Listening to women: experiences of using closed-loop in type 1 diabetes pregnancy

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ABSTRACT

Introduction: Recent high-profile calls have emphasized that women's experiences should be considered in maternity care provisioning. We explored women's experiences of using closed-loop during type 1 diabetes pregnancy to inform decision-making about antenatal rollout and guidance and support given to future users.

Methods: We interviewed 23 closed-loop participants in the Automated insulin Delivery Amongst Pregnant women with T1D (AiDAPT) trial following randomization to closed-loop and ~20 weeks later. Data were analysed thematically.

Results: Women described how closed-loop lessened the physical and mental demands of diabetes management, enabling them to feel more normal and sleep better. By virtue of spending increased time-in-range, women also worried less about risks to their baby and being judged negatively by healthcare professionals. Most noted that intensive input and support during early pregnancy had been crucial to adjusting to, and developing confidence in, the technology. Women emphasised that attaining pregnancy glucose targets still required ongoing effort from themselves and the healthcare team. Women described needing education to help them determine when, and how, to intervene and when to allow closed-loop to operate without interference. All women reported more enjoyable pregnancy experiences as a result of using closed-loop; some also noted being able to remain longer in paid employment.

Conclusions: Study findings endorse closed-loop use in type 1 diabetes pregnancy by highlighting how the technology can facilitate positive pregnancy experiences. To realise fully the benefits of closed-loop, pregnant women would benefit from initial, intensive oversight and support together with closed-loop specific education and training.

INTRODUCTION

To reduce risks of obstetric and neonatal complications, pregnant women with type 1 diabetes are advised to keep glucose between 3.5-7.8 mmol/L [63-140.4 mg/dL] for ≥70% of the time (1). Women are acutely aware of the risks type 1 diabetes poses to their babies and highly motivated to address them (2,3). However, pregnancy-related physiological changes (e.g. nausea and vomiting, variations in insulin sensitivity and/or resistance) and limitations of subcutaneous insulin regimens can make attainment of pregnancy glucose targets extremely challenging (4,5). Moreover, the pressure to attain pregnancy glucose targets can cause significant psychological distress (2,6). Throughout pregnancy, women with type 1 diabetes receive intensive clinical support (weekly/fortnightly contacts) to assess maternal glucose levels and optimise insulin doses. However, this 'medicalisation' can further undermine women's pregnancy enjoyment (7).

Continuous glucose monitoring (CGM) has been shown to improve glucose levels and newborn health outcomes (8,9) and is now widely offered in type 1 diabetes T1D pregnancy in the UK and internationally (10). Closed-loop systems, which link an insulin pump and CGM via a control algorithm that automates basal insulin delivery, have potential to provide additional glycaemic benefits, with early reports showing promising biomedical results (11–15). Studies reporting pregnant women's experiences of using closed-loop technology are extremely limited and investigated early generation prototype devices used for short durations (16,17). Hence, their findings have limited relevance for decision-making about closed-loop use in pregnancy.

In response to high-profile calls to listen to women and take their experiences seriously in maternity care provisioning (18), and concerns about inadequacies in existing quality-of-life measures for pregnant women with type 1 diabetes (19), we conducted longitudinal interviews with women who used the first commercially available closed-loop (CamAPS FX) system licensed for use in type 1 diabetes pregnancy. The purpose of these interviews was to explore how women used the system, and how closed-loop use affected their diabetes management and pregnancy experiences. Our objective was to allow women's

experiences to inform decision-making about antenatal closed-loop rollout and guidance and support given to future closed-loop users.

METHODS

Overview

We interviewed women randomised to the closed-loop arm of the Automated insulin Delivery Among Pregnant women with Type 1 diabetes (AiDAPT) trial, which is a UK-based open-label, multi-centre, randomised trial comparing closed-loop with standard insulin delivery (20). Participants used the CamAPS FX system for ~24 weeks during their type 1 diabetes pregnancy (~13-37 weeks). The CamAPS FX app included functions enabling users to input mealtime boluses, personalise their glucose targets and increase ('Boost') or reduce ('Ease-off') basal insulin delivery by ~33%. Users could initiate and specify a start time and duration (≤12 hours) for 'Boost' when they felt more insulin was needed (e.g. during periods of inactivity, increased food intake, illness or stress) or 'Ease-off' when less insulin was needed (e.g. during early pregnancy, exercise, or when nausea, vomiting or decreased food intake occurred). The app facilitated automatic data upload to the cloud, enabling data-sharing with healthcare professionals (HCPs).

Further details about the trial (including eligibility criteria) and the CamAPS FX system are provided elsewhere (20) and in Table 1. Ethics and governance approvals were obtained as part of the main trial. Our approach to reporting follows Standards for Reporting Qualitative Research (SRQR) (21).

<<Table_1>>

Sampling and recruitment

Women were recruited and consented into the interview study when they consented to participate in the AiDAPT trial. Recruitment took place at seven clinical sites in England and Scotland. Purposive sampling was used to encourage diversity with respect to women's socio-economic status, age, and parity. Recruitment continued until data saturation was reached.

Data collection

Women were interviewed twice by a highly experienced (non-clinical) qualitative researcher (DR), who had no prior relationship with participants, following randomization to closed-loop and ~20 weeks later. Baseline interviews explored women's experiences of managing diabetes during previous pregnancies (if relevant) and before using closed-loop to set the context for understanding their subsequent experiences of closed-loop use. Interviews were informed by topic guides (see Table_2): these ensured the conversation remained relevant to addressing the study aims while allowing participants opportunities to raise issues they considered important, including those unforeseen at the outset. Topic guide development was informed by previous studies reporting user experiences of closed-loop (22–24), input from clinical co-investigators, and revised in response to emerging findings. Interviews took place by telephone between April 2020 and April 2022, were digitally recorded and transcribed. Interviews lasted 1-2 hours.

<<Table_2>>

Data analysis

As this work was informed by *a priori* as well as emergent interests, data analysis sought to identify both descriptive and analytical themes (25) with relevance to clinical practice. Four experienced qualitative researchers (JL, BK, DR, MN) analysed the data using the technique of constant comparison (26). First, all interview transcripts were read through repeatedly and cross-compared to identify key cross-cutting themes. Next, a coding frame was developed to capture data relevant to each of these themes. Coded datasets were then subject to further analyses to identify subthemes and illustrative quotations. Throughout, qualitative research team members undertook independent analyses and wrote separate reports before meeting to discuss their interpretations and agree on the main findings/themes. The qualitative software package Nvivo 20 (QSR international, Doncaster, Australia) was used to facilitate data coding and retrieval.

RESULTS

Twenty-three women participated. See Table_3 for information about the sample, including demographic characteristics and pre-trial glucose monitoring and insulin regimens.

<<Table_3>>

We begin by reporting women's experiences of diabetes management during previous pregnancies and prior to using closed-loop in their current pregnancy to set the context for their subsequent closed-loop use. We then describe the perceived benefits and limitations to closed-loop use, and the importance most women placed upon collaborating both with the system and HCPs to attain pregnancy glucose targets. Finally, we present women's views about the impact of closed-loop use on their overall pregnancy experiences. Key illustrative quotations are included below; for additional quotes see Table 4.

Managing type 1 diabetes pregnancy before closed-loop

Physical, mental and emotional demands

Women described their experiences of glycaemic management during previous pregnancies, in preparation for a planned pregnancy, and/or in the early stages of pregnancy as having been "such hard work… it's so intense" (010). Women, for instance, described having to "constantly prick my finger, constantly correct" (007) or "constantly chang[e] my basal rates, it was relentless" (005), and how their diabetes management had been "constantly at the forefront of my mind" (019). Some described needing to set alarms at night to collect information needed to inform frequent adjustments to background insulin doses/basal rates or address worries about hypoglycaemia, with resultant detrimental impacts on their sleep and wellbeing [Table 4]. Women also noted how needing to make frequent alterations to background insulin doses/basal infusion rates had caused anxiety and heightened the mental demands of glycaemic management throughout pregnancy:

> *"I'm not very good at calculating things. So when they're throwing like new calculations at me… it made me really anxious… you know, constantly trying to figure out: oh, my numbers are doing this thing and they're doing that thing. What am I doing?" (012)*

Blunt instruments

Women noted that previous type 1 diabetes management had been made more challenging by using blunt and inadequate instruments, including finger-prick glucose monitoring which had resulted in them having limited and inadequate glucose information to inform self-management decisions: "I didn't have a sensor, so I couldn't look back on what my sugars were doing through the night. So it was literally guessing" (005). Excepting those who had been using CGM pre-trial, women also noted how their glycaemic management had been compromised by not having alarms alerting them to glucose excursions: "I wouldn't have gone all night before I realised I was at 15 [mmol/L - 270 mg/dL] or 17[mmol/L - 306mg/dL] or something, and I could have taken a correction sooner" (015).

Negative pregnancy experiences

Most women reported how resultant difficulties keeping glucose within pregnancy/pre-pregnancy target ranges had led to feelings of anxiety and guilt, wherein, "every reading you see, you think, 'oh my God, I'm harming the baby'" (010). Some noted having become "a bit obsessed" (017) about monitoring and over-correcting out-of-range glucose as a consequence, which heightened feelings of anxiety and distress [Table 4]. Due to the physical, mental, and emotional demands of type 1 diabetes management, women also described experiencing early pregnancy and/or previous pregnancies as "tiring and draining" (005), "very stressful" (013) and feeling that "it deprived me of enjoying it [pregnancy]" (002).

Experiences of using closed-loop

Adjusting to the system

Most women described taking several weeks to develop confidence and trust in the system, with some reporting frequent data-checking to seek reassurance that the closed-

loop was working correctly [Table_4]. Women noted how HCPs' intensive input (e.g., changing closed-loop settings), oversight and emotional support in the initial days of use had been critical to developing confidence in, and adjusting to, the system:

> *"I trusted it, because… I just… knew that obviously the ladies at the hospital were monitoring quite closely to make sure that it was correct, and so they could change it sort of from day to day if needed." (021)*

Women further noted that, while they had found the initial closed-loop training helpful and comprehensive, it had been necessary "to learn by doing" (017). Hence, they described valuing being able to text/call/email HCPs after transitioning onto the system to seek practical guidance, refresh their understanding of the closed-loop's functions and seek reassurance they were using it correctly [Table 4].

Less work, less worry… better glucose control

After this adjustment period, women reported multiple ways closed-loop had helped reduce the physical, mental, and emotional demands of glycaemic management in type 1 diabetes pregnancy, albeit several emphasised that: "the sensor would have helped even without closed-loop" (007). The key benefit, highlighted by all women, was the system's ability to automatically adjust basal insulin rates, with women noting how this had helped to reduce their physical and mental workloads whilst improving time spent in target glucose range:

> *"Before… I was on it, like every couple of weeks I was having to keep changing all my basal rates and everything to try and keep up, whereas this just automatically does it, so it makes it much easier, it just takes a lot off you, like even the mental side of just constant viewing the data, it does all that for you." (010)*

Women also welcomed being able to administer insulin via the app on their mobile phone, rather than via the pump or by injecting. As well as lessening their workloads and helping them feel more normal, some reported having administered correction doses more promptly due to this task being so easy and discrete to undertake [Table_4].

By virtue of closed-loop automatically reducing or suspending insulin delivery when glucose levels fell and knowing that the CGM would alert them to glucose excursions, women described feeling more confident striving for pregnancy glucose targets:

> *"It's definitely helped with the anxiety of running myself high to not go low, because I've got the alerts that tell me if it is gonna go low… And knowing that the closed loop will be picking up if you are starting to get low, that it's going to ease off." (007)*

Women also described experiencing better sleep [Table_4] and less stress and anxiety despite using tighter glucose targets, because of knowing that the closed-loop was operating in the background to help keep them safe:

> *"It took the worry away for me, 'cause I'm quite active in the day with my kids, so if I'm dipping low and I'm busy with the kids, I'm alerted before anything goes wrong, because if I was to have a hypo and not be responsive it would be awful." (011)*

But still work… user collaboration with closed-loop

Most women, however, emphasised that closed-loop was not a panacea and that, to optimise time spent in glucose target range, they still needed to undertake some work:

> *"Maybe just anecdotally I've heard…it's like an artificial pancreas. And I think that sounds just wrong. And I think it gives false hope… because for me it's still a lot of your management." (011)*

Women, for instance, described needing to pay close attention to dietary choices, carbohydrate counting and the timing of mealtime boluses to help create the conditions under which closed-loop could work optimally [Table 4]. Furthermore, while a minority welcomed being able to delegate glucose management tasks to the system "and let it do its thing" (010), the majority expressed a strong motivation and perceived responsibility to work with, and alongside, the technology to help address and/or pre-empt glucose excursions. In doing so, women emphasised how having easy access to 'real-time' CGM glucose data, which included information about whether, and how quickly, glucose levels were rising or falling, had prompted and enabled more timely and informed action.

> *"So I can see if my levels right now are stable, if they're going up, if they're going quickly up, if they're going down… So with that allows me to make a better decision… [for instance] I can see it's giving me more basal at this time, so I don't do a correction right now." (002)*

Some also noted how having access to 'real-time' insulin as well as CGM glucose data when using closed-loop meant that they had better information to inform glucose management decisions [Table 4]. To help ensure timely and appropriate interventions, women emphasised the importance of receiving clear instruction and education to help them determine whether, when, and how, they should intervene to address out-of-range readings and when they should allow closed-loop to operate without interference [Table 4].

Collaboration with closed-loop technology; using Ease-off and Boost

Women described the Ease-off and Boost functions as being particularly valuable tools to support attainment of tight pregnancy glucose targets. Some, for instance, described benefiting from using Boost in situations where they felt the algorithm had been too sluggish and/or had struggled to keep up with their rapidly changing insulin requirements [Table 4]. Women also valued using these features on occasions when, in conjunction with the closed-loop system's insulin adjustment capabilities, they felt that applying their own knowledge could help prevent glucose excursions. This included situations where they were about to undertake physical activity, eat a meal with a high fat-to-carbohydrate content, or delay a meal [Table 4].

Better collaboration with healthcare teams

Alongside their own collaborative role, women saw their healthcare team as playing a pivotal role in supporting effective closed-loop use by guiding and advising on appropriate courses of action, such as when to alter insulin-to-carbohydrate ratios. In doing so, women noted how, by having easy access to their data and, hence, being able to monitor their progress between, and in preparation for, antenatal appointments, their healthcare team had been able to provide more effective and timely input:

> *"They check on me very few days and if they can see that: oh, you're going high at this point, or low at this point, they'll message me or ring me and say: ooh, would you mind tweaking this on your pump, or on your app." (003)*

Some women described calling or texting HCPs between scheduled appointments and receiving better feedback because they did not need to rely on retrospective or self-reported information/data [Table 4]. While some such women voiced initial (privacy) concerns about HCPs being able to access their insulin as well as glucose data when using closed-loop [Table_4], most emphasised that they had received better and more personalised input as a result of HCPs having access to data which allowed them "to know me, know my body…know what influences what" (002) [Table 4]. Some further suggested that this enhanced data access had helped them develop more honest, positive, and trusting relationships with their healthcare team [Table 4].

Positive pregnancy experiences

Women emphasised that using closed-loop had had a positive impact on their pregnancy experiences. They partly attributed this to expending less time and effort on type 1 diabetes management and, hence, enjoying a "more normal life" (002), which, in some cases, included feeling able to work for longer than in previous pregnancies [Table_4] and/or having more time to devote to childcare and other family activities.

As a result of spending increased time in target glucose range, women also described worrying less about their baby's development [Table 4] and feeling less anxious about attending antenatal appointments and receiving negative judgements:

> *"I didn't want to go into the hospital and be told off… so I didn't really like going in, speaking to anybody. But now my sugars are so much better…it's not a worry for me anymore. I don't ever really have any issues. So it's a nicer experience for me." (011)*

All women noted that, as a result of using closed-loop, they had been able to better enjoy their pregnancy:

"In terms of enjoyment factor, and how I feel about the baby, and how I feel about the coming labour, and how excited I am to meet them and the bonding process and stuff like that, I'd say I've had a lot more time for it this time round." (016)

<<Table_4>>

DISCUSSION

Women from diverse socio-economic backgrounds reported wide-ranging glycaemic and quality-of-life benefits to using closed-loop in pregnancy. In doing so, women emphasised that closed-loop was not a panacea and that, to optimise clinical gains, ongoing involvement and effort was required. Indeed, women's accounts suggest that closed-loop should be understood as one pillar in a three-party collaboration involving themselves, the technology and their healthcare team.

While women reported some anxieties when they first transitioned onto closed-loop, they did not describe the substantial negative psychosocial impacts highlighted in earlier studies.[16,17] Instead, women emphasised quality-of-life gains resulting from lessened physical and mental workloads, experiencing better sleep, having more positive interactions with the healthcare team, and knowing that their baby was less 'at risk' because closed-loop increased time in target glucose range. Arguably, these important benefits were not captured in earlier studies which reported women's experiences in the initial weeks of closed-loop use when 'obsessive' data-checking was more common (16,17). Furthermore, women in previous studies used prototype devices that were prone to anxiety-provoking, technical malfunctions (16,17). Women described benefitting from intensive oversight and support from healthcare teams in the initial period of using closed-loop to receive practical/technical support and reassurance that the closed-loop was working effectively. Hence, similar initial, intensive support should be provided to pregnant women using the technology in non-trial settings, a view shared by healthcare professionals in a companion study, who suggested ways this support could be actualised, including provisioning of a 24-hour helpline (27). Women also described gaining reassurance from knowing that healthcare teams had easy access to their data and reported receiving better and more timely input as a result; parents of young children who

used the same (CamAPS FX) system have reported similar benefits (23). Women also reported experiencing more positive interactions with healthcare teams; in part, because they were less worried about being criticised for spending time out-of-target glucose range. Importantly, while some women raised initial concerns about their privacy, most described having more honest, positive, and effective, collaborative relationships with HCPs by virtue of them having access to their insulin as well as glucose data. As others have observed, access to such data can offer insight into users' personal lives (28). Hence, it is important that healthcare teams use non-judgemental, collaborative approaches to ensure these positive, trusting relationships are replicated in 'real-world' settings (28).

Unlike other user groups who (mostly) welcomed opportunities to delegate glucose management to the system (23,24,29), most pregnant women described wanting, and expecting, to maintain active self-management roles and, hence, needing training and skills in order to be able to do so. Arguably, this finding is partly due to the tighter glucose targets required in type 1 diabetes pregnancy and the (perceived) moral mandate pregnant women experience to do everything possible to protect their babies (2,3). Indeed, women in our study emphasised the importance of receiving pregnancy-specific closed-loop education and training to help empower them to make informed, responsible self-management decisions. It is vital, therefore, that users be given comprehensive type 1 diabetes pregnancy advice and tailored information to support optimal closed-loop use in routine care settings. Women in our study valued opportunities to use the system's Ease-off and Boost features to attain pregnancy glucose targets. Future pregnant women with type 1 diabetes would therefore benefit from systems that offer this kind of functionality; albeit, with appropriate training in place to help ensure they use these functions correctly.

As well as highlighting glycaemic benefits that mirror main trial results; namely that use of hybrid closed-loop can significantly improve maternal glycemia during type 1 diabetes pregnancy (30), women described substantial, quality-of-life benefits. Women, for example, reported feeling more normal as a result of using closed-loop, and being able to administer insulin discreetly via their mobile phone app; a benefit adolescent users also reported (29). Some pregnant women also reported that using closed-loop allowed them to remain in paid work for longer. This is very encouraging given that other studies have found that the

pressures of managing diabetes in pregnancy can result in women prematurely leaving employment (3). Most crucially, women described how using closed-loop enabled them to worry less and enjoy their pregnancy more. This is a very important finding as adverse birth outcomes have been associated with maternal anxiety during pregnancy (31).

Women emphasised that some of the benefits to using closed-loop were attributable to the CGM component. This included having access to better information to inform diabetes-management decisions, and alarms facilitating use of tighter targets and ameliorating anxieties about hypoglycaemia. Research involving other groups of CGM users has identified similar benefits (32,33). However, our findings are important as benefits to using CGM in pregnancy have not previously been reported. Moreover, they provide support for UK and international guideline recommendations that CGM be universally offered to all pregnant women with type 1 diabetes (10).

Strengths and limitations

We have reported women's experiences of using the first commercially available closed-loop system licensed for use during pregnancy. In doing so, we have highlighted multiple quality-of-life benefits to using closed-loop in pregnancy which are unlikely to be captured in questionnaire studies (19). While we were able to explore pregnant women's experiences over a relatively long duration, it was not possible to explore closed-loop use during antenatal hospital admissions, labour and birth. Additionally, we did not interview women in the trial's control arm. However, we did have access to women's accounts of managing type 1 diabetes without a closed-loop in their previous pregnancies and/or prior to using closed-loop in their current pregnancy. Future research could directly compare accounts from pregnant women using closed-loop with those of pregnant women using other diabetes regimens. Unlike previous diabetes technology studies, our sample was not skewed towards middle-class individuals. Many interviews took place during the Covid-19 pandemic; hence, we may have captured women's perspectives when their anxiety levels were high, and this may have influenced their accounts.

CONCLUSIONS

By showing that closed-loop use can lead to more positive and enjoyable pregnancy experiences, our findings, alongside main trial results (30), offer powerful endorsement for closed-loop use in type 1 diabetes pregnancy and recent guidance in the United Kingdom to make this technology available to all pregnant women with type 1 diabetes (34). However, as women's accounts powerfully highlight, closed-loop is not a panacea. To realise fully the benefits this technology can offer and support successful adoption and rollout in routine clinical care, women would benefit from initial, intensive input, oversight, and support from their healthcare team together with comprehensive closed-loop specific education and training.

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Authors' contributions:

J.L. conceived and designed the interview study with input from H.R.M. D.R. collected the data, which was then analysed by J.L., B.K., M.N. and D.R. J.L. conceived the concept for this article. J.L. and B.K. produced the first draft with input from D.R. All authors reviewed, edited, and approved the final version of the manuscript. J.L. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest:

S.H. serves as a member of the Medtronic advisory board, is a director of Ask Diabetes Ltd providing training and research support in healthcare settings, and reports having received training honoraria from Medtronic, Dexcom and Ypsomed and consulting fees for CamDiab. T.T.M.L. reports having received a personal research grant from the Diabetes

Research and Wellness Foundation Sutherland-Earl Clinical Fellowship. A.R.D reports receiving royalties from Elsevier for author contributions to the textbook 'Macleods Clinical Examination; and, honoraria from Abbott Ltd. R.H. reports having received speaker honoraria from Dexcom, Eli Lilly and Novo Nordisk, serving on advisory panel for Eli Lilly and Novo Nordisk; receiving consulting fees from Abbott Diabetes Care; receiving licensing fees from BBraun and Medtronic; patents related to closed-loop insulin delivery; and, being a shareholder and director at CamDiab. H.R.M sits on the Medtronic UK and European Scientific Advisory Board and reports receiving speaker honoraria from Dexcom, Abbott, Medtronic, Sanofi and Novo Nordisk; chairing the National Pregnancy in Diabetes (NPID) audit; and is a member of the editorial board for Diabetes Care and Diabetologia. J.L., B.K., M.C., D.R., R.M.R., K.B-K. and C.C. have no conflicts of interest to declare.

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Table 1. Information about the trial, devices used, and data sharing

The AiDAPT trial

The AiDAPT trial (ISRCTN: 56898625) was conducted at nine maternity clinics across England, Scotland and Northern Ireland (Norwich, Cambridge, Ipswich, Glasgow, London (Kings College Hospital, Guys and St Thomas' Hospital), Edinburgh, Leeds and Belfast). One hundred and twenty-four women were recruited. To be eligible, women had to be aged 18-45yrs, have lived with T1D for at least 1 year, have a viable pregnancy confirmed by ultrasound (up to 13 weeks and 6 days gestation), been using intensive insulin therapy (MDI or an insulin pump) and have an HbA1c of 48 to ≤86 mmol/mol (6.5 to ≤10.0%). For further details about inclusion/exclusion criteria see Lee et al (20). Women were randomised to use either the CamAPS FX closed-loop (intervention arm) or standard insulin delivery with CGM (control arm). Participants were asked to contact their local study team for any problems related to diabetes management. They also had access to a 24-h telephone helpline with a research educator to seek technical support.

The CamAPS FX hybrid closed-loop system

The CamAPS FX is a 'hybrid' closed-loop system calculating and delivering basal (background) insulin automatically, which requires the user to administer boluses to cover meals/food. The system comprised:

- Dana RS insulin pump (Sooil, Seoul, South Korea).
- Dexcom G6 real-time CGM sensor (Dexcom, San Diego, CA, USA).
- An unlocked Android smartphone (Galaxy S7-10, 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. Participants could opt to use their personal smartphone if compatible.

CamAPS FX app

In addition to being used to administer mealtime boluses, the CamAPS FX app includes functions enabling users to:

(1) insulin delivery, insulin boluses and carbohydrate intake, high/low glucose range, glucose trend arrows, 'Boost' and 'Ease-off' status, and system status (operational or interrupted/switched off).

(2) view summary statistics for daily, weekly, monthly or 3-monthly periods, including: mean CGM glucose, Glucose Management Indicator (GMI) or estimated HbA1c, time in/below/ above target glucose range, number and average duration of hypos, total daily dose/bolus/basal insulin, and percentage of time in operation.

(3) adjust the rate of insulin delivery using a 'Boost' or 'Ease-off' mode of operation.

(4) set personal glucose targets, typically 5.5mmol/L (99mg/dL) in early pregnancy and 5.0mmol/L (90mg/dL) after 14-16 weeks consistent with achieving pregnancy glucose targets.

(5) receive and personalise alarms (audio and vibration settings) triggered by high/low-glucose levels and signal loss with the sensor and/or pump.

Data sharing/remote monitoring capabilities

The app automatically facilitates data upload to the cloud, which enables data-sharing with other individuals, including healthcare teams. Clinical and research teams could view a woman's data via the Glooko/Diasend mobile app or the Diasend web application (Glooko/Diasend; Göteborg, Sweden). Healthcare teams had remote access to real-time data and summary statistics listed in points (1) and (2) above. HCPs could also receive summary CamAPS FX reports by email, either daily, weekly or monthly, for participants using the closed-loop at their site. These included key glycaemic metrics (mean glucose; time in/above/below target glucose range), insulin doses, and system metrics (closed-loop use, CGM use and number of alarms issued during the day and at night).

Table 2. Topics explored in interviews of relevance to this analysis

Background information and pre-trial experiences

- Age, occupation, living arrangements, number, and age of other children.
- Diabetes duration; devices (e.g., pump, injections, CGM, finger pricks) used pre-trial.
- Views, hopes, and concerns about managing diabetes while pregnant and related pregnancy/health impacts.
- Experiences of managing diabetes during previous pregnancies (if any) and/or current pregnancy before joining the trial, including:
    - Regimen used (insulin administration and glucose monitoring); adjustments to basal rates/background and insulin-to-carbohydrate ratios; dietary choices and managing diabetes at mealtimes; undertaking physical activity; attainment of pregnancy glucose targets.
    - Management of and worries/concerns about hypo- and hyperglycaemia.

Impact of regimen used on everyday life (e.g. sleep, work/family/social life) and overall pregnancy experience.

- Experiences of and views about receiving support from healthcare professionals during previous pregnancies and/or pre-pregnancy planning.

Experiences of using the closed-loop system during the trial

- Experiences of initial training and education, learning to use and adapting to closed-loop; developing confidence and trust in closed-loop technology; any concerns about using closed-loop (and components) during the trial.
- Experiences of and views about using the closed-loop to manage diabetes while pregnant, including:
    - Use of the app to inform decisions about diabetes management tasks (e.g. calculating/administering mealtime bolus doses, managing/treating hypo- and hyperglycaemia).
    - Use of 'Boost' and 'Ease-off' functions; use of corrective doses of insulin.
    - Impact of closed-loop use when physically active.
    - Ability to attain (and maintain) pregnancy glucose targets.
    - Impact of closed-loop use on worries/concerns about hypo- and hyperglycaemia.

- Engagement with and access to insulin and glucose data via app on phone (and if and how this changed over time); which of the available data participants used; if/how data access affected how they managed diabetes.
- Perceived impact of closed-loop use on everyday life (e.g. sleep, work/family/social life)

- Impact of closed-loop use on worries/concerns about managing diabetes while pregnant and related pregnancy/health outcomes.
- Experiences of and views about contact and support received from healthcare professionals (e.g. mode and frequency of, and reasons for, contacts; impact of closed-loop use on participants' experience of healthcare encounters and interactions)
- Experiences of and views about healthcare teams having remote access to their real-time glucose and insulin data (e.g. concerns, perceived (dis)advantages).

Table 3. Sample characteristics, n=23 pregnant women with type 1 diabetes

Characteristic	**n**	**%***	**Mean, SD, (range)**
Married/co-habiting	20	87·0	
Employment			
Full-time	10	43·5	
Part-time	10	43.5	
Unemployed/student	1	4.3	
Full-time mother/carer	2	8·7	
Occupation^			
Managers	1	4.3	
Professionals	6	26.1	
Technicians and Associate	5	21.7	
Professionals	1	4.3	
Clerical Support Workers	2	8.7	
Service and Sales Workers	1	4.3	
Craft and Related Trades Workers	4	17.4	
Elementary Occupations (e.g. manual)	1	4.3	
Student/Unemployed	2	8.7	
Full-time mother/carer			
Ethnicity			
White, British	21	91·3	
White, other nationality	2	8·7	
Age at time of interview; years			31·5 ± 4·6 (22-39)
Number of previous pregnancies			1·3 ± 1·2 (0-5)
Diabetes duration; years since diagnosis			18·6 ± 6·8 (2-28)
Baseline HbA1c			
mmol/mol			59 ± 10·6 (48-90)
%			7·5 ± 1·0 (6·5-10·4)
Devices used before current pregnancy			
Insulin regimen:			

Multiple daily injections	12	52·2	
Insulin pump	11	47·8	
Self-reported glucose monitoring:			
Finger-prick testing	10†	43·5	
Freestyle Libre1	7	30·4	
Freestyle Libre2	2	8·7	
Dexcom – G6	4	17·4	

* Figures may not add up to 100% due to rounding.

^ Defined using the International Standard Classification of Occupations 2008 (ISCO-08).

† Seven of these women were given use of a sensor (in most cases, Freestyle Libre 1) near the start of their current pregnancy, i.e. shortly before joining the AiDAPT trial.

Table 4: Additional participant quotations

Themes/*subthemes*	Participant quotations
Managing T1D pregnancy before closed-loop	
Physical, mental, and emotional demands	<u>Needing to set alarms at night:</u> "The hardest thing is at night I think, 'cause I've quite a fear of going low. So I'd set about three alarms overnight (laughs). You just end up not sleeping very well at all and I think that can kind of get you down." (010) "With my other pregnancy they wanted overnight readings. They wanted them at a certain time, so I'd have to set my alarm, wake myself up, test my blood, go back to sleep… it was exhausting." (014)
Negative pregnancy experiences	<u>Becoming obsessed about monitoring and over-correcting:</u> "I've been using a lot of temporary basals, and if anything I was doing overcorrection sometimes. So I was finding I was, you know, I'd be hypo and then sort it out, and then I'd get a massive rebound high... So I was getting a lot of peaks and troughs, and I was finding that very stressful." (022)
Experiences of closed-loop	
Adjusting to the system	<u>Frequent data checking to seek reassurance:</u> "It felt as though I was just constantly watching, making sure that it was doing its job, so I would be probably looking at it anywhere between- I would probably say six to ten times a day. I was constantly checking on it." (019) <u>Contacting HCPs for information and support:</u> "It was easier to explain when you are using it, rather than as you set it up, you know, it's easy to say: oh this one means it's rising, this one

	means it's lowering, but it's not until I started using that that I realised I didn't actually fully understand the function and needed a bit more support." (014) "The training was very good, it was thorough, but you will be learning as you start to use it… I've messaged [names staff member] a couple of times, initially particularly when my sugars were going high, I was like: normally I'd give a correction here, I'm going to put the Boost function on: is that right?... Shall I use it for this amount of time or longer? - So it's just that clarification." (022)
Less work, less worry… better glucose control	<u>Remote insulin administration facilitating more time in range:</u> "Before… if my Libre said I was 12 [mmol/L - 216 mg/dL] and I was in the playground with lots of other mums … and I knew I was going home in half an hour, then I wouldn't get my insulin pen out to give myself a correction… especially when you're pregnant, you don't wanna get your tummy out to (laughing) give yourself an injection… whereas you can do that now. So again, that's another factor that just means your time in target must be, yeah, just hugely better." (011) <u>Experiencing better sleep:</u> "I think obviously being the closed loop, it adjusts for you…in the background… 'cause I never really knew what my overnights were. Even with the Libre you have the Libre lows, my overnights were sort of all over the place. Whereas now I could have a steady night, and obviously sleep, and not have to worry too much about it." (021) "It's definitely took the worry away for me, 'cause I'm quite active in the day with my kids anyway, so if I'm dipping low and I'm busy with the kids, I'm then alerted before anything goes wrong, because if I

	was to, God forbid, have a hypo and not be responsive with my children, it would be awful." (011)
But still work… user collaboration with closed-loop	<u>Needing to create the conditions to help the technology work optimally:</u> "I still think… a lot of it is your own doing and the information you're putting in and when. Em, so your carb counting, the time before you're gonna eat…" (017) <u>Seeing both insulin and glucose data helps make better management decisions:</u> "Having the visualisation of the graph, knowing that it's not delivering any insulin at the minute… I think that's really helpful to know that it's already eased off, so I probably haven't got that much insulin in me that's going to send me lower. So you know, that one jelly baby is going to bring me back up to the level." (007) <u>Needing to know when and how to intervene:</u> "The main thing I've struggled with is, like, obviously before when my levels went high I would just put a correction dose in… But I've still kind of struggled to know… when I should put a correction in or whether I should just let the phone do its own thing." (010) "I've messaged (names trial staff) a couple of times, when I was sort of- initially particularly when my sugars were going high, I was like: normally I'd give a correction here… I'm gonna put the boost function on: is that right?" (022)
Collaboration with closed-loop features: using Ease-off and Boost	<u>Using Boost when the closed-loop is perceived as being too sluggish:</u> "Sometimes I use [Boost] where I think the algorithm hasn't been as generous as I think it needs it to be, because that's just the algorithm still learning, because I'm extremely insulin resistant." (022)

	<u>Applying own knowledge to help prevent glucose excursions:</u> "Basically it [closed-loop] does know what it's doing, but you've got that manual override if you need to, so I think… you definitely still need to have an element of knowing what you're doing as well, knowing… the bits that the [closed-loop]… doesn't know, so like your physical exercise, the food that you've just eaten and things like that." (007) "I used Ease-off a lot at work, especially if I could see that my blood sugar was sitting just slightly lower and I knew that maybe I wasn't having lunch for like another two hours or something, to then just try and prevent a hypo." (013)
Better collaboration with healthcare teams	<u>Access to more detailed real-time data facilitates… better ad-hoc clinical input:</u> "I think it's a good thing that you can basically do a live feed to them, because it means that they've got up-to-date data that they can look at and very quickly change something if it needs to be changed. They're not looking at the five days prior, and you're saying well, now, you're having troubles now. And they're going: well, we can't see that data, so we can only go by what happened three days ago." (019) <u>… raises initial privacy concerns</u> "It felt a bit Big Brother-ish at first, particularly when they would say: 'oh well you had, you know, X number of carbs after 7 pm last Wednesday or something." (015) <u>…more personalised advice:</u> "It's nice that somebody else can look at this data… they can see the graph of what's going on, how it's happening, how much insulin I've

	had, how much background insulin I've had. So just because they've got all that data, they can then tell me the exact thing that I need to do, which then sorts it out straightaway." (020) <u>… closer, more honest and trusting relationships with healthcare teams:</u> "[It] allows me to communicate better, for them to understand better what I'm trying to say. And that communication, by being better, it builds trust… So I trust them more than if it was the opposite." (002) "They have a little bit more trust in me, because they see my data and they see it's going well, so they understand my independency (sic), while maybe before they were a little bit more hesitating in giving me that independence." (008)
Positive pregnancy experiences	<u>Enjoying more normality and being able to work for longer:</u> "Honestly, it allowed me to work. I would never be able… to work at the job that I was doing [waitressing] at all, if I didn't have the machine." (002) "[Without the closed-loop] I wouldn't have gone out as much, and I wouldn't have done as much as what I done. I would have stopped work a lot more sooner than what I did...especially when you're self-employed, it does make a helluva lot of difference." (018) <u>Worrying less about their baby's development</u>: "I didn't have that much fear for the pregnancy itself. And I think that's because of the closed loop. So there are not that many concerns about the development of the- and the growth of the baby." (007)