Supplementary Materials

Semi-Structured Interview Topic Guide

1. Overview

- Leaving aside the artificial pancreas system for the moment, how has life been in the months since we last spoke in terms of:
    - Challenges of parenthood/final stages of pregnancy
    - Changes to routine/sleep/interactions with family and friends
    - Wider changes – job, partner's job, home life in general

2. Usability

- Can you describe a typical day and night using the closed-loop system?
    - Specific memorable events
- How did the system compare with your previous diabetes care regimen?
- How did you feel about being randomised to Closed Loop or Open Loop at first?
- Did you use the system as intended, or did you suspend or stop it at any time? If so, why?
- Regarding the Closed Loop system, what are your specific thoughts on:
    - Training sessions and personnel
    - User manuals
    - Smartphone
    - Insulin pump
    - CGM sensors
        - Any differences between own testing vs CGM readings (and any changed behaviour as a result)
        - Trust levels
    - Navigator Transmitter and Receiver
    - Alarms
    - Other equipment (e.g. chargers)
    - Set changes
    - Data uploading

- Did you have any problems with the system, and if so what kinds of support did you seek out?

3. Acceptability

- Did you trust the Closed Loop system to manage your diabetes?
- How good was the technology at fulfilling its purpose(s)?
    - Has it improved your control of diabetes?
    - Has it reduced your experiences of and fears about hypo/hyperglycaemia?
    - Has it changed how you respond to hypo/hyperglycaemia?
- How easy was the system to incorporate into your everyday life? Specifically, regarding:
    - Pregnancy
    - Clothing
    - Work
    - Leisure
    - Sleep (especially if people have had nocturnal hypos in the past)
    - Diet
    - Physical activity
    - Family routines and arrangements
- How did you feel about being hooked up to an automated system?
    - How did this experience compare with your expectations pre-study?
- How did you feel about sending your data to the clinical team?
    - What was your understanding of why the data was sent to the clinical team?
    - Did you receive feedback about the data?
- Were you comfortable with others seeing the system and/or knowing that you were using it?
    - What did you tell others about the system?
- What did partners/relatives/friends think of the system? What kinds of support did they offer?
- Did the experience match your expectations before you started the study?
- Has it changed your views about technology in diabetes?
- Do you think you would be likely to continue to use the Closed Loop system (or some of its component devices) over a longer time period?
- Did you seek to continue to use the system after the study ended? If so/if not, why?
- Would you recommend its use to others?
- What kinds of support would you see as necessary for others using the system?
- Would you participate again or in similar studies?

Table 1 Perceived Benefits of Closed-Loop Therapy

Benefit arising from closed-loop system usage	Sample key-words used by participants	Illustrative quotation	Number of participants mentioning benefit* (%)
Peace of mind	Mental freedom, relaxing, less worried, easy, does everything for you, don't have to think about diabetes, reassuring for others, relying on machine, confident, less diabetic, freeing, less guilty about baby, liberating	It is kind of amazing that the technology is there. I find that quite exciting. And to have had a go using it is brilliant…So I think I'll probably just feel a bit more excited, feel bit more positive about the future really. That's kind of…it's made me feel that there's something out there and hopefully at some point it will be available to use properly, if you see what I mean? Or use for longer periods of time. Yes, it's kind of made me feel even more positive which is scary. It's probably dangerous. P10	14 (87.5)
Wonderment at new technology	Exciting, interesting, cool, positive, impressed, life-changing, fantastic, intuitive, optimistic, great, amazing, incredible, fascinating	it all works so well, yeah, I was never kind of really worried about what my blood sugars were. If they were ever a little bit high, well that was because I'd a) miscalculated my carbohydrate, or b) I'd eaten some kind of fast relief carbohydrate. But then ultimately I always knew that the best way to bring my blood sugars under control was actually to leave well alone and let the system do it. P16	13 (81.3)
Superior glycaemic control	Improved, good job, brilliant, really happy, much better, 95% better, pretty good, smoothed highs out, tighter	I can rely on it alarming, so I'm just going to run at what I want to run at, and then if it does alarm, then it'll alarm and I'll deal with it. So, that's really good… I think there's definitely less effort if you can rely on it to get on with what it needs to do, and that's an enormous thing in managing diabetes. That's so amazing, to be able to get on with your life without having to use the brain power that you do, all the time P1	12 (75)
Smartphone interface experiences	User-friendly, intuitive, easy to use, fine, talked to other devices well, helpful, useful	I think having the CGM for me has been probably the best part, regardless open-loop, closed-loop, just having that visibility and being able to see my blood sugars at any point throughout the day I've found personally has been a great comfort or has enabled me to make changes to my insulin for the benefit of my diabetes, so that I would say is the best thing, in that it's freed up time in having to deal with the finger stick tests, and it's just so much easier and straightforward and discreet, so that has definitely been the biggest win for me. P7	11 (68.8)

CGM-related benefits (other than learning experiences)	Accurate, helpful, reassurance, easy, insight, continuous, constant	[A]t the end of all this I've learnt a lot about how my body reacts to different foods and things like porridge, which is supposed to be a slow release, it's not at all, every time I have porridge I peak and then drop afterwards…So it's been interesting looking at that kind of thing and also seeing if I do have some chocolate and I haven't had the insulin to match the chocolate, it doesn't always affect my blood sugar as much as I thought it might have done, as long as I'm on top of it and not too high to start with when I've had some and had the right amount of insulin to match it. So, yeah, the graphs are really good, that's fascinating. P14	9 (56.3)
Flexible lifestyle	Easier, enjoying eating, fewer finger-pricks, convenient, others used to seeing phones in public, nice feeling, independence	It was all really intuitive, really easy to use and obviously that's the only [app] that's on [the smartphone]. So it makes it very simple. P3	9 (56.3)
Learning experiences	Helpful, useful, more informed, better clinic appointments, surprising, better than health professionals	It wasn't any different really because I've got two children so I have bags and I always use to…I've always carried a bag with me because I've always had my blood tester in that bag. P5	9 (56.3)
Alarms	Useful, fine, confident, helpful, more aware	[I]t was easier to maintain with eating and…at different times of the day because I knew that even if my blood sugar did pick up a little bit after a meal then it would correct itself. I didn't have to think, oh, I can't eat…because generally I wouldn't eat too late in the day because of going to sleep and I wouldn't be able to check my blood sugars but knowing that that would be okay it was a bit more reassuring. P5	7 (43.8)
Study insulin pump	Fine, good, really good, straightforward	[The study pump is] much lighter and small than a Medtronic which is good. It seems much more geared up to using temporary basal rates, 'cause it doesn't alarm at you like the Medtronic does if you're on a temporary basal. P1	6 (37.5)
Bodily assimilation of devices	Didn't feel any different, part of me, got used to it, intuitive	I got used to wearing the pump anyway, so I've kind of come to terms with, personally, like being bionic, having a thing attached to me. And it is a bit more having another sensor under your skin, but I've got used to wearing that now really. P1	5 (31.3)

| Sleep | Better, comfort, not worrying | [M]y sleep was a lot better knowing I had those machines and stuff, because then I hadn't got to worry that I was going low and stuff... if I was asleep and I needed a bit more insulin, that would do it and all that automatically… Also it's probably the fact that I could just roll over and touch the machine to check my bloods rather than have to be half asleep, get a finger pricker out, test my finger and all that. P6 | 5 (31.3) |
| Ease of maintenance and logistics | Not too bad, not a huge problem, not any different from normal | [T]he navigator has got quite a strong vibrate which kind of would wake up a whole house when the thing's going off which is good because it obviously wants to tell you something. P10 | 3 (18.8) |

Table 2 Perceived Burdens arising from Closed-Loop Therapy

Burden arising from closed-loop system usage	Sample key-words used by participants	Illustrative quotation	Participants mentioning burden (%)
Technical glitches (non-CGM)	Connectivity loss, temperature errors, disconnects, reverts to open loop, error messages, system freezes, battery life, phone dies	For more than half of the time that the CGM has been slightly out of synch with the reality of my blood glucose levels… What it's telling me on the meter is about ten minutes behind what's actually happening P1	16 (100)
Technical glitches (CGM)	Inaccurate, time lag, insertion problems, calibration difficulties, dodgy sensor batch, compression events, reversion to open-loop	Sometimes, like when they [system devices] all lose connection and stuff, that was frustrating and sometimes the phone used to say that system error quite a lot and then used to restore or turn it off. Yeah, I found that annoying. [Interviewer: Did it make you concerned about the system, that it was having these errors?] Yeah…to an extent because sometimes when I had to use it at work, I wouldn't know that it had resorted back to open loop, so that was annoying. What else was annoying? I do have a few problems…I don't know if you're really bothered about this, but like, say the translator and the CGM, the stuff like the battery life didn't ever go down and I had to look at the phone and the phone would tell me when the translator was low…. Sometimes the pump…it would say like, pump out of range, or something like that and you'd be right near it or…you had to keep…you had to keep connector or sensor with the pump and the phone, so maybe that's something, I don't know, that needs work I think, I'd say. P9	14 (87.5)
System bulk	Nuisance, bulky, a pain, inconvenient, quite big, difficult, cumbersome, many components, chunky	It took a lot of time to get used to it and thinking then making sure you've got all your bits and your supplies, because that's another thing you've got a lot of stuff to go with it, like with an insulin pen you've got your pen, you've got your insulin, you've got your needles. You know, the whole trial you do have a lot of bits, you have like testers and syringes and sets and sensors. P11	13 (81.3)
Maintenance and logistical requirements	Annoying, hard work, overwhelmed, need knowledge to use	I still don't like really that you can see it, I've got a dress on today which is obviously quite tight because I've got a big belly now, and you can see the pump at the front and the sensor at the back. Yeah, I don't really like it but it doesn't really bother me a huge amount. I think if someone wanted to know what it was, they'd just ask I suppose. P4	12 (75)

	properly, full-time job, self-care responsibility		
Alarms	Frustrating, annoying, unhelpful, sleep problems, constant bleeping	I don't really sleep at all, just really being uncomfortable, and that's what made me get rid of the phone in the end, because I'd just get off to sleep and it would beep or go off or vibrate or, yeah, so sleep has been a bit of an issue. P9	11 (68.8)
Cautious algorithm leading to suboptimal control	Frustrating, rubbish, slightly worse, random, surprising, not aggressive enough	[T]he technology did seem to be a little bit old school almost… little things were annoying with [the study pump]. Like there's a backwards thread when you put the refill back in with the reservoir bit. When you then put the part that connects the line to the pump there's one bit that you then screw back on and it's a backwards thread. And the amount of times that I'd try and screw it the wrong way was probably every time I did a set change. P3	8 (50)
Need for human input (bolusing)	Bolus administration, meal announcements, difficult	I didn't know that in terms of what fluctuates during pregnancy, it's not just your basal rates that fluctuate, your bolus does fluctuate. So, given that it can't cope with that, then you're never going to be at the point of [complete automation], you've still got to do that pattern recognition, or adjustment when it isn't a pattern, it's a one off, and you don't know this until you do it. P1	7 (43.8)
Study insulin pump	Old school, annoying, casing cracked, backwards, fiddly, noisy	[W]hat I found the most frustrating was that I was going, it felt like I was going high, and then it wouldn't bring it down, there'd be long periods I was high, and then actually felt sick, because I'd had such good control before, like I wouldn't have those long periods of highs. Not super high, like maybe a 12 or something, but it's still not great. P2	7 (43.8)
System visibility	Unattractive, visible, odd looks, cyborgs, annoying, hiding	It was really scary, the idea of handing it over to something else was quite frightening. P13	7 (43.8)
Adhesive problems	Hurts, irritation, annoying	I definitely don't think I would go back to injections, to the point that a couple of weeks ago a few of my sensors…was it, no, I think it was maybe last week, I ran out of sensors, one the thing came up, like, the sticky bit came off and I couldn't then put it back in, so I didn't have any and I just said to…Zoe sent a courier in the end, like, the same day and I just said…I literally wouldn't have a clue if I had to go to injections, I wouldn't have a clue what to do. And that's only in a seven month period, like, everything I've ever known, like, so I've become reliant on the pump and I feel like that's, you know, what I will have	5 (31.3)

		moving forward, but the thought of having to inject and, like, know ratios and when to do it and…freaked me out a bit, obviously I would get used to it, but… P9	
Challenges of surrendering control to technology	Frustrating, apprehensive, inflexible, controlled, odd, frightening, weird	I don't particularly like it showing, so it's quite nice to have it on my tummy, but then I started getting very sensitive skin and also rashes on my elbows and all sorts of things coming up and it was reacting to the adhesive. P13	5 (31.3)
Anxiety arising from system use	Panic, lack of freedom	I think because you notice it more because you've got a gadget in front of you that's sat there beeping and vibrating at you that you're still less than three, you're like oh my goodness, I still haven't gone higher. P3	4 (25)
Exercise	Frustrating, hard work, stopped exercise	At the beginning, yes, I was like 24 hours just watching this arrow going up and down and, oh my God, it's going up, it's going up, why it is high, why it's low. P8	3 (18.8)
Addiction to system	24 hours a day	I found [using the system while exercising] quite challenging to be honest… I considered dropping out a few times… the exercise function… was really not doing a very good job. I was kind of going high, and would just go really low, it wasn't working very well. P2	1 (6.3)
Deskilling	Reliant	I'm having to think a bit even more ahead and make sure that you've got enough insulin in your pump and things like that, and with the sensor, what time is that going to expire, because actually if it expires at three in the afternoon, actually probably want to change it in the morning because I don't want to be waking up in the middle of the night. So from that side of things, it's been harder work. P7	1 (6.3)
Smartphone interface experiences	Slow, frustrating	I liked the idea of it, but, you know, if you want to put in you're having carbohydrates, for example, it takes ages for the phone to, like, get onto that screen and then, by the time you've then said how many components you're having, how many…so that just adds extra time onto your day, when actually you could just tell the pump to do it straight away… it was slightly frustrating that that technology wasn't quicker. P9	1 (6.3)