# Automated insulin delivery during the first 6 months postpartum (AiDAPT): a prespecified extension study

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## Summary

**Background** Clinical guidelines in the UK and elsewhere do not specifically address hybrid closed loop (HCL) use in the postpartum period when the demands of caring for a newborn are paramount. Our aim was to evaluate the safety and efficacy of HCL use during the first 6 months postpartum compared with standard care.

**Methods** In this prespecified extension to a multicentre, randomised controlled trial, pregnant women with type 1 diabetes at nine UK sites were followed up for 6 months postpartum. Eligible participants (AiDAPT participants recruited after the implementation of the postpartum protocol amendment approval, those still pregnant or within six months of delivery at the time of amendment implementation and still using HCL or continuous glucose monitoring [CGM] therapy) continued their randomly assigned treatment, either standard insulin therapy with CGM or HCL therapy (CamAPS FX system version 0.3.1, CamDiab, Cambridge, UK). Participants were randomised in a 1:1 ratio with stratification by clinical site using randomly permuted block sizes of 2 or 4. The primary outcome was the between-group difference in percentage time in range ([TIR] 3·9–10·0 mmol/L [70–180mg/dL]), measured during the periods of month 0 up to 3, months 3 to 6, and over 6 months postpartum. The study is registered at ClinicalTrials.gov (ISRCTN56898625) and is complete.

**Findings** Of the 124 AiDAPT trial participants, 66 (53%) were ineligible for inclusion in the postpartum extension, and 57 participants consented to continue their treatment per original random allocation. The mean age was 31 years (SD 4), and all participants had early pregnancy $HbA_{1c}$ 59·4 mmol/mol (SD 10·5 [7·6% SD 1·0%]). In the 6 months postpartum, mean time with glucose levels within the target range was higher in the HCL group compared with the standard care group (72% [SD 12%] *vs* 54% [17%]), with an adjusted treatment difference of 15% (95% CI 7 to 22). Results for hyperglycaemia (>10·0 mmol/L) and mean CGM glucose also favoured HCL (–14% [95% CI –23% to –6%] and –1·3 mmol/L [–2·3 to –0·3], respectively). Hypoglycaemia rates were low, with no between-group differences (2·4% *vs* 2·6%). There were no treatment effect changes depending on postpartum period (0 up to 3 months *vs* 3 to 6 months) and no unanticipated safety problems.

**Interpretation** Participants in the HCL group maintained 70% TIR during the first 6 months postpartum, supporting continued use of HCL rather than standard insulin therapy for people with diabetes once they have given birth.

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## Introduction

The daily management of glucose levels in type 1 diabetes is challenging. Maintaining safe maternal glycaemia in the postpartum period is complicated by the profound physiological changes that occur after delivery and the lifestyle changes associated with caring for a newborn. Following delivery of the placenta, insulin sensitivity dramatically increases, however, there is considerable inter-individual variability with some individuals requiring minimal exogenous insulin in the initial 12–24 h.[1,2] During the months following delivery, changing maternal hormones, unpredictable daily routine, and variable maternal and infant feeding patterns further complicate diabetes management and insulin dose adjustment.[2–5] Sleep deprivation and exhaustion can exacerbate the mental burden of glycaemic self-management alongside caring for a newborn—both of which need constant attention. These postnatal diabetes challenges are further compounded by a gap in care as women transition from intensive antenatal support (two to four weekly appointments) to general diabetes services (two to four appointments per year), which can lead to feelings of being lost and not knowing who to turn to when they had trouble or needed support.[6]

Hybrid closed-loop (HCL) systems are increasingly effectively used in type 1 diabetes management across many populations globally (adult, paediatric, and

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See Online for appendix

## Research in context

### Evidence before this study

We searched PubMed for articles published before June 12, 2024, without restriction on language or start date. We included the search terms ("diabetes mellitus" OR "diabetes") AND ("pregnancy" OR "postpartum" OR "postnatal") AND ("closed loop" OR "automated insulin delivery"). We identified five case reports or case series and an additional four studies of commercially available hybrid closed loop (HCL) systems in pregnancy which examined their use in the postpartum period. In three of the four studies HCL was continued from pregnancy, while in the last study, HCL was commenced 1 week after birth. While these studies demonstrated good glycaemic outcomes associated with HCL use, over 70% of time in range ([TIR] 3·9–10·0 mmol/L), and low rates of hypoglycaemia, there was no improvement in glycaemic outcomes compared with sensor-augmented pump therapy in the two randomised trials examining the Medtronic MiniMed HCL systems, which included participants with optimal baseline glycaemia (mean $HbA_{1c}$ <53 mmol/mol [<7%]). Given the insufficient size and scope of existing studies of postpartum HCL use, current NICE guidance in the UK does not specifically address diabetes management in the postpartum period nor postpartum HCL continuation.

### Added value of this study

To our knowledge, this is the largest study of HCL use in the postpartum period. 57 out of 58 eligible participants with type 1 diabetes continued their assigned diabetes management (HCL or standard care of insulin pump or multiple daily injections with CGM) following random allocation in early pregnancy. We found that participants in the HCL group who used CamAPS FX (version 0.3.1, CamDiab, Cambridge, UK) spent more time in the target glycaemic range over the 6-month postpartum period compared with those continuing standard care, with no increase in hypoglycaemia rates. Trial participants spanned a range of glycaemia categories, were representative of the UK type 1 diabetes population, and over half were pump-naive.

### Implications of all the available evidence

Our study demonstrates sustained gycaemic benefits of HCL use from pregnancy into the postpartum period. Women continuing HCL returned to non-pregnancy target glycaemia during both the immediate and 6-month postpartum periods, while those using standard care experienced a marked glycaemic deterioration (approximately 50%). These findings support the continued use of HCL into the postpartum period, when clinical care is fragmented and diabetes self-management is challenged by the constant new demands of caring for a newborn.

pregnant populations) to help users meet glycaemic targets and reduce the mental burden of diabetes self-management.[7–11] In December 2023, the UK National Institute for Health and Care Excellence (NICE) updated its guidance for diabetes technology, supporting HCL use. Based on data from Automated insulin Delivery Amongst Pregnant women with Type 1 diabetes (AiDAPT) trial (ISRCTN56898625), the NICE Technology Appraisal TA943 now recommends offering HCL therapy use before and during pregnancy.[12] However, because postnatal studies were restricted in size and scope, NICE did not specifically address the use of diabetes technology and HCL therapy during the postpartum period. As more women use HCL before and during type 1 diabetes pregnancy, this omission and gap in postpartum diabetes management requires urgent attention, so that women are empowered to choose evidence-based therapy during this challenging period.

Four small studies have examined postnatal use of commercially available HCL systems. In the two UK Closed-Loop in Pregnancy studies (CLIP-03 and CLIP-04)[13,14] and American Pregnancy Intervention with a Closed-Loop System study (PICLS),[15] HCL therapy was initiated during pregnancy and continued postnatally. In the Canadian Closed-Loop Insulin in Mothers with Type 1 Diabetes and Baby feeding practices study (CLIMB),[16] HCL therapy was started de novo 1 week after birth. The UK CLIP studies reported safe inpatient use of previous prototype versions of the CamAPS FX system (CamDiab, Cambridge, UK) in 27 participants throughout labour, birth, and the initial 48 h postpartum.[17] We subsequently described target glycaemic attainment after delivery (83·3% time in range [TIR] 3·9–10·0 mmol/L [70–180 mg/dL]) with low rates of hypoglycaemia (2·4%) among 12 participants who continued using CamAPS FX for 6 weeks postpartum as part of an observational analysis.[14] The Canadian CLIMB study of 18 participants and American PICLS study of 23 participants reported similar glycaemic outcomes (TIR 79·2% *vs* 78·2% HCL *vs* sensor-augmented pump for CLIMB and 75·1% *vs* **76**·5%, respectively, for PICLS) associated with use of the Medtronic MiniMed 670G and 770G HCL systems.[15,16] The CLIMB and PICLS studies also reported low rates of maternal hypoglycaemia (1·7% *vs* 5·5% and 4·5% *vs* 9·2%, respectively). While reassuring from a safety perspective, these feasibility studies do not demonstrate definitive proof of efficacy. They also included participants with near optimal glycaemia which limits their generalisability, in real-world settings.

In this study, we examined the continued use of CamAPS FX HCL therapy from pregnancy and its effects on maternal glycaemia from day one after delivery through the first 6 months postpartum.[18] We also examined whether there were any changes in treatment effect during the earlier (from 0 up to 3 months) or later (3 to 6 months) postpartum period.

## Methods

### Study design and participants

This study was performed as an extension to AiDAPT (Automated insulin Delivery Amongst Pregnant women with Type 1 diabetes [ISRCTN56898625]), a multicentre, parallel group, randomised controlled trial, recruiting pregnant women with type 1 diabetes across nine UK National Health System (NHS) sites. Participants were randomly assigned during pregnancy to receive HCL (CamAPS FX system; intervention group) or to continue standard insulin therapy (multiple daily injections or an insulin pump, and continuous glucose monitoring [CGM]; standard care group). The AiDAPT study protocol and primary results were previously published and are briefly summarised below.[10,18]

After pregnancy, trial participants were provided with three to four sensors allowing for up to 6–8 weeks of postpartum CGM use to allow safe transition back to usual clinical care. However, approximately halfway through trial recruitment, the UK NICE Diabetes Pregnancy guidelines were updated to recommend 12 months of real-time CGM use for all pregnant women with type 1 diabetes.[19,20] This was accompanied by ring-fenced pregnancy-specific funding to accelerate nationwide implementation of CGM use during 2021.[21] Thus, pregnant women with type 1 diabetes who did not participate in the AiDAPT trial were allocated 5–6 months of NHS-funded postnatal CGM sensors (ie, based on women starting CGM at 10–12 weeks' gestation and delivering at around 36–38 weeks' gestation). This raised an ethical dilemma, potentially disadvantaging AiDAPT trial participants who at that time point could only access 6–8 weeks of postnatal CGM use.

Additional changes in maternity and diabetes service provision during and after the COVID-19 pandemic included increased clinical pressures among trial staff and restricted face-to-face appointments. As a result of the expanded access to CGM and service provision pressures, we sought Research Ethics Committee approval to extend the use of CGM sensors, with or without HCL therapy, to eligible trial participants for 6 months postpartum. This was approved (AiDAPT protocol version 5.0) to comply with national CGM recommendations and ensure safe postnatal transition for the remaining AiDAPT participants. Registration of the postpartum extension study was included in the AiDAPT trial registration (ISRCTN56898625) and was previously described in the published study protocol paper.[18]

Pregnant women aged 18–45 years, with at least one year's duration of type 1 diabetes and an early pregnancy $HbA_{1c}$ within the range of 48–86 mmol/mol (6·5% to ≤10·0%) were recruited to AiDAPT before reaching 14 weeks' gestation. Participants who were recruited after implementation of the postpartum protocol amendment approval (Nov 12, 2021), those still pregnant, or those within 6 months of delivery at the time of amendment implementation and still using CGM or HCL therapy from pregnancy were eligible for inclusion in postpartum follow up extension study. The exclusion criteria remained the same as for the AiDAPT study.[10,18]

### Randomisation and masking

Participants continued their assigned treatments following random allocation during early pregnancy (median of approximately 11 weeks' gestation). They were randomised in a 1:1 ratio, with stratification by clinical site, using a computer-generated randomisation system with randomly permuted blocks sizes of 2 and 4. Once a participant was randomly allocated to a treatment group, both the investigator and participant were aware of the treatment assignment. Investigators were masked to the results until the study was completed. The primary outcome was based on the downloaded CGM data. Statisticians at the coordinating centre (Jaeb Center for Health Research, Tampa, FL, USA) who used the CGM data to calculate the time in range were not masked to the study treatment.

### Procedures

Eligible participants at the time of implementation of the postpartum protocol amendment (those still pregnant or within 6 months of delivery and for whom CGM data were available) were approached for inclusion. Those recruited after implementation of the postpartum amendment were consented at the same time as recruitment to the AiDAPT trial. Following delivery of their baby, participants in both groups received usual clinical care.

Participants allocated to the intervention group used the HCL system as per the AIDAPT trial (ie, the CamAPS FX application version 0.3.1, hosted on an Android smartphone (Samsung, Suwon-si, South Korea). A Dana Diabecare RS insulin pump (Sooil, Seoul, South Korea) and Dexcom G6 continuous glucose monitor (Dexcom, San Diego, CA, USA) communicated via Bluetooth with the algorithm for insulin administration and glucose monitoring, respectively. Postnatal plans with starting setting guidance for the insulin pump and HCL system were agreed between the woman and her diabetes antenatal team, and plans were documented before delivery (approximately 36 weeks' gestation). Women were advised to switch to recommended starting postpartum settings (described below) immediately before caesarean section or as soon as the placenta delivered. Recommended initial postpartum settings included a personal glucose target of 6·0 mmol/L (108 mg/dL) and insulin to carbohydrate ratios of between 1:12 g and 1:15 g, depending on infant feeding status. Following delivery, while still in hospital, participants titrated their own personal glucose targets, insulin to carbohydrate ratios, and pre-meal insulin boluses, aiming for CGM TIR targets (70% time between

3·9–10·0 mmol/L and <5% time below 3·9 mmol/L). Participants were also encouraged to use the boost and ease-off features for at least 2–4 h at a time if they felt that other setting changes were not fast enough to counter higher or lower glucose levels. They were encouraged to continue self-titrating their settings as needed when discharged from hospital, having been given contact details for their usual NHS diabetes clinical support (adult diabetes services, including diabetes specialist nurses and midwives) if they had any questions or concerns, given the variable nature of insulin dosing and requirements between individuals and from day-to-day.[22]

Participants assigned to the standard care group continued their usual insulin therapy, either multiple daily injections or insulin pump therapy, with clinical support from their local teams. During the postpartum period, insulin doses (both pre-meal insulin boluses and basal insulin doses) were titrated to meet CGM targets (70% time between 3·9–10·0 mmol/L [70–180 mg/dL]).[23]

Participants were followed up by telephone at 8–12 weeks and 24 weeks after delivery, at which CGM data, insulin doses and insulin delivery method, safety outcomes, and infant feeding status were reviewed. Participants received a review of their diabetes management with adjustments to insulin dosing and advice if required. To assess diabetes and treatment-related lived experience, participants were sent open ended questions (appendix p 2) to provide self-reported free text feedback on their lived experiences through descriptive writing.

## Outcomes

The primary outcome was the between-group difference in the percentage of time with CGM glucose measurements in the postpartum target range (TIR 3·9–10·0 mmol/L [70–180 mg/dL]). The 6-month postpartum extension was split into two periods: first, from the day of delivery to 3 months and then from 3–6 months post-delivery (0–3 months and 4–6 months [weeks 1–12 and 13–24 postpartum]). In each 3-month period, CGM outcomes were calculated overall and overnight (23:00 to 07:00). Pre-specified secondary outcomes were the percentage of time spent with hyperglycaemia (level 1 >10·0 mmol/L [>180mg/dL] and level 2 >13·9 mmol/L [>250mg/dL]), hypoglycaemia, and other sensor glucose metrics, mean CGM glucose, and glucose variability metrics (glucose coefficient of variation and glucose SD). Safety outcomes of special interest were severe hypoglycaemia (defined as requiring third party assistance), diabetic ketoacidosis, and device-related adverse events. Infant feeding methods and women's lived experience free text feedback were also included as exploratory outcomes.

## Statistical analysis

A minimum of 300 h of CGM data in each 3-month period were required to calculate overall CGM outcomes, and a minimum of 200 h and 100 h of CGM data were required to calculate daytime and overnight CGM outcomes, respectively.

A repeated measures linear regression model was fit for the 3-month period outcomes, with CGM outcome as the dependent variable adjusting for pre-pregnancy insulin delivery method (insulin pump or multiple daily injections), CGM metrics during the baseline pre-randomisation run-in period (approximately 10–11 weeks' gestation), and clinical site as a random effect. A point estimate and 95% CI were calculated for the adjusted

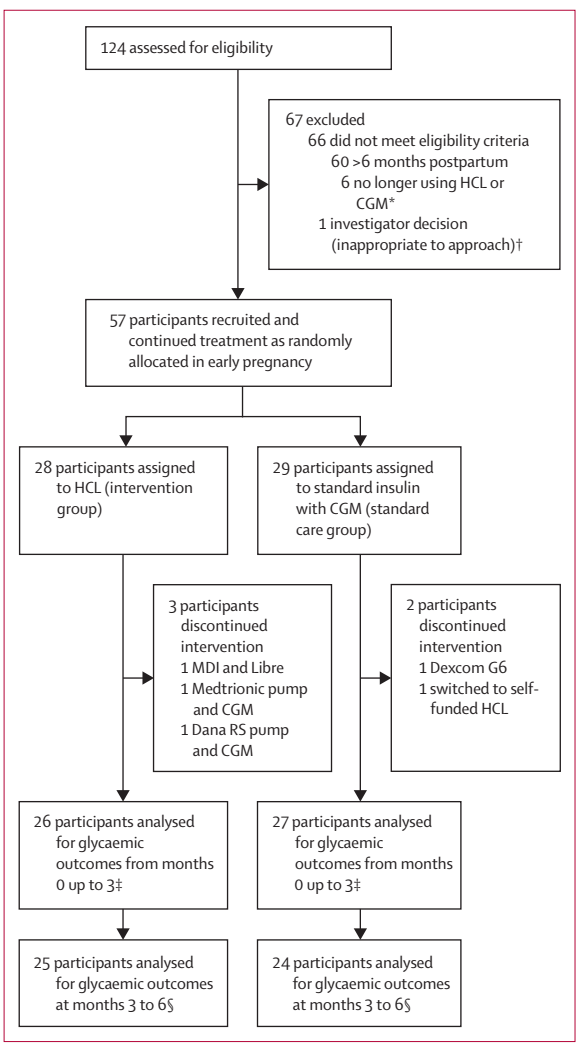


***Figure 1:*** **Trial profile**
AiDAPT=Automated insulin Delivery Amongst Pregnant women with Type 1 diabetes. CGM=continuous glucose monitoring. HCL=hybrid closed-loop. MDI=multiple daily injections. Libre=FreeStyle Libre (Abbott, Maidenhead, UK) flash CGM. *Participants had completed the study and returned to UK National Health Care service care before the study extension being implemented and so these participants were no longer using HCL (CamAPS FX) or CGM (Dexcom G6). †Participant had a neonatal death. ‡Two participants with missing data from HCL group and two participants with missing data in the standard care group. §Three participants with missing data in the HCL group and five participants with missing data in the standard care group.

treatment difference based on the linear regression model. A two-sided p-value was calculated for the treatment effect based on the linear regression model, and a 5% α level was used to declare statistical significance. Residual values were examined for an approximate normal distribution and homogenous variance. A histogram and q-q plot of the residuals were examined for an approximate normal distribution, and a residual versus fitted plot was examined for homogenous variance. If values were highly skewed, the model used a t distribution with 10 degrees of freedom for the errors. The same model was repeated with an interaction between postpartum period (0 up to 3 months, and 3 to 6 months) and treatment group to examine if the treatment effect changed depending on postpartum period.

There was no imputation for missing data. The false discovery rate was controlled using the adaptive Benjamini-Hochberg procedure for multiple comparisons. Analyses were performed with the use of SAS, version 9.4. Qualitative software (Qualcoder version 3.5) was used to facilitate data coding and retrieval for the qualitative analysis of the lived experience data.

| | Hybrid closed-loop (n=28) | Standard care (n=29) |
|---|---|---|
| Age, years | 32 (4) | 30 (4) |
| Race* | | |
| White | 25 (89%) | 25 (86%) |
| Asian | 1 (4%) | 1 (3%) |
| Black or African | 1 (4%) | 2 (7%) |
| Multiple races | 1 (4%) | 1 (3%) |
| BMI at first pregnancy appointment, kg/m² | 28·6 (4·5) | 25·8 (3·9) |
| Education | | |
| Secondary education | 3 (11%) | 5 (17%) |
| Further education | 8 (29%) | 9 (31%) |
| University undergraduate degree or equivalent | 14 (50%) | 11 (38%) |
| University postgraduate degree or equivalent | 3 (11%) | 4 (14%) |
| Number of previous births | | |
| 0 | 7 (25%) | 16 (55%) |
| 1 | 13 (46%) | 11 (38%) |
| 2 | 6 (21%) | 1 (3%) |
| 3 | 2 (7%) | 1 (3%) |
| Duration of diabetes, years (SD) | 17 (8) | 16 (7) |
| $HbA_{1c}$ during early pregnancy | | |
| $HbA_{1c}$, % | 7·6 (1·1) | 7·6 (0·9) |
| $HbA_{1c}$, mmol/mol | 59·5 (11·6) | 59·3 (9·5) |
| Diabetes complications | 15 (54%) | 17 (59%) |
| Early pregnancy insulin modality | | |
| Pump | 15 (54%) | 11 (38%) |
| Multiple dose injections | 12 (43%) | 17 (59%) |
| Automated insulin delivery† | 1 (4%) | 1 (3%) |

(Table 1 continues in next column)

## Role of the funding source

The funders had no role in the design of the study; in the collection, handling, analysis or interpretation of data; or in the decision to submit the protocol manuscript for publication.

## Results

This postnatal extension ran from Nov 12, 2021, to May 4, 2023. Out of the 124 AiDAPT trial participants, 66 (53%) were not eligible for inclusion in the postpartum extension study, with 60 (91%) participants over 6 months postpartum and six (9%) participants who had discontinued HCL or control interventions (standard insulin with CGM) within the first 6 months. One participant in the control group had a neonatal death and the investigators considered it inappropriate to approach her about the extension study (figure 1).

57 participants consented to continue their treatment per their original random allocation (standard care, which included CGM with multiple daily injections or insulin pump therapy *vs* HCL therapy) into the postpartum extension study. Postnatal participants were recruited from nine NHS clinical sites, spanning England, Scotland, and Northern Ireland, had a mean age of 31 years (SD 4), 50 (88%) of participants were White, and had baseline $HbA_{1c}$ during early pregnancy of 59·4 mmol/mol (SD 10·5 [7·6% SD 1·0%]; table 1). Both groups spent approximately 70% TIR at 3·9–10·0 mmol/L

For more on **Qualcoder version 3.5** see https://github.com/ccbogel/QualCoder/releases

| | Hybrid closed-loop (n=28) | Standard care (n=29) |
|---|---|---|
| (Continued from previous column) | | |
| Adverse events in previous 12 months pre-pregnancy | | |
| Pre-pregnancy DKA, participants | 0 | 3 (10%) |
| Previous severe hypoglycaemia‡ | 1 (4%) | 2 (7%) |
| Percentage of time in target range 3·9–7·8 mmol/ (63–140 mg/dL) during pregnancy§ | 67% (8%) | 58% (11%) |
| Percentage of time with CGM use,§ median (IQR) | 96% (82–98) | 97% (94–98) |
| Number of adverse events during pregnancy§ | | |
| Severe hypoglycaemia during pregnancy‡ | 5 | 1 |
| DKA during pregnancy | 1 | 1 |
| Maternal weight gain, kg | 11·5 (6·1) | 15·3 (6·0) |
| Pregnancy duration at delivery, weeks | 36·6 (1·7) | 37·0 (1·1) |
| Mode of delivery | | |
| Operative vaginal | 2 (7%) | 2 (7%) |
| Primary caesarean | 8 (29%) | 18 (62%) |
| Repeat caesarean | 14 (50%) | 7 (24%) |
| Vaginal | 4 (14%) | 2 (7%) |

Data are n (%) or mean (SD) unless otherwise stated. *Race was reported by the participant. †Participants using alternative hybrid closed-loop systems were eligible. ‡Hypoglycaemia was considered severe if the event required third-party assistance. §16 weeks' until delivery.

***Table 1:*** **Baseline characteristics**

during early pregnancy at baseline before random allocation (table 2). Participant characteristics appeared similar for participants who consented to continue in the postpartum extension and those who did not (appendix pp 4–5).

Of the 29 participants in the standard care group compared with the 28 participants in the intervention group, there were more participants for whom this was their first pregnancy (16 [55%] *vs* seven [25%]), lower maternal BMI (25·8 kg/m² *vs* 28·6 kg/m²), higher gestational weight gain (15·3 kg *vs* 11·5 kg), and more primary caesarean section deliveries (18 [62%] *vs* eight [29%]). During pregnancy, participants in the HCL group spent more time in the pregnancy-specific target range of 3·5–7·8 mmol/L (63–140 mg/dL) from 16 weeks' gestation until delivery (67% *vs* 58%); table 1.

Five participants did not adhere to their randomised treatment allocation during the 6-month postpartum extension period. Three participants in the intervention group discontinued CamAPS FX HCL use; one resumed her pre-pregnancy Medtronic insulin pump; one had increased personal and social difficulties and decided to discontinue HCL therapy, and one resumed multiple daily injections at 3 months postpartum after multiple Dana RS pump infusion set failures. Two participants in the standard care group discontinued their standard care; one who discontinued Dexcom G6 sensor use after delivery, and one who switched to self-funded HCL therapy with CamAPS FX after random allocation, starting in early pregnancy and continuing throughout the 6-month postpartum period (figure 1).

All available periods with CGM data were included in the models. One participant was missing baseline CGM data and was excluded from the analysis. Two participants in the HCL group were missing CGM data in the 0 up to 3 months period and three participants were missing

| | Baseline* | | Postpartum† | | Adjusted treatment difference‡ (95% CI) | p value for treatment effect‡ | p value for interaction‡ |
|---|---|---|---|---|---|---|---|
| | Hybrid closed-loop (n=28) | Standard care (n=29) | Hybrid closed-loop (n=28) | Standard care (n=29) | | | |
| CGM data, h | NA | NA | 3893 (622) | 3636 (989) | NA | NA | NA |
| Number of participants§ | | | | | | | |
| From 0 to 3 months | 26/28 | 27/29 | 26/28 | 27/29 | .. | .. | .. |
| 3 to 6 months | 25/28 | 24/29 | 25/28 | 24/29 | .. | .. | .. |
| Percentage of time with glucose levels 3·9–10·0 mmol/L | 73% (14%) | 70% (13%) | 72% (12%) | 54% (17%) | 15% (7 to 22) | 0·0037 | 0·83 |
| From 0 to 3 months | 74% (14%) | 70% (13%) | 75% (12%) | 57% (16%) | 15% (7 to 23) | .. | .. |
| 3 to 6 months | 73% (13%) | 72% (13%) | 70% (9%) | 50% (19%) | 16% (7 to 24) | .. | .. |
| Percentage of time with glucose levels 3·9–7·8 mmol/L | 50% (15%) | 47% (12%) | 51% (11%) | 33% (13%) | NA | NA | NA |
| From 0 to 3 months | 50% (15%) | 47% (12%) | 54% (12%) | 35% (12%) | NA | NA | NA |
| 3 to 6 months | 51% (15%) | 48% (12%) | 48% (10%) | 30% (15%) | NA | NA | NA |
| Mean glucose (mg/dL) | 142 (24) | 142 (18) | 153 (26) | 180 (37) | –23 (–41 to –5) | 0·036 | 0·78 |
| From 0 to 3 months | 142 (24) | 142 (18) | 148 (27) | 174 (33) | –23 (–40 to –6) | .. | .. |
| 3 to 6 months | 141 (23) | 140 (18) | 154 (18) | 189 (43) | –26 (–46 to –6) | .. | .. |
| Mean glucose (mmol/L) | 7·9 (1·3) | 7·9 (1·0) | 8·5 (1·5) | 10·0 (2·0) | –1·3 (–2·3 to –0·3) | 0·036 | 0·78 |
| From 0 to 3 months | 7·9 (1·3) | 7·9 (1·0) | 8·2 (1·5) | 9·7 (1·9) | –1·3 (–2·2 to –0·3) | .. | .. |
| 3 to 6 months | 7·8 (1·3) | 7·8 (1·0) | 8·6 (1·0) | 10·5 (2·4) | –1·5 (–2·6 to –0·3) | .. | .. |
| Percentage of time with glucose levels >10·0 mmol/L (SD) | 22% (15%) | 22% (12%) | 26% (12%) | 42% (18%) | –14% (–23 to –6) | 0·0055 | 0·78 |
| From 0 to 3 months | 22% (15%) | 22% (12%) | 22% (13%) | 39% (17%) | –15% (–23 to –6) | .. | .. |
| 3 to 6 months | 21% (15%) | 21% (12%) | 28% (10%) | 47% (21%) | –15% (–25 to –6) | .. | .. |
| Median percentage of time with glucose levels >13·9 mmol/L (IQR) | 3% (1 to 9) | 3% (1 to 7) | 7% (3 to 11) | 15% (8 to 30) | –9% (–16 to –2) | 0·029 | 0·18 |
| From 0 to 3 months | 3% (1 to 9) | 3% (1 to 7) | 4% (2 to 10) | 13% (6 to 22) | –9% (–16 to –2) | .. | .. |
| 3 to 6 months | 2% (1 to 7) | 2% (1 to 6) | 8% (4 to 12) ) | 19% (9 to 37) | –12% (–20 to –3) | .. | .. |
| Median percentage of time with glucose levels <3·9 mmol/L (IQR) | 5·0% (3·1 to 6·8) | 4·6% (2·3 to 11·8) | 2·4% (1·5 to 4·0) | 2·6% (1·4 to 5·2) | –0·7% (-2·0 to 0·5) | 0·49 | 0·78 |
| From 0 to 3 months | 5·0% (3·1 to 6·8) | 4·6% (2·3 to 11·8) | 2·5% (1·4 to 4·3) | 2·9% (2·0 to 5·0) | –0·8% (-2·2 to 0·6) | .. | .. |
| 3 to 6 months | 4·9% (3·1 to 6·8) | 4·0% (2·3 to 12·9) | 2·3% (1·6 to 3·7) | 2·2% (1·1 to 6·0) | –0·6% (-2·0 to 0·7) | .. | .. |

(Table 2 continues on next page)

| | Baseline* | | Postpartum† | | Adjusted treatment difference‡ (95% CI) | p value for treatment effect‡ | p value for interaction‡ |
|---|---|---|---|---|---|---|---|
| | Hybrid closed-loop (n=28) | Standard care (n=29) | Hybrid closed-loop (n=28) | Standard care (n=29) | | | |
| (Continued from previous page) | | | | | | | |
| Median percentage of time with glucose levels <3·0 mmol/L (IQR) | 1·2% (0·2 to 2·2) | 0·7% (0·3 to 3·1) | 0·4% (0·3 to 0·6) | 0·6% (0·2 to 1·3) | −0·2% (−0·6 to 0·1) | 0·33 | 0·78 |
| From 0 to 3 months | 1·2% (0·2 to 2·2) | 0·7% (0·3 to 3·1) | 0·4% (0·3 to 0·7) | 0·6% (0·2 to 1·2) | −0·3% (−0·8 to 0·1) | .. | .. |
| 3 to 6 months | 1·0% (0·2 to 2·2) | 0·6% (0·3 to 3·1) | 0·4% (0·2 to 0·7) | 0·5% (0·2 to 1·5) | −0·2% (−0·6 to 0·1) | .. | .. |
| Glucose CV (%) | 36% (6%) | 37% (7%) | 39% (4%) | 40% (5%) | 0% (−2 to 3) | 0·012 | 0·019 |
| From 0 to 3 months | 36% (6%) | 37% (7%) | 37% (5%) | 40% (6%) | −1% (−4 to 1) | .. | .. |
| 3 to 6 months | 35% (5%) | 36% (7%) | 39% (4%) | 39% (6%) | 2% (−1 to 5) | .. | .. |
| Glucose SD (mg/dL) | 51 (12) | 53 (13) | 60 (16) | 72 (17) | −8 (−16 to 1) | 0·026 | 0·054 |
| From 0 to 3 months | 51 (12) | 53 (13) | 56 (17) | 70 (17) | −10 (−19 to −1) | .. | .. |
| 3 to 6 months | 50 (11) | 51 (12) | 61 (12) | 73 (18) | −6 (−14 to 2) | .. | .. |
| Glucose SD (mmol/L) | 2·8 (0·7) | 2·9 (0·7) | 3·3 (0·9) | 4·0 (1·0) | −0·4 (−0·9 to 0·0) | 0·026 | 0·054 |
| From 0 to 3 months | 2·8 (0·7) | 2·9 (0·7) | 3·1 (0·9) | 3·9 (1·0) | −0·6 (−1·1 to −0·1) | .. | .. |
| 3 to 6 months | 2·8 (0·6) | 2·9 (0·7) | 3·4 (0·7) | 4·0 (1·0) | −0·3 (−0·8 to 0·1) | .. | .. |

Data are mean (SD), unless otherwise stated. CV=coefficient of variation. *Baseline values were calculated with the use of data assessed by continuous glucose monitoring during the pre-randomisation run-in phase during early pregnancy. One participant was missing baseline data assessed by continuous glucose monitoring. †The postpartum phase is from delivery until 24 weeks postpartum. Outcomes were assessed with the use of sensor data assessed by continuous glucose monitoring. ‡Based on a repeated measures linear regression model adjusting for baseline trial outcome, insulin delivery modality, and site as a random effect. Difference is closed-loop minus standard care. p values and 95% CIs adjusted using the adaptive Benjamini-Hochberg procedure. §In the hybrid closed-loop group, two participants had missing data in the 0 up to 3 months period and three had missing data in the 3 to 6 months period as assessed by continuous glucose monitoring. In the standard care group, two participants had missing data in the 0 up to 3 months period and five had missing data in the 3 to 6 months period as assessed by continuous glucose monitoring.

***Table 2:*** **Overall postnatal maternal glycaemic outcomes by treatment group and 3-month postpartum period ***

CGM data in the 3–6 months period; in the standard care group, two participants were missing CGM data in the 0 up to 3 months period and five were missing CGM data in the 3 to 6 months period.

Participants in the HCL group maintained mean percentage TIR ($\%_{TIR}$, 3·9–10·0 mmol/L) from 73% (SD 14%) in early pregnancy (baseline run-in before random allocation) to 72% (12%) throughout the 6-month postpartum period (table 2). For participants in the standard care group, $\%_{TIR}$ decreased from 70% (13%) in early pregnancy to 54% (17%) during the 6 months postpartum. The mean adjusted treatment difference between the HCL intervention and standard care control group was 15% (95% CI 7–22). Differences in glycaemia were apparent from the first 4 weeks postpartum and in each subsequent 4-week period following delivery, with consistently higher TIR for the HCL group (figure 2). Post hoc analysis of maternal glycaemia over the first 2 weeks postpartum starting from the day of delivery, requested during peer review, demonstrated the immediate beneficial effect of HCL versus standard insulin therapy with CGM use (HCL TIR 80% *vs* standard care TIR 67%; appendix p 8). The between-group treatment difference appeared similar when examined separately during the first 3 months after delivery and 4–6 months postpartum (15% [95% CI 7–23] *vs* 16% [7–24]), suggesting consistency of the treatment effect across both follow-up periods.

Associated glycaemic benefits of HCL use included lower mean glucose and less time spent above both the level 1 (10·0 mmol/L [180 mg/dL]) and level 2 (13·9 mmol/L [250 mg/dL]) hyperglycaemic thresholds (table 2). Participants in the HCL group spent 15% less time [95% CI −23% to −6%] above 10·0 mmol/L (>180 mg/dL) during the first 3 months after delivery, with sustained reductions over months 4 to 6 postpartum. Likewise, participants in the HCL group had lower mean glucose levels during both follow-up periods, with −1·3 mmol/L (95% CI −2·2 to −0·3) and −1·5 mmol/L (−2·6 to −0·3), respectively. The 6 month change in mean CGM was −1·3 mmol/L (95% CI −2·3 to −0·3). Hypoglycaemia rates were low, comparable between groups, and stable over the 6-month follow-up period (2·4% [IQR 1·5 to 4·0] and 2·6% [1·4 to 5·2] for HCL and standard care respectively). There were temporal changes in glycaemic variability metrics (glucose coefficient of variation and glucose standard deviation) consistent with higher glycaemic variation and less improvement in the standard care group at 3 to 6 months postpartum.

Overnight maternal glycaemic outcomes were similar to the 24 h results (appendix pp 6–7). The overnight treatment difference in time in range was similar between the first 3 months and 4–6 months postpartum (19% [95% CI 11–27] and 20% [11–29], respectively). There were marked reductions in mean glucose and nocturnal

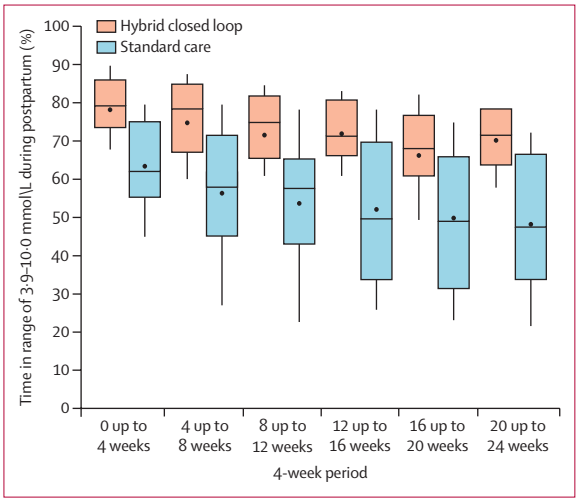


***Figure 2:*** **Time in target range during the 6 months postpartum**
Dots are means, and the boxes are medians and quartiles. The whiskers are the 10th and 90th percentiles. Time in range for the first 4-week period from day of delivery was 78% for HCL and 64% for standard care. Non-pregnant target glucose range in the 6 months postpartum 3·9–10·0 mmol/L (70–180 mg/dL).

hyperglycaemia in the HCL group compared to standard care (mean glucose –1·5 mmol/L [95% CI –2·4 to –0·5], mean percentage of time >10·0 mmol/L –18% [95% CI –26 to –10%], and median percentage time >13.9 mmol/L –13% [IQR –20% to –4%]; appendix pp 6–7). Insulin doses were mostly consistent for each group for both months 0 up to 3 and months 3 to 6 (appendix p 8). Glycaemic outcomes were similar within the HCL group regardless of insulin modality at baseline (appendix pp 9–10).

Adverse events were similar between the two groups. There was one instance of severe hypoglycaemia in standard care group and none in the HCL group. There were no episodes of diabetic ketoacidosis in either group during the 6-month postpartum period. The rate of device-related adverse events in the HCL group was 7·0 (table 3).

Exclusive breastfeeding rates were lower in the HCL group compared with the standard care group at hospital discharge (11 [39%] of 28 *vs* 15 [52%] of 29) and at 8–12 weeks postpartum (seven [25%] of 28 *vs* 12 [43%] of 29). However, breastfeeding rates were similar (ten [36%] of 28 *vs* 11 [42%] of 29) at 6 months postpartum (appendix p 11). Glycaemic outcomes were similar between all three categories of infant feeding patterns in the HCL group. However, women in the standard insulin therapy group who fed their babies exclusively with breastmilk had better glycaemia as measured by percentage time in range (66% for exclusive breastfeeding *vs* for 45% mixed feeding and for 54% exclusive formula feeding; appendix pp 12–13).

In the lived experience feedback, participants in the standard care group emphasised the challenges during the postpartum period and how this affected their diabetes management (appendix pp 14–15); with one participant reporting "My glucose control during pregnancy was probably the best it had ever been, then since giving birth it's been all over the show with the new (and huge) lifestyle changes, irregular eating patterns and breastfeeding". HCL participants focused more on the benefits of HCL (appendix pp 16–17); with two examples of patient feedback including "Breastfeeding and sleepless nights were much easier to manage while on closed loop system. I had no concerns about my BG and was able to focus on my recovery and caring for a newborn" and "Having that mental headspace and freedom to not be thinking about my blood sugars all the time has allowed me to

| | Hybrid closed loop (n=28) | Standard care (n=29) |
|---|---|---|
| **Severe hypoglycaemia** | | |
| Number of events | 0 | 1 |
| Participants with ≥1 event | 0 | 1 (3%) |
| Incidence per 100 person years | 0·0 | 7·0 |
| **Hyperglycaemia with ketosis** | | |
| Number of events | 0 | 0 |
| Mild-to-moderate* | 3 | 0 |
| Severe† | 0 | 1 |
| Diabetic ketoacidosis‡ | 0 | 0 |
| Participants with ≥1 event | 2 (7%) | 1 (3%) |
| Incidence of diabetic ketoacidosis per 100 person-years | 0·0 | 0·0 |
| **Serious adverse events§** | | |
| Number of events | 2 | 6 |
| Hypoglycaemia | 0 | 2 |
| Hyperglycaemia with ketosis | 0 | 1 |
| Other | 2 | 3 |
| Participants with ≥1 event | 1 (4%) | 6 (21%) |
| Incidence per 100 person-years | 14·5 | 42·0 |
| **Device-related adverse events with the closed-loop system** | | |
| Number of events¶ | 1 | 0 |
| Participants with ≥1 event | 1 (4%) | 0 |
| Incidence per 100 person-years | 7·0 | 0·0 |
| **Device-related adverse events with the continuous glucose monitor** | | |
| Number of events | 0 | 0 |
| Participants with ≥1 event | 0 | 0 |
| Incidence per 100 person-years | 0·0 | 0·0 |

*Mild-to-moderate events include ketosis (ketones >0·5 mmol/L) that were treated by the participant and resolved without hospital admission. †Severe ketosis was defined as a level of plasma ketones above 1·0 mmol/L that resulted in hospital admission and treatment with intravenous insulin. One participant had 20 events, none of which occurred while using closed-loop therapy. ‡Diabetic ketoacidosis was defined as ketosis with acidosis that resulted in treatment with fixed-rate intravenous insulin infusion. §Serious adverse events were defined as adverse events that resulted in death, a serious deterioration in health, life-threatening illness or injury, permanent impairment, in-patient or prolonged hospitalisation. ¶There was one device-related adverse events occurring in the closed-loop group. This was due to a pump infusion set failure (kinked cannula) resulting in hyperglycaemia without ketosis.

***Table 3:*** **Adverse events**

focus on my child and the value of that can't be underestimated".

## Discussion

Women continuing HCL from pregnancy into the postpartum period spent 15% more time within the non-pregnancy glucose target range, an additional 3·6 h a day, compared with those assigned to CGM alongside standard care insulin delivery. Glycaemic improvements were met by a marked reduction in maternal hyperglycaemia, especially evident overnight, and the improvements were not accompanied by an increase in hypoglycaemia.

The baseline glycaemic metrics, obtained during early pregnancy at approximately 10 weeks' gestation, were similar at approximately 70% TIR 3·9–10·0 mmol/L in both groups. Women assigned to HCL returned to target glycaemia (70% TIR) in the immediate postpartum period, whereas women assigned to standard care alongside real-time CGM, showed a marked deterioration. The HCL treatment benefit was apparent from the first 2 weeks postpartum and consistently maintained over the 6 month follow-up period. The first few weeks after birth, when women experience the most profound physiological and lifestyle transitions, often coincides with insufficient clinical input and oversight compared with the intensive support women receive during pregnancy.

Our results differ from the smaller CLIMB and PICLS studies, which described participants with lower baseline $HbA_{1c}$ (52 mmol/mol [6·9%] and 51 mmol/mol [6·8%], respectively), and directly compared HCL with standard care over shorter time-frames (10 weeks and 4 to 6 weeks, respectively). These two studies found continued optimal glycaemia both in HCL and in control group participants using sensor-augmented pump therapy (TIR 79·2% *vs* 78·2% for CLIMB and 75·1% *vs* 76·5% for PICLS), without demonstrable clinical efficacy of HCL system use.[15,16] Rates of hypoglycaemia (<3.9mmol/L) were similar (approximately 2%) among HCL participants between our AiDAPT trial participants and the CLIMB study (1·7%), but higher in the PICLS study (4·5%), most likely reflecting differences in baseline glycaemia, CGM sensors used, or both. It is notable that the CLIMB study participants commenced use of HCL with the MiniMed 670/770G system 1 week postpartum "because of concerns that the basal modulation could be too aggressive in the first postpartum week", reflecting HCL algorithm differences.[16] The MiniMed 670G/770G algorithm used by CLIMB participants is "strongly influenced by total daily dose of insulin used in the previous 6 days", whereas previous evaluations of the intrapartum and first 6 weeks postpartum data supported continued use of CamAPS FX during labour, delivery and after immediately following birth.[16,17] The PICLS study, although examining the continuation of MiniMed 670G use from pregnancy, also stopped HCL automode during maternal hospital admissions for labour and delivery and resumed use 3–7 days postpartum.[15] These studies have a delayed start of HCL, shorter duration of postnatal follow-up, and limited statistical power to detect between-group differences. It is important to note that CLIMB and PICLS both have intensive schedules of postpartum follow-up visits, with monthly specialist endocrinology clinic visits and more study contacts including up to weekly remote glucose management; this level of intensive postpartum support is not representative of postpartum care in the UK.[24]

In this study, although breastfeeding rates were initially low in the HCL group they were similar in both groups by 6 months postpartum, and comparable to national breastfeeding rates in the general maternity population, where prevalence of any breastfeeding is 55% at 6 weeks postpartum and 34% at 6 months postpartum.[25] Several factors beyond glycaemic control influence women's infant feeding decision, including maternal age, parity, BMI, socioeconomic and educational status, gestational age at birth, and mode of delivery.[26,27] Our study was not designed to evaluate the complex interactions between maternal glycaemia, HCL therapy, and infant feeding choices.

Strengths of this trial include its randomised design, larger sample size compared with similar trials, generalisability of participants across a range of glycaemic categories, and the inclusion of pump-naive participants, which is important for widening access to diabetes technology. Baseline characteristics of postpartum participants mirrored the overall characteristics of the main AiDAPT study, which is highly representative of national population-based data for type 1 diabetes pregnancy.[10] A further strength is the continuation of the same insulin delivery modality from pregnancy into the postpartum period, thereby eliminating any transition period between modalities which could affect maternal glycaemia. In this pragmatic postpartum extension study, there were no additional visits over and above usual clinical care. Limitations are that these postpartum results are specific to the CamAPS FX and cannot be extrapolated to other commercially available HCL systems. We designed this pragmatic postpartum extension study specifically not to add burden to health-care teams in the immediate aftermath of the COVID-19 pandemic or to participants navigating life with a newborn baby. Therefore, we did not collect data, including maternal weight or frequency of clinical postpartum contacts, that were unavailable by maternal telephone contact. There is the possibility of measurement bias in the treatment estimates due to missing data, although the number of participants missing was very low, with only four out of 57 participants missing data for all periods (overall, eight participants were missing data in the 0 up to 3 month period and four were missing data in 3 to 6 months period). Additionally, unmeasured random confounding is a possible

limitation, however, participants were randomly allocated to their treatment groups and baseline characteristics appeared similar. Our study was not powered to examine specific HCL settings (insulin to carbohydrate ratios and personal glucose targets), and the sample size is inadequate for examining complex interactions between maternal glycaemia, HCL therapy and infant feeding, or health economic analyses, all of which warrant future study. An evaluation of HCL therapy use during the inpatient admission for labour and delivery involving 119 participants will be reported separately.

The AiDAPT trial established the efficacy of HCL therapy during type 1 diabetes pregnancy with glycaemic benefits over and above CGM with standard insulin therapy.[10] Our current findings support continued use of HCL from pregnancy into the postpartum period. Clinical benefits are sustained throughout the first 6 months postpartum compared to a marked deterioration in glycaemic control with CGM and standard insulin delivery. Provision and funding of health care is currently siloed into different streams and departments. For many patients this contributes to a sense of abandonment as they transition from team to team (maternity to adult diabetes care or general practice) with little to no continuity of care. This postpartum continuation of CamAPS FX HCL use allows mothers to maintain target glycaemic control while navigating clinical care transitions and adjusting to life with a newborn.

#### Contributors

TTML, SB, and HRM co-wrote the first draft of the manuscript. The statistical analysis plan was written with input from CK, SB, and JS. CC, SH, EMS, RSL, KFH, DRM, RMR, MEW, JS, CK, and RH reviewed and edited the manuscript. All authors approved the final version of the manuscript. TTML, SB, JS, CK, and HRM had access to the raw data. Funders had no role in the design of the study; in the collection, handling, analysis or interpretation of data; or in the decision to submit the protocol manuscript for publication.

#### Declaration of interests

HRM sits on the Medtronic European Scientific Advisory Board and reports speaker honoraria from Dexcom, Abbott, Medtronic, Novo Nordisk, and Ypsomed. EMS reports receiving speaker honoraria from Abbott Diabetes Care and Eli Lilly. RH reports receiving speaker honoraria from Eli Lilly, Dexcom, and Novo Nordisk, receiving license or consultancy fees from B Braun and Abbott Diabetes Care; patents related to closed-loop systems, and being a director at CamDiab. MEW reports patents related to closed-loop systems, and being a consultant at CamDiab. SH is a UK member of the Medtronic Advisory Board, reports being a consultant at CamDiab, and providing training for Dexcom. Dexcom was supplied continuous glucose monitoring (CGM) systems at reduced cost.

#### Data sharing

The data that support the findings were used under license for the current study and therefore are not publicly available. Data will be made available upon reasonable formal written request to HRM.

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