as enabling them, their child and siblings to lead more normal lives which were less dictated and dominated by diabetes. Parents slept better and worried less about their child due to the system's ability help keep glucose in range;

albeit, as reported in our companion paper [29] and by others [31], such benefits were reinforced by using a CGM with remote-monitoring capabilities. Parents also described being better placed to get on with their own lives (e.g., returning to employment, going out for meals as a couple) as caregiving demands were lessened, other people felt more confident caring for their child, and parents felt more confident entrusting their child's care to others. This increased confidence was facilitated by the closed-loop system's ability to keep the child's glucose levels stable, though, as we report elsewhere [29], parents also gained reassurance from being able to remotely access their child's insulin and glucose data and issue advice/instructions to caregivers if required. They also noted how their child had more opportunities to socialise with peers without feeling different. Some parents also described how their child had experienced improved concentration and mood due to better glucose control, improved sleep and not being distracted by diabetes management tasks. Siblings also experienced a more normal childhood, due to parental time and effort no longer being so focused on diabetes management. This benefit is critical, as research suggests that siblings of children with diabetes can feel isolated and 'invisible', and can experience consequent emotional and behavioural difficulties [32].

Some parents reported initial challenges stepping back and allowing the system to address high/low glucose without interference; indeed, some worried that they had undermined the system's efficacy as a consequence. Given that using a closed-loop system requires a radical shift from 'active' to more 'passive' caregiving roles, the difficulties these parents reported are understandable [33]. It is also likely that these challenges will be lessened if children use closed-loop systems from the outset, as parents will not have been habituated into such active caregiving roles. Indeed, a desire to step in and override the system was not reported by individuals who used a closed-loop system from diagnosis, albeit, in this instance, these individuals were adolescent users [15].

In keeping with potential users' expectations of closed-loop technology, most parents, like adolescent and adult users [17,34], noted how their confidence and trust in the system had been fostered by having easy access to graphical information, which allowed them to observe, and understand, how the system worked. Hence, it is vital this capability is retained in future systems [17].

In line with experiences of adolescents who used the CamAPS FX system [15], and recommendations from users of earlier iterations of closed-loop technology [17,20], parents welcomed opportunities to work with the algorithm on occasions when their own knowledge could enhance its efficacy (e.g., when the child had a viral infection, was about to undertake planned physical activity or eat a high fat/carb meal). Parents also praised Ease-off and Boost features for being easy to use. Hence, this study, like others [15], suggests that these user-interaction features should be retained/included in future systems. We would also recommend that in this age group, where variable insulin requirements and higher insulin sensitivity are commonplace [22], such functions, especially Boost, should offer flexible, customisable functionality.

Many parents reported difficulties keeping the smartphone near the pump/CGM to avoid signal loss, because this device was too large to easily stow on the child's body. This experience stands in contrast to that reported by adolescents using the CamAPS FX system, who described finding it easy to keep the devices in range as they always carried a smartphone with them [15]. Hence, closed-loop systems may need to be tailored to different age/user groups [35]. Our findings suggest that very young children would benefit from using a small(er) smart device or the algorithm being integrated into the pump (albeit parents did not make the latter suggestion). However, given the quality-of-life benefits young children gain from having insulin administered remotely, it is also important that parents have the capability to administer insulin through a separate device. It is encouraging that interoperable devices and data management platforms should soon be available, as these will permit users to customise closed-loop systems to their own (age-based) preferences and needs [1].

Parents' suggestion that they had had less need for health professional support echoes health professionals' own suggestions that, after initial training, individuals using closed-loop technology need less support to achieve clinically-recommended glycaemic control than those using pump and injection regimens [36,37]. However, long-term follow-up of individuals using closed-loop technology in routine clinical care would be required to confirm/quantify this finding.

We recognise that, in contrast to previous closed-loop studies [10-13,19], parents' accounts in this study were overwhelmingly positive. These studies, however, involved earlier iterations of the technology and most negative user feedback related to aspects of the system (device size/appearance, functionality and technical difficulties) which have since been addressed. While it is encouraging that parents reported wide-reaching psychosocial benefits to using a closed-loop system, these systems still demand user engagement and input [13]; as such, they cannot be said to facilitate a truly 'normal' experience. Hence, it is vital that user feedback continues to be taken into account in the development of future systems.

A key study strength is the inclusion of parents from different countries and with young children of different ages, who used a closed-loop system in real-life settings for four months. A key limitation is that our sample was skewed towards white individuals in professional occupations. These individuals also chose to take part in closed-loop system research; hence, they may have been a particularly motivated group who wished to help evidence the benefits and efficacy of these systems [38]. To help promote equitable access, it is vital that people from lower socio-economic and minority ethnic groups are consulted. We also recommend future work focus on parents who use closed-loop systems from the outset of a child's diagnosis to establish whether these individuals experience less difficulty handing over control to the system. As our paper only reports parents' experiences of using one type of closed-loop system, the benefits and challenges described here may not extend to other systems, such as the Tandem t:slim X2 with Control IQ and MiniMed 670G, which have recently been assessed for safety and efficacy in very young children [39,40]. Hence, to help optimise the technology for use in this population, we recommend undertaking qualitative studies with parents using other closed-loop systems.

5. CONCLUSION

Using a closed-loop system in very young children can facilitate greater normality for the child, their parents and siblings. To maximise such benefits, it is important that parents are given access to technology that enables them to administer insulin remotely and customise

select functions. There are promising indications that using this technology may lead to a lessened demand on health professionals' resources.

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CONFLICTS OF INTEREST

RH reports having received speaker honoraria from Eli Lilly and Novo Nordisk, serving on advisory panels 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. CKB has received consultancy fees from CamDiab. FC has attended advisory boards, obtained speaking fees and educational support from Abbott, Dexcom, Medtronic, Lilly, Insulet and Novo Nordisk. EFR reports having received speaker honoraria from Eli Lilly and Novo Nordisk, and serving on advisory boards for Eli Lilly and Sanofi. The authors BK, DR, RIH, JMA, SEH, TMK, BRM, US, AT, JW and JL report no conflicts of interest relevant to this article.

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Table 1: Trial eligibility criteria and description of the CamAPS FX system

Trial eligibility criteria

To be eligible for trial participation, children had to be aged between 1 and 7 years, have lived with type 1 diabetes for at least 6 months and used an insulin pump for at least 3 months. For further details about inclusion/exclusion criteria see Fuchs et al [25].

The CamAPS FX hybrid closed-loop platform comprised:

- Dana RS insulin pump (Sooil, Seoul, South Korea).
- Dexcom G6 factory calibrated real-time CGM sensor (Dexcom, San Diego, CA, USA).
- An unlocked Android smartphone (Galaxy S8, Samsung, South Korea) running Android 8 OS or above, which hosted the CamAPS FX App incorporating the Cambridge model predictive control algorithm (CamDiab, Cambridge, UK) and communicating wirelessly with the insulin pump. Parents of participants could opt to use their personal smartphone if compatible.

Parents of CamAPS FX users were required to use the bolus calculator on the app to deliver meal boluses; change their child's pump infusion set every 2-3 days; replace their child's CGM sensor at least every 10 days; respond to alarms alerting them to their child's high/low glucose levels; ensure that study devices (smartphone) are charged; and, ensure the smartphone is kept in close proximity (5-10 metres) to avoid signal loss with the pump/CGM. Further detail about the CamAPS FX app is provided below.

CamAPS FX app

In addition to being used to administer mealtime boluses of insulin, the app included functions enabling parents of users to:

- view a 'real-time' graph displaying their child's sensor glucose levels, rate of insulin delivery, mealtime boluses and carbohydrate intake, high/low glucose range, glucose trend arrows, whether 'Boost' or 'Ease-off' functions were activated (see below), and whether the closed-loop system was operational (Automode on) or interrupted (Automode off).
- view summary statistics for daily, weekly, monthly, or three-monthly periods, including: average glucose, estimated HbA1c, time in/below/above target, number and average duration of hypos, total daily dose/bolus/basal insulin; and percentage of time in Automode.
- issue instructions to the closed-loop to initiate a 'Boost' or 'Ease-off' mode of operation.

- change glucose target (default value 5.8mmol/L; range 4.4 to 11 mmol/L) throughout the day in 20-minute intervals.
- receive and personalise alarms/alerts triggered by high/low glucose and signal loss with the sensor and/or pump by adjusting the threshold, repeat time and audio sound or vibration which accompanied an on-screen display, and turn on/off all alerts (except the 'Urgent Low' glucose alarm).
- share (by automatically uploading to the cloud) with health professionals, and other caregivers, near 'real-time' glucose levels, insulin, and mealtime bolus data, which could be accessed using the Diasend/Glooko app (Glooko/Diasend; Göteborg, Sweden), and an option to relay alarms to a parent-determined set of 'followers' alerting them to high/low glucose, sent via SMS texts. (Note: findings pertaining to this feature are reported in separate publications).

Table 2: Topic guide for parent interviews

Background information/pre-trial experiences

- Age of child with diabetes, is the child attending school/nursery, any siblings, parental occupations, whether parents live together/separately (caregiving arrangements).
- When was the child diagnosed? Impact of diagnosis on parents (e.g., employment), the child and other family members.
- What devices (pump, CGM) were being used before the trial? Parents' experiences of and views about using these devices.
- Experiences of managing diabetes before the trial (e.g., at mealtimes, when the child was physically active, use of glucose targets, experiences of hypo- and hyperglycaemia, experiences of managing diabetes overnight).
- Role of other people (e.g., informal caregivers, teachers) in diabetes management; did parents feel confident and able to entrust diabetes care to other people (who and why)?
- Impact of living with and managing diabetes on parents, the child with diabetes and other family members (e.g., siblings).
- Views about their child's glucose control before the trial.
- Experiences of and views about the care received from diabetes professionals pre-trial.

Experiences of using the closed-loop system during the trial

- Initial impressions, any concerns about using the system (what and why)?
- Views about handing control to the closed-loop system. How, when and why did confidence/trust in the algorithm develop?
- Experiences of diabetes management using the closed-loop system (e.g., mealtimes, when the child was physically active, use of glucose targets, experiences of hypo-and hyperglycaemia, management of diabetes overnight).
    - Probe to explore whether food choices, physical activity, use of targets, etc changed as a result of using the closed-loop system, and why (not).
- Understandings of the purpose of Boost and Ease-off functions. In what situations (and why) did parents use these features? Did they find these features helpful; why (not)?
- Any difficulties encountered using study devices; how were these addressed/overcome?
- Confidence/willingness to allow the child to be cared for by others (and other people's willingness to care for the child); did using the closed-loop system make any difference; if so, why?

- Perceived impact of the closed-loop system on glucose control and quality of life of the parent(s), child and other family members; impact of using the technology on everyday work and family life.
- Experiences of, and views about, the contact and support parents received from staff during the trial/when using the closed-loop system. Did parents' need for contact/support change as a result of using the closed-loop system; how and why? Views about the level/type of support needed to use a closed-loop system in routine clinical care.
- Views about how the technology might be further refined/improved for use in very young children.

Table 3: Parent and child participant characteristics and devices used before the trial

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	
Ethnicity			
White	28	93.3	
Mixed race	2	6.7	
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)
Baseline HbA1c (%)			7.4 (6.1-9.0)
Living with siblings	24	80.0	
Devices used before joining the trial			
Insulin pumps:			
Medtronic MiniMed 640G	25	83.3	
AkkuChek	4	13.3	
Animas	1	3.3	
Sensors:			
Freestyle Libre flash monitor	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 involving both parents. Of the 26 follow-up interviews, 19 were conducted with mothers, four with fathers and three were joint interviews involving 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.

Table 4: Participant quotations

Theme	Participant quotations
Better control, less work	Keeping child's glucose levels more in range after meals: "If there's a meal he won't shoot up as high as he would with when it's not the closed loop. It's definitely a lot better, which means I don't spend the rest of the day trying to fight to get him down." (011M_child_3yrs) Fewer glucose fluctuations arising from errors in carbohydrate counting: "If he had a snack somewhere in between times it's no problem, the system will deal with it. And also when we knew we had given too little [insulin], because he ended up eating more than we'd thought, the system would just correct all of that." (030M_child_8yrs) System offering input beyond parents' own capabilities "The algorithm is giving so many small doses of insulin over a long period of time that I think, like for me that would be so time-expensive to be doing it. I mean, I would never try to emulate exactly what it was doing, because that would just be ridiculous." (025M_child_6yrs)
Enhancing control using Ease-off and Boost	Managing planned physical activity: "I can manage easily with sport. That is incredible, or very, very beautiful, when we put on the Ease-off... [child's name] can do an hour and a half or two hours of sport and with the Ease-off I have no low blood sugar." (016M_child_7yrs) When unwell: "And the Boost was helpful in situations where… when he was high, through that period he did get ill a couple of times, so his levels, sometimes we don't know where it's going to go, if it's going to go low or high. But in these situations he was going slightly higher, so the Boost was very helpful in those situations." (028M_child_6yrs) Parents' experience when child consumes high-carbohydrate meals: "It [closed-loop] doesn't necessarily know what kind of carbs you put in and therefore it's always chasing the game, whereas we do know if she's had something really high [in carbohydrates] that's going to come through quickly." (026F_child_6yrs) "[We] always [use Boost] when she ate her muesli, always, or when we ate out at a restaurant. Or when I noticed that I'd given her carbohydrates but she then went up very high very quickly, then I would use it too, so that she would come down again… I think it worked very well, yes." (021M_child_3yrs) Not having to calculate temporary basal rates: "It's so much easier to do a Boost and an Ease-off, 'cause you don't have to think: how much insulin is she getting this hour, the last hour, the next hour, and then think: okay, well, how was she running? What- how much do I want to improve that by? What's her insulin sensitivity factor for that time of day?" (020M_child_4yrs)

Facilitating normality	Benefits of using smartphone to administer insulin – less distress: "Oh that is so much easier. So with a two-year-old, they don't like to be restrained at the best of times, and with the pump we would have to literally restrain him and hold him down, which would result in him screaming." (004M_child_2yrs) Increased dignity and privacy for child: "We don't need to be physical all the time, we don't need to take the bloody Medtronic pump to put in some units and put it back into the T-shirt, or wherever she has it. So that is good, we will give her more private space." (017F_child_5yrs)
Refining the technology for very young children	Smartphone too big and heavy to stow on child's body: "He doesn't carry the phone at the moment, it's just… too much, he's too small. He already has to carry the pump around with the pump bag, and for him to carry the phone as well, and it is a pretty big phone, it's just too much." (008M_child_2yrs) Keeping smartphone in range of other components: "So we carry the phone and try and keep him in range at home running around. We've got a house that you can run the whole way round in a circle, so we're trying to make sure it's in a central place, so that he's in range all the time. And then at nursery his keyworker carries the phone round for him." (022M_child_2yrs) Recommendations to use a small smart device: "He is a little monkey and he climbs and he does everything… the mobile phone is big… and it is rather bulky… so a wristwatch would be, of course, much less bulky and he could move even more freely." (012M_child_4yrs) Having the ability to administer insulin using a separate smart device: "It would be great if it was on a smartwatch. But then he would need two. Or let me put it like that, the problem is that the pump needs to communicate with the mobile… With children, the mobile is with the parents, basically. If the child moves away from the mobile, it won't work anymore. If I give the mobile phone to the child, the connection is given, but the parents can't do anything anymore, because the mobile is stowed with the child." (001F_child_3yrs)