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Experiences of closed-loop insulin delivery among pregnant women with Type 1 diabetes

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What's new?

- This is the first study to examine the psychosocial experiences of pregnant women with Type 1 diabetes who were using automated overnight closed-loop systems, and the first to use mixed methods to compare women's perceptions with objective glucose control data.
- Our findings highlight the complexities of experience surrounding automated closed-loop systems in pregnancy. Women described a mix of benefits and burdens, and varied in the accuracy of their perceptions of glucose control. Women with more positive technology attitudes had higher degrees of overestimation and poorer glycaemic control.
- To ensure appropriate and safe use of closed-loop systems in pregnancy, clinicians should account for varying user perceptions and seek to manage expectations.

Abstract

Aims To explore the experiences of pregnant women with Type 1 diabetes, and the relationships between perceptions of glucose control, attitudes to technology and glycaemic responses with regard to closed-loop insulin delivery.

Methods We recruited 16 pregnant women with Type 1 diabetes [mean ± SD age 34.1 ± 4.6 years, duration of diabetes 23.6 ± 7.2 years, baseline HbA1c 51±5 mmol/mol (6.8 ± 0.6%)] to a randomized crossover trial of sensor-augmented pump therapy vs automated closed-loop therapy. Questionnaires (Diabetes Technology Questionnaire, Hypoglycaemia Fear Survey) were completed before and after each intervention, with qualitative interviews at baseline and follow-up.

Results Women described the benefits and burdens of closed-loop systems during pregnancy. Feelings of improved glucose control, excitement and empowerment were counterbalanced by concerns about device visibility, obsessive data checking and diminished attentiveness to hyper- and hypoglycaemia symptoms. Responding to questionnaires, 80% of participants felt less worry about overnight hypoglycaemia and that diabetes 'did not run their lives'; however, 45% reported that closed-loop increased time thinking about diabetes, and 33% felt it made sleep and preventing hyperglycaemia more problematic. Women slightly overestimated their glycaemic response to closed-loop therapy. Most became more positive in their technology attitudes throughout pregnancy. Women with more positive technology attitudes had higher degrees of overestimation, and poorer levels of glycaemic control.

Conclusions Women displayed complex psychosocial responses to closed-loop therapy in pregnancy. Perceptions of glycaemic response may diverge from biomedical data.

Introduction

Pregnancy in women with Type 1 diabetes is associated with increased risk of adverse outcomes, with two- to fivefold increased risk of congenital anomaly, stillbirth and neonatal death compared with the background maternity population [1–4]. These and other diabetes-related risks can be minimized by strict glucose control before and during pregnancy [5]. Pregnant women with Type 1 diabetes are therefore highly motivated to improve their glucose control, and are unlike almost any other group of people with diabetes in terms of sustained effort and motivation. At this highly motivated life stage, they invest more time and effort to optimize dietary intake, glucose monitoring and insulin dose adjustment than at any other time during decades of living with diabetes. They have frequent clinical contacts (typically every 1–2 weeks) with specialist antenatal diabetes pregnancy healthcare teams.

Despite these intensive efforts, pregnant women with Type 1 diabetes spend only 12 h/day with near-optimum glucose control [6], and rates of preterm delivery, macrosomia and neonatal intensive care unit admissions remain high [1,7]. Not surprisingly, this sustained effort, and the difficulty in achieving and maintaining optimum glucose control, can affect psychosocial wellbeing. Previous psychosocial research describes pregnant women with Type 1 diabetes alternating between 'mastery' of their condition and being 'enslaved' by it [8].

Technology to help pregnant women with Type 1 diabetes improve glucose control, such as continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion therapy, is constantly evolving [9,10]. More recently, closed-loop systems have been introduced [11,12]. Closed-loop systems still require carbohydrate counting and manually administered pre-meal boluses, but they incorporate computer algorithms to provide automated, glucose-responsive basal insulin delivery every 10–15 min [13]. Conventional insulin pumps typically provide four to six pre-programmed basal rates, which are adjusted based on capillary glucose profiles. The addition of CGM to continuous subcutaneous insulin infusion (collectively known as sensor-augmented pump therapy) facilitates more glucose-responsive insulin delivery, but in practice many women struggle with the sheer volume of minute-to-minute CGM data and the complexity of insulin dose adjustment [14]. By assuming a substantial burden of basal insulin adjustment, automated closed-loop systems have the potential to improve glucose control in Type 1 diabetes pregnancy [15], but their psychosocial impact is unknown. The aim of the present study was to explore pregnant women's experiences of automated closed-loop therapy overnight and over an extended period of daytime use, in addition to their perceptions of glycaemic control and wider attitudes to technology.

Research design and methods

Between April 2014 and December 2015 we performed an open-label, randomized, crossover trial incorporating both biomedical (maternal glycaemic and obstetric/neonatal health outcomes) and psychosocial evaluations. Full details of the study design (including sample size and power calculations) and biomedical outcomes have been reported previously [15]. In brief, after 2–4 weeks for device training, women were randomly assigned to either 4 weeks of overnight closed-loop or 4 weeks of user-directed sensor-augmented pump therapy, with a 2-week washout between study phases. Pre-meal boluses were manually administered using the study pump (DANA Diabecare R Insulin Pump; SOOIL, Seoul, Korea) bolus calculator in both phases.

During closed-loop therapy, a computer algorithm, housed on a tablet computer, used CGM glucose values to calculate an appropriate basal insulin dose, which was delivered via an insulin pump every 12 min (see Supporting Information for system images). Women were instructed only to use closed-loop therapy overnight, turning it on after their evening meal and switching it off before breakfast. During a follow-up phase, women could choose to continue sensor-augmented pump or closed-loop therapy during the day and night. Of the 16 participants,14 opted to use day-and-night closed-loop therapy, providing data for an additional median (interquartile range) 11.6 (7.1–12.7) weeks.

Pregnant women, aged 18–45 years and with HbA_{1c} levels of 48–86 mmol/mol (6.5–10%), were recruited at 8–24 weeks' gestation from three UK National Health Service (NHS) sites. All were using intensive insulin therapy administered either by multiple daily injections (n=6) or continuous subcutaneous insulin infusion (n=10) before pregnancy. Key exclusion criteria were multiple pregnancy and severe physical or psychiatric comorbidity. All participants provided written informed consent.

The primary outcome for the randomized trial was the percentage of time that women spent with glucose levels in the target range of 3.5–7.8 mmol/l overnight, as recorded by the study CGM FreeStyle Navigator II (Abbott Diabetes Care, Witney, UK) during each 4-week crossover phase. The objective glycaemic response was described as the relative difference in overnight time-in-target during each 4-week crossover period.

User-reported outcomes

Participants completed the Diabetes Technology Questionnaire (DTQ) 'standard' version and the Hypoglycaemia Fear Survey II (HFS-II) at baseline (*n*=16). The DTQ standard version is a 30-item measure of the impact of and satisfaction with current diabetes technology [16]. Participants repeated the HFS-II and completed the 'change' version of the DTQ to account for any ceiling effect within 7 days of completing the closed-loop (*n*=12) and sensor-augmented pump phases (*n*=11). The change version of the DTQ was used to evaluate the impact of the current treatment, as compared with previous treatment (i.e. sensor-augmented pump therapy vs automated closed-loop therapy). Higher scores indicate higher treatment satisfaction. The HFS-II questionnaire consists of a 10-item 'behaviour' subscale that measures behaviours involved in avoidance and overtreatment of hypoglycaemia and a 13-item 'worry' subscale that measures anxiety and fear surrounding hypoglycaemia [17]. Higher scores indicate higher fear of hypoglycaemia.

Qualitative interviews

We administered semi-structured interviews according to a topic guide developed from reviewing relevant literature (Supporting Information). We interviewed women twice: at baseline during device training (T1) and after completion of the study (T2; mean gestation 14.6 and 27.7 weeks, respectively). This provided an opportunity to explore experiences of closed-loop therapy over a longer timeframe. For clinical and logistical reasons, two participants were not interviewed at follow-up (severe pre-eclampsia and emergency caesarean delivery) and one participant was interviewed at follow-up only, thus providing data from 27 interviews with 14 women. In line with previous qualitative interview studies [18], we found this sample sufficient to attain data saturation (i.e. the point in data collection when no new data are found to develop emerging conceptual themes).

Interviews were conducted in person, in clinical settings (*n*=13), at participants' homes (*n*=8), or by telephone (*n*=6). Interviews were digitally recorded and transcribed verbatim. The interviews lasted on average 26.5 and 32.5 min (baseline and follow-up, respectively). Interview transcripts were coded using NVIVO software (QSR International Pty Ltd., Version 10, 2012, Daresbury, UK). Three investigators (C.F., Z.S., H.M.) identified key themes relating to the burdens and benefits of diabetes technology using a six-stage thematic analysis approach: familiarization with the data; generating initial codes; searching for themes; reviewing themes; defining and naming themes and producing a final analysis [19]. Our approach was informed by theories of sensemaking, according to which experience is influenced by users' preceding experiences, attitudes and values in conjunction with technological 'affordances', or capacities [20,21].

We supplemented this with framework analysis, a method involving the use of a matrix with cells into which summary data are entered by category (columns) and cases (rows; Table 3).

In the context of this study, this allowed us to present data on how individuals responded to closed-loop insulin delivery in terms of two categories: (1) biomedical data (i.e. level of glycaemic control, rated on a 1–5 scale); and (2) quantized psychosocial data, also rated on a 1–5 scale, referring to: women's opinions of their glycaemic control; disparities between women's opinions and the biomedical data; women's opinions towards technology; and changes in women's attitudes to technology over time.

For the framework analysis, psychosocial interview data were quantized by coding comments about perceived glucose control as entirely positive or negative, mostly positive or negative, or mixed. This coding method drew on the sentiment analysis approach, in which language is examined for underlying emotional content, and positive and negative content in particular [22]. Women's views about technology were categorized in the same way.

Our analytical approach to qualitative data thus allowed us to identify new and unforeseen themes inductively (thematic analysis) as well as deductively eliciting participants' opinions on desired topics of relevance to diabetes technology use (framework analysis). In turn, this allowed a flexible mixed-methods approach to exploring both individual and collective data.

Results

Benefits of closed-loop therapy

The questionnaire data suggested a range of potential benefits from closed-loop therapy, ranging from improved glucose control to reduced worry, reduced discomfort, and 'time off' from diabetes (Table 1). Worry about hypoglycaemia during sleep was improved among 80% of participants, with 70% reporting that less effort was required to prevent hypoglycaemia during sleep. Women using closed-loop therapy also reported some modest benefit in terms

of pain or discomfort from insulin injections or pumps (27% better), family arguments about diabetes (18% better), pain from fingerpricks or sensors (20% better) and getting the insulin dose right on sick days (29% better).

The interview data confirmed the questionnaire data with regard to glucose control, improved sleep, reassurance for users and family members and 'time off' from diabetes (Table 2). The notion of 'time off' was often expressed in terms of perceived normality: 'I'm less worried and less anxious about [diabetes]… and I'm just feeling a bit more normal' (T206) – or, relatedly, in terms of having a system that replicates a fully-functioning pancreas: 'this study … mimics what a pancreas does' (T216).

The more wide-ranging character of semi-structured interviews also enabled exploration of additional salient themes. A prominent theme related to feelings of excitement, e.g. 'I thought it was amazing… The outcome definitely has exceeded my expectations… Overall the experience has been brilliant' (T201; Table 2). For some, excitement was generated by anticipation at the start of the study: 'I was quite excited to do it and I couldn't wait to get to grips with it really' (T206). Excitement also arose with regard to the future potential of diabetes technology, with one woman stating: 'I think it's made me look forward to even more what future developments we might have… I'm going to end up having just a smartphone app that can control everything.' (T211).

Another prominent theme concerned feelings of empowerment arising from participants' feelings of heightened control over their bodies, e.g. 'it just makes me think [diabetes is] manageable, it's not as hard as it used to be… it can only get better, it can only get easier' (T202). One woman expressed a sense of empowerment in terms of a more equal relationship with clinicians: 'Even though I have this … disease that's not going to go away, you… feel really, well (a) you're in control, because I'm a control freak, I like to be in control of my

own health and (b) it's more a partnership, I don't have to sit cap in hand in a waiting room waiting for, you know, two hours for someone to then give me five minutes of time.' (T203)

Participants rarely experienced these positive views as an immediate or inevitable consequence of closed-loop therapy. Most women (*n*=8) expressed initial concerns about automation, remarking for instance that: 'I felt like I was giving the control to a device and I found that strange … you're handing that control over to a device that initially you don't have any confidence in.' (T115)

For some women, experience of closed-loop led to feeling that they had incorporated the system into their body, with diminished perceptions of the system as a signifier of illness. One woman remarked on how she had come to accept the system as 'part of her': '[The system] used to be this thing that used to have to hang on my hip or my trousers or be in my pocket… And I think it just took a couple of weeks, just seeing the difference it made … And as the blood sugars got better and I felt better I was just like, this is just a part of me.' (T102)

Burdens of closed-loop therapy

Questionnaire data show that participants also experienced burdens arising from closed-loop therapy. Most notably, seven women (67%) reported increased time thinking about diabetes during closed-loop, compared with only three participants (27%) during sensor-augmented pump therapy. This seems to contradict our finding, noted above, that participants saw closed-loop therapy as allowing them 'time off' from diabetes; however, it was also noted that participants' remarks in interviews often framed discussion of 'time off' in terms of feelings of normality rather than an actual reduction of time spent thinking about diabetes. Because the closed-loop system requires user input, it is perhaps unsurprising that use of this

initially unfamiliar system can lead to a greater amount of time thinking about diabetes. One woman stated: ‘I think you’d have to have the artificial pancreas for at least a year to feel confident [with it]’ (T202).

In addition to increased time thinking about diabetes, eight participants (50%) reported that worry about hyperglycaemia was still ‘very much’/‘quite a lot’ of a problem, compared with 18% during sensor-augmented pump therapy, while 33% reported that closed-loop made sleep and preventing hyperglycaemia more problematic.

Interview data also attested to additional perceived challenges, including device connectivity issues, inaccurate sensor readings (e.g. CGM dropouts from sensor compression during sleep), pump occlusions, unplanned reversion to sensor-augmented pump therapy owing to software issues, and erroneous low battery readouts (Table 2). For some participants, these kinds of problems impacted negatively on their levels of trust in the system. As one woman stated: '[The pump] is this thing that’s become… part of your life and… you trust it and…it lets you down and it’s like, no, you cannot let me down, I’ve let you into my life and I trusted you and look what you’ve done.' (T103)

Interviews also revealed women’s concern regarding system alarms and their negative impact on sleep, and anxiety arising from the possibility of overnight system failure. As noted, a small number of participants mentioned difficulty sleeping while using the system, mostly as a result of system alarms and glitches rather than anxiety about glycaemic control. As one woman stated: ‘I’ve had an awful lot of sleepless nights, with the equipment malfunctioning, just beeping at me all the time, which was quite annoying’ (T204; Table 2). This woman also went on to note, however, that she was ‘getting less sleep anyway’ because she was pregnant, a theme echoed by a number of other participants. Once again, however, participants learned to deal with these challenges over time: '[T]he first time you have to do it on your own, it’s a

bit of a struggle… you do get used to it, but it was a bit of a.. aargh! for a while… you have to watch it just for a while, to make sure it's actually going to work.' (T204)

We also identified wider concerns arising from the experience of closed-loop in day-to-day living (Table 2). Nine women expressed initial or ongoing device visibility concerns because of the physical bulk of the prototype system (tablet computer, CGM and pump) and the limitations placed on clothing and lifestyle choices. Surprisingly, the questionnaire data showed that only 18% participants thought the issue of 'looking different because of diabetes and using devices' was worse than before the study (Table S1). During interview, one of the women who subsequently discontinued closed-loop stated: 'It's not ideal… during the winter when you're layered up, its maybe not such an issue, you can hide it easier, but as the weather gets warmer, and you're [wearing] more summery things, it is a little bit restrictive as to what you do with it, where you wear it.' (T205)

Prompted by the greatly increased quantity of data that closed-loop provided, some women described obsessive checking of system readouts. They acknowledged that although the system was physically cumbersome it was also an addictive and powerful piece of technology that women interacted with as they would their smartphones: 'I wouldn't even be able to tell you how often I [check my levels on the tablet]' (T205). For some, this was a potentially negative phenomenon: 'I don't like the whole addiction… I was reading about the young mums where they're not getting their actual physical face time with their children… because they're texting while they're breastfeeding.' (T105); 'It would be very easy to get so caught up in it, so absorbed and so fixated.' (T103)

Some participants raised the concern that closed-loop therapy diminished their attentiveness to symptoms of hyper- and/or hypoglycaemia, and were concerned about the potential 'deskilling' arising from the 'outsourcing' of bodily symptoms to system devices: '[W]hen

my blood sugars have been… starting to decrease, I haven't necessarily felt like I was having a hypo. So maybe that is me, putting all my trust in it, and almost taking my trust out of myself.' (T110)

The two women who stopped using closed-loop therapy after completing the crossover trial had concerns related to battery life, inter-device connectivity and the physical bulk of the system. Both expressed concerns regarding sensor accuracy, leading to a relative lack of trust in the system: 'I wouldn't say I trust it massively, [around] 50 or 60 per cent… there's always that little doubt in my head… there's always glitches that can happen' (T206). Additionally, both found closed-loop insufficiently aggressive in terms of glycaemic control, with one participant stating that she believed there was little difference between closed-loop and sensor-augmented pump therapy: 'my control on… closed-loop overnight, I didn't find was any better than not being on the closed-loop' (T205).

Potential use of closed-loop in routine clinical care

In terms of potential future mainstream use of closed-loop therapy, a number of women expressed concerns about how the level of 24-h support offered during a research study would translate into mainstream clinical care. Nine women stated that they would have considered dropping out without such support. When asked if they would recommend the system to others, most were supportive. Some (*n*=4) added caveats, suggesting that the system may not be suitable for children, 'people with busy practical jobs', 'those without motivation to use the system successfully', or those who are 'less technologically competent'. In this context, one woman stated that: 'Personally, I would recommend it to anyone [but] maybe not my granddad who's diabetic because he hasn't really got a clue' (T206).

Perceptions of glucose control

We compared the biomedical data on individual participants' glucose control obtained during overnight closed-loop to quantized qualitative data of women's perceptions of their glucose control (Table 3). Women very slightly overestimated their glycaemic response compared with the objectively measured change in glucose levels (mean overestimate of 0.1 on a five-point scale). There was marked variation among individuals: two women correctly estimated their glycaemic response, four overestimated their response to closed-loop therapy (mean overestimate of 2.3) and seven underestimated their response (mean underestimate of 1.3). There was wider variation between women's objectively measured change in glucose levels (ranging from 2 to 5) than between their perceptions of their response (from 3 to 5).

Attitudes to technology

Women's attitudes to technology had a complex and in some ways counterintuitive relationship with their objectively measured change in glucose levels and with their own perceptions of their glycaemic control (Table 4). Overall, women's attitudes towards technology became more positive by 0.4 on a five-point scale over the course of the study; however, seven women showed no change in attitudes towards technology. Of these seven, three correctly estimated their glycaemic control response, while the remaining four underestimated their response (mean underestimate of 1.25). Five women showed a positive change in attitudes to technology (mean change 1.4). Of these, two correctly estimated their glycaemic response, two overestimated their response (mean overestimate of 3.5) and one underestimated their response (by 1). One woman, substantially underestimated her glycaemic response to closed-loop therapy (underestimate of 2.0), with a negative change in attitudes (–1), meaning that despite >25% increased time-in-target, she still perceived poor

control during closed-loop therapy and was less positive about technology in general. Overall, those who ended the study with the most positive opinion of glucose control and most positive attitudes to technology had poorer levels of glycaemic control and higher degrees of overestimation regarding their levels of control.

Discussion

The present findings constitute the first insights into the complex psychosocial experiences of women using closed-loop therapy in pregnancy. Reflecting the perceived benefits, 14 of 16 women chose to continue using day-and-night closed-loop for ~12 weeks post-study. While our data indicate that closed-loop therapy is, broadly, a positive technological experience, they also show that very positive technology attitudes may be associated with unrealistic expectations.

Our key findings relate to the balance between excitement and empowerment alongside concerns about visibility and lifestyle choices, digital addiction and loss of bodily sensitivity. These findings have not markedly emerged in previous closed-loop studies, although two studies reported participants' feelings of 'hope for the future' and concerns about lifestyle issues [23,24]. We also confirm previously reported benefits and burdens of closed-loop therapy over shorter study durations (4 weeks), including feelings of 'normality' and 'time off' from diabetes alongside technical difficulties, alarms, and the physical bulk of the system [23–26].

In terms of perceptions of glucose control, our novel multi-method approach revealed substantial variation in women's estimates of their glycaemic response to closed-loop therapy and the extent to which these aligned (or otherwise) with the objective biomedical data. Our

findings suggest that individual users may substantially underestimate or overestimate the control they achieve with closed-loop therapy. We also found that the relationship between attitudes to technology and glucose control was complex and in some ways counterintuitive, because women who ended with more positive perceptions of control and more positive attitudes to technology had comparatively poor glycaemic control. As such, positive attitudes towards technology may be associated with unrealistic perceptions of glucose control arising from closed-loop therapy.

It is possible that some women's overly positive opinions of control derived in part from antecedent personal characteristics (e.g. positive attitudes to technology) and satisfaction and excitement generated by trial participation rather than their actual response to therapy. This echoes previous structured education research, in which positive psychosocial outcomes co-existed with limited improvements in glycaemic control [27]. Alternatively, participants may have expressed positive views because of experienced benefits not directly related to glucose control, such as improved sleep and 'time off' from diabetes. Conversely, women who underestimated their glycaemic response may have done so because of perceived study burdens and technical glitches, or because of unease arising from obsessiveness or perceived deskilling.

The closed-loop system incorporates multiple interconnected devices (insulin pump, CGM device and tablet computer), each of which has its own distinct attributes and 'affordances'. In particular, participants considered the CGM system both as one of the most beneficial and burdensome components of closed-loop therapy. The study pump also had specific drawbacks, such as manual priming, and was less sophisticated than many commercially available pumps. The tablet was larger and more cumbersome than subsequent iterations which house the algorithm on a mobile phone. In the future, specific device burdens should be reduced as hybrid closed-loop systems become commercially available [28].

The strengths of the present study include our mixed-method approach, integrating qualitative and quantitative psychosocial data with biomedical data, in addition to our use of a longitudinal rather than cross-sectional approach, thus allowing us to examine changes in attitudes over time. In contrast to previous research, which examined intention to use closed-loop therapy, we offered participants a real-life choice to continue using closed-loop therapy or not. The study was limited by the small number of participants and the fact that this was the first home study of closed-loop in pregnancy, which may have contributed to women's excitement and positive perceptions.

While future technological progress may obviate specific concerns regarding physical bulk/device visibility issues, other potential challenges such as outsourcing/deskilling and addiction may be more enduring features of automated diabetes technologies. When engaging with users/carers who risk over-optimistic reliance on closed-loop therapy and those who may discontinue use because of negative perceptions of control, clinicians will need to take account of these wider factors to manage expectations and use technology appropriately. Consequently, clinicians should consider closed-loop therapy not just in terms of its potential impact on biomedical outcomes but also in terms of its impact on users' lives. To minimize burdens and maximize benefits, automated insulin delivery systems should consider using co-design approaches to take account of the perspectives of a range of stakeholders, including users and clinicians [29].

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Competing interests

H.R.M. reports having received speaker honoraria from Medtronic, Abbott Diabetes Care, Eli Lilly and Novo Nordisk and serves on a scientific advisory board for Medtronic. R.H. reports having received speaker honoraria from Eli Lilly, Novo Nordisk and Astra Zeneca, serving on advisory panel for Eli Lilly and Novo Nordisk, receiving license fees from BBraun and Medtronic, and patents and patent applications in closed-loop technology. No other potential conflicts of interest are reported.

Prior Presentation

Parts of these data were presented at the 10th International Conference on Advanced Technologies and Treatment s for Diabetes (ATTD), Paris, 17 February 2017.

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Table 1 Changes in diabetes treatment satisfaction and Hypoglycaemia Fear Survey II scores during automated closed-loop and sensor-augmented pump therapy

	Diabetes treatment satisfaction		**HFS-II***		
	Current problem	**Change**	**Total**	**Behaviour subscale**	**Worry subscale**
Baseline (*n*=16)	3.6 (0.7)		62.3 (13.2)	30.6 (5.4)	31.7 (9.9)
End of sensor-augmented pump therapy (*n*=12)	3.6 (1.0)	3.6 (0.5)	60.5 (10.4)	30.8 (6.0)	30.0 (7.4)
End of closed-loop therapy (*n*=11)	3.1 (0.8)	3.3 (0.3)	60.8 (11.3)	29.4 (4.8)	30.6 (7.0)

HFS-II, Hypoglycaemia Fear Survey II.

*There were no statistically significant differences between cohorts on the Diabetes Treatment Satisfaction Questionnaires or HFS II, either as a total score or on either behaviour or worry subscale.

Table 2 Benefits and burdens from qualitative interviews

Category	Themes	Illustrative quotations
Benefit	Improved control	I think it's brilliant because I can come in [on] target …yesterday when I was printing off [the data], I think it was 77% of the time I was on target. T206
	Improved sleep	When you're asleep it is nice to be able to get a full night's sleep knowing that something else is taking control. T201
	Reassurance	I think the best [thing] has been not having to think too much about my blood sugars overnight, you know, having that reassurance that it's doing, hopefully, what it should be doing. T205
	Normality	[B]ecause my blood sugar control is so good and I feel so positive about it it's almost like I'm a normal person and I'm not diabetic. T210
	Empowerment	I don't know what the word is but just...you just feel a little bit at ease that you're not having to worry about something all the time. And even though I like to think that I don't worry I know that deep down something like being diabetic is...you do worry about it every day all the time because you don't know when anything's going to happen. I think that was the biggest pro for me is not being, oh I must check my blood sugar, must eat something… can't do this, can't do that. And with this [system] it made me feel well no actually I can. (T202) It was like, it's like being completely blind and then having somebody open your eyes... It puts the power back into your hands because it's all going on inside of you (T216)
	Excitement	[T]he only word I can think of [is] it's quite exciting to know that I can learn something like that and make it work. T202 I think it's been quite exciting because people ask, what is that, and then I get to explain. I'm quite excited about the study, I really like explaining and people are really curious… My husband's really interested in how well the closed loop works so he's looking at my data and, how did that go, and things. He's been really excited. It's been great that we're both really excited about the study. T211
	Glitches	[P]robably about one in four of the CGM [sensors] has failed… I've had five or six that just wouldn't even connect. T204
	Alarms	Yeah, that's probably been the biggest irritation, yeah, being woken up once or twice a night by alarms. T217
	Trust issues	I don't distrust the doctors, it's the kit… because if anything is going to fail it's the kit. T103
	Lifestyle limits	I am finding it really difficult. I mean, I like to wear things like dresses, and skirts and

Burden		tops. And it just feels like its protruding out. I don't…I suppose I don't mind putting it on show, but I do find it quite restrictive in what I can wear. T110 I'm not entirely sure what I'm going to do when I have the baby, because I can see it getting tangled up in it quite a lot… I'm forever waking up and finding me tangled in it, or lying on it. T204
	Obsessiveness	I think the biggest thing is just being able to see your blood sugars in front of you all of the time, and seeing what they're doing. And, it's actually quite scary to begin with… it does come as a little bit of a shock to the system. Now, I think, if I were to not have the CGM, …you'd miss it, you wouldn't know what to look at. … it's a bit like a smart phone, you know… . T205 I've been a bit obsessed looking at that actually because I was always an avid blood sugar tester anyway, so I'd test eight to ten times a day. So the fact that I haven't had to prick my finger that much and I can literally just pick it up and look at it, so particularly at work if I've been busy I've been managing to just have a look at it. T212
	Deskilling	I feel as though my hypo-awareness has dropped, because I think I've become too dependent on [the system] I feel as though, rather than being conscious of how I'm feeling all the time, I'll just wait for the [CGM handheld device] to beep and tell me that I'm going to go low. T214 [O]ne of the negative things is it's made me slightly more passive… it definitely made me lazier and slightly more passive in my own care, which is, I guess, not a good thing. T217

CGM, continuous glucose monitoring.

Table 3 Women's views of glycaemic control in relation to objective glycaemic control and wider attitudes to technology

ID	Glycaemic response* (1–5)	Participant opinion of glycaemic response† (1–5)	Disparity between biomedical data and participant opinion‡	Participant attitudes to technology† Baseline (1–5)	Participant attitudes to technology† Follow-up (1–5)	Change in participants' technology attitudes
001	5	4	-1	3	3	0
002	3	4	+1	2	5	+3
003	5	3	-2	4	3	-1
004	5	4	-1	3	3	0
005	4	3	-1	3	3	0
006	4	3	-1	4	4	0
007	5	5	0	3	4	+1
008	5	5	0	4	4	0
009	5	4	-1	4	5	+1
010	3	5	+2	5	5	0
011	2	5	+3	5	5	0
012	2	5	+3	3	4	+1
013	4	3	-1	2	3	+1
014	4	4	0	*n*/a	*n*/a	*n*/a
Mean	4	4.1	+0.1	3.5	3.9	+0.4

*Objective glycaemic response as measured by the relative change in overnight continous glucose monitoring time-in-target between automated closed-loop insulin therapy vs self-directed sensor-augment pump therapy is rated on a 1–5 scale: 5: very positive (>15% increase); 4: positive (5-15% increase); 3: neutral (-5 to 5% increase/decrease); 2: negative (–5 to –15% decrease); 1: very negative (<15% decrease).

†Women's views of glycaemic control were obtained during qualitative interview and rated on a 1–5 scale: 5: entirely positive; 4: mostly positive; 3: mixed (positive and negative); 2: mostly negative; 1: entirely negative.

‡Negative values denote that women underestimated their actual glycaemic control; positive values that they overestimated actual glycaemic control.

Table 4 Women's wider attitudes to technology at baseline and at follow-up, in relation to objective glycaemic control and opinions of glycaemic control

	Technology attitude*	Number of participants	Glycaemic response†	Opinion of glycaemic response*	Disparity between glycaemic response and opinion of glycaemic response
		Mean	Mean	Mean	Mean
Baseline interview	Entirely negative	0	n/a	n/a	n/a
	Negative	2	3.5	3.5	0
	Mixed	5	4.2	4.2	0
	Mostly positive	4	4.8	3.8	-1
	Entirely positive	2	2.5	5	+2.5
	Mean				+0.7
Follow-up interview	Entirely negative	0	n/a	n/a	n/a
	Negative	0	n/a	n/a	n/a
	Mixed	5	4.6	3.2	-1.4
	Mostly positive	4	4	4.5	+0.5
	Entirely positive	4	3.3	4.5	+1.2
	Mean				+0.1

*Participants' attitudes to technology were obtained during qualitative interview and rated on a 1–5 scale: 5: entirely positive; 4: mostly positive; 3: mixed (positive and negative); 2: mostly negative; 1: entirely negative.

†Glycaemic response as measured by the relative change in overnight continuous glucose monitoring time-in-target between closed-loop automated insulin therapy vs self-directed sensor-augmented pump therapy is rated on a 1–5 scale; very positive (>15% increase) 5, positive (5–15% increase) 4, neutral (–5 to 5% increase/decrease) 3, negative (–5 to –15% decrease) 2, very negative (<15% decrease) 1.