Journal of Diabetes Science and Technology
2018, Vol. 12(6) 1125–1131

DOI: 10.1177/1932296818800065
journals.sagepub.com/home/dst
SAGE

Women's Experiences of Day-and-Night Closed-Loop Insulin Delivery During Type 1 Diabetes Pregnancy

Conor Farrington, PhD[1], Zoe Stewart, MD[2,3], Roman Hovorka, PhD[2], and Helen Murphy, MD[2,4]

Abstract

Aims: Closed-loop insulin delivery has the potential to improve day-to-day glucose control in type 1 diabetes pregnancy. However, the psychosocial impact of day-and-night usage of automated closed-loop systems during pregnancy is unknown. Our aim was to explore women's experiences and relationships between technology experience and levels of trust in closed-loop therapy.

Methods: We recruited 16 pregnant women with type 1 diabetes to a randomized crossover trial of sensor-augmented pump therapy compared to automated closed-loop therapy. We conducted semistructured qualitative interviews at baseline and follow-up. Findings from follow-up interviews are reported here.

Results: Women described benefits and burdens of closed-loop systems during pregnancy. Feelings of improved glucose control, excitement and peace of mind were counterbalanced by concerns about technical glitches, CGM inaccuracy, and the burden of maintenance requirements. Women expressed varied but mostly high levels of trust in closed-loop therapy.

Conclusions: Women displayed complex psychosocial responses to day-and-night closed-loop therapy in pregnancy. 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.

Keywords

pregnancy, closed-loop, day-and-night, type 1 diabetes

Pregnant women with type 1 diabetes experience higher rates of fetal, maternal, and neonatal complications than the general maternity population of women without diabetes.[1-5] In England, structured antenatal care for women with pregestational diabetes involves frequent clinical contact (typically every 1-2 weeks) with specialist diabetes pregnancy health care teams. Together with strict glucose control before and during pregnancy, this care model allows treatment to be individually tailored to address physiological changes and can thus minimize diabetes-related risks during pregnancy.[5-7] As a result of the potential consequences of hyperglycemia, many women with type 1 diabetes are highly motivated to improve their self-care routines (eg, dietary intake, insulin dose adjustment, and glucose monitoring) during the course of their pregnancy.

Nevertheless, a recent cohort study in the UK found that only 16% and 40% of women in early and late type 1 pregnancy respectively met HbA1c targets of <6.5%.[7] The combination of sustained intensive effort and the difficulty of achieving optimal outcomes can impact negatively on women's psychosocial well-being by adding to existing cognitive and emotional burdens arising from continued self-care.[8-9] Consequently, significant clinical and research effort has focused on the potential contribution of diabetes technologies in terms of minimizing self-care burdens and maximizing positive outcomes. Recent studies have demonstrated benefits arising from the use of continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion (CSII), or insulin pumps, in selected patient groups during pregnancy.[10-12] CONCEPTT, a large multicenter

[1]THIS Institute, University of Cambridge, Cambridge, UK
[2]Wellcome Trust–Medical Research Council Institute of Metabolic Science, University of Cambridge, Cambridge, UK
[3]Department of Obstetrics and Gynaecology, University of Cambridge, Cambridge, UK
[4]Norwich Medical School, University of East Anglia, Norwich, UK

Corresponding Author:
Helen Murphy, MD, Norwich Medical School, University of East Anglia, Floor 2 Bob Champion Research and Education Building, Norwich NR4 7UQ, UK.
Email: helen.murphy@uea.ac.uk

randomized controlled trial of real-time CGM, found that pregnant women using CGM spent an additional 100 min per day in the recommended control range and experienced significant reductions in the rate of large for gestational age birthweight and other neonatal outcomes.[10] CGM data can also provide detailed information on glucose pathophysiology, helping women with diabetes and clinicians to target insulin delivery with CSII (ie, sensor-augmented pump therapy) or multiple daily injections (MDI) to avoid the risk of neonatal complications such as neonatal hypoglycemia and neonatal intensive care unit admission, albeit by requiring extensive commitment from users and health care professionals.[11]

In terms of CSII, there are no contemporary randomized controlled trial data. Kallas-Koeman et al performed a cohort study comparing CSII and MDI in pregnancy, finding lower HbA1c levels in CSII than MDI across all trimesters of pregnancy.[12] The National Pregnancy in Diabetes (NPID) audit found that insulin pump users were more likely to achieve HbA1c levels during the first trimester.[7] However, another study found no significant difference in HbA1c between CSII and MDI.[13] These studies are all subject to important confounders such as indications for pump therapy, with outcomes dependent on patient and health care professional training and competency with insulin dose adjustment, which is arguably more complex with pump use. More widely, a recent review of technology in diabetes pregnancy highlighted uncertainty regarding the benefits of pump usage in terms of HbA1c and pregnancy outcomes.[5]

Closed-loop systems represent the latest stage in diabetes technology evolution, building on established technologies such as CGM and CSII but seeking to reduce the cognitive burdens required for effective use of sensor-augmented pump therapy. Closed-loop systems utilize control algorithms to provide automated, CGM-responsive basal insulin delivery via an insulin pump every 10-15 minutes.[14] These systems are often described as "hybrid" systems rather than fully automated systems because they require carbohydrate counting and manually administered premeal boluses. Nevertheless, they assume a substantial burden of basal insulin adjustment between meals and overnight compared to user-administered sensor-augmented pump therapy, arguably the best available alternative. Recent trials have demonstrated the safety of closed-loop, and its potential to improve glucose control in type 1 diabetes pregnancy without increasing maternal hypoglycemia,[15,16] but less is known about its psychosocial impact. Our aim in this study was to build on a previous psychosocial study of perceived benefits and burdens of overnight closed-loop therapy in pregnancy[17] by exploring pregnant women's experiences of day-and-night automated closed-loop therapy, in addition to women's levels of overall trust in closed-loop therapy. To the best of our knowledge, this is the first study to report psychosocial responses to day-and-night closed-loop therapy in type 1 diabetes pregnancy.

Research Design and Methods

We performed an open-label, randomized, crossover trial of a closed-loop system (Florence D2a, University of Cambridge) incorporating both biomedical outcomes and psychosocial evaluations. Full details of the study design, including sample size, power calculations, and biomedical outcomes, have been previously reported.[16] After 2-4 weeks of device training, women were assigned randomly to either 4 weeks of day-and-night closed-loop or 4 weeks of user-directed sensor-augmented pump therapy, with a 2-week washout between study phases. Premeal boluses were manually administered using the study pump (DANA Diabecare R Insulin Pump SOOIL) bolus calculator in both phases.

During closed-loop, an adaptive computer algorithm (University of Cambridge, version 0.3.41p) housed on an Android mobile phone (Samsung Galaxy S4, Samsung, South Korea) used CGM glucose values (FreeStyle Navigator 2, Abbot Diabetes Care, Alameda, CA, USA) to calculate an appropriate basal insulin dose, which was delivered via an insulin pump every 12 minutes. After the trial, women could opt to resume their previous intensive insulin regimen or continue using any combination of study devices through pregnancy and delivery and up to 6 weeks postpartum.

We recruited 19 participants between 18-45 years of age with HbA1c level between 6.5 and 10% and between 8 and 24 weeks' gestation from three UK National Health Service sites. We consciously enrolled a broad patient population with varied technology experience, diabetes education, and prior glycemic control as measured by HbA1c. Key exclusion criteria were multiple pregnancy and severe physical or psychiatric comorbidity. Three participants withdrew for varied reasons (dislike of study pump, mental health deterioration, pregnancy complications). Sixteen participants completed the randomized crossover trial. All were using intensive insulin therapy administered either by multiple daily injections ($n = 8$) or CSII ($n = 8$) before pregnancy. Six participants had previous experience of CGM. Over half had suboptimal booking HbA1c levels (>7.5%).

Qualitative Interviews

We administered semistructured interviews according to a topic guide developed from reviewing relevant literature (Supplementary Materials). We interviewed women twice, at baseline during device training (T1) and following completion of the study (T2). This study reports findings from 16 T2 interviews focusing on participants' experiences of closed-loop therapy, with individual participants numbered P1, P2, and so on. In line with previous qualitative interview studies,[18] we found this sample sufficient to attain data saturation (ie, the point in data collection when no new data are found to develop emerging conceptual themes).

Interviews were digitally recorded and transcribed verbatim. Interview transcripts were coded using NVivo software

Table 1. Perceived Benefits of Closed-Loop Therapy.

Benefit arising from closed-loop system usage	Sample keywords used by participants	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	14 (87.5)
Wonderment at new technology	Exciting, interesting, cool, positive, impressed, life-changing, fantastic, intuitive, optimistic, great, amazing, incredible, fascinating	13 (81.3)
Superior glycemic control	Improved, good job, brilliant, really happy, much better, 95% better, pretty good, smoothed highs out, tighter	12 (75)
Smartphone interface experiences	User-friendly, intuitive, easy to use, fine, talked to other devices well, helpful, useful	11 (68.8)
CGM-related benefits (other than learning experiences)	Accurate, helpful, reassurance, easy, insight, continuous, constant	9 (56.3)
Flexible lifestyle	Easier, enjoying eating, fewer finger-pricks, convenient, others used to seeing phones in public, nice feeling, independence	9 (56.3)
Learning experiences	Helpful, useful, more informed, better clinic appointments, surprising, better than health professionals	9 (56.3)
Alarms	Useful, fine, confident, helpful, more aware	7 (43.8)
Study insulin pump	Fine, good, really good, straightforward	6 (37.5)
Bodily assimilation of devices	Didn't feel any different, part of me, got used to it, intuitive	5 (31.3)
Sleep	Better, comfort, not worrying	5 (31.3)
Ease of maintenance and logistics	Not too bad, not a huge problem, not any different from normal	3 (18.8)

(QSR International Pty Ltd, Version 10, 2012, Cheshire, UK). We identified key themes relating to the burdens and benefits of diabetes technology using a 6-stage thematic analysis approach.[19] Our approach was informed by theories of sensemaking, according to which technology experience is influenced by users' preceding experiences, attitudes and values in conjunction with technological "affordances," or actions and capacities that technology allows or "affords."[20]

Results

Benefits of Closed-loop Therapy

Table 1 presents in summary form the benefits that interviewees reported from their experience of closed-loop therapy, presented in order of number of participants mentioning each perceived benefit and with a range of alternate keywords provided by participants (see Supplementary Materials for further illustrative quotations regarding both benefits and burdens). The most frequently mentioned benefit (n = 14) related to the peace of mind that users gained by using closed-loop therapy, such as, "It's very freeing. A lot less, kind of, thought went into organizing my diabetic insulin ratios, and so that's kind of handed over to the technology, which was really good" (P10). A related perceived benefit, mentioned by 9 women, emphasized the increased flexibility of lifestyle during pregnancy with diabetes due to greater convenience, fewer fingerpricks, and increased ease of dietary planning: "It was easier to maintain with eating. . . . I knew that even if my blood sugar did pick up a little bit after a meal then it would correct itself" (P5).

Interviewees also emphasized technological benefits of the closed-loop system, including positive attitudes to the system's smartphone interface (n = 11) and excitement at experiencing cutting-edge technology (n = 12): "It's kind of amazing that the technology is there. I find that quite exciting" (P11). With regard to the glycemic control they experienced while using the system, 12 women expressed significantly positive opinions, such as,

> It all works so well, yeah, I was never kind of really worried about what my blood sugars were. . . . 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)

A number of participants mentioned benefits related specifically to CGM use, including reassurance arising from the ability to access continuously updated data on glucose levels (n = 9) and new insights regarding bodily response to diet, exercise, stress, and pregnancy (n = 9). Smaller numbers of women discussed further benefits, including the utility of system alarms (n = 7) and insulin pump (n = 6), improved sleep (n = 5), and perceived ease of operation (n = 3). Additionally, several individuals (n = 5) described positive experiences of incorporating study devices into their bodily sensations: "I've kind of come to terms with, personally, like being bionic, having a thing attached to me" (P1).

Burdens of Closed-loop Therapy

By comparison with perceived benefits, participating women mentioned a wider range of perceived burdens (as presented

Table 2. Perceived Burdens Arising From Closed-Loop Therapy.

Burden arising from closed-loop system usage	Sample keywords used by participants	Participants mentioning burden (%)
Technical glitches (non-CGM)	Connectivity loss, temperature errors, disconnects, reverts to open loop, error messages, system freezes, battery life, phone dies	16 (100)
Technical glitches (CGM)	Inaccurate, time lag, insertion problems, calibration difficulties, dodgy sensor batch, compression events, reversion to open-loop	14 (87.5)
System bulk	Nuisance, bulky, a pain, inconvenient, quite big, difficult, cumbersome, many components, chunky	13 (81.3)
Maintenance and logistical requirements	Annoying, hard work, overwhelmed, need knowledge to use properly, full-time job, self-care responsibility	12 (75)
Alarms	Frustrating, annoying, unhelpful, sleep problems, constant bleeping	11 (68.8)
Cautious algorithm leading to suboptimal control	Frustrating, rubbish, slightly worse, random, surprising, not aggressive enough	8 (50)
Need for human input (bolusing)	Bolus administration, meal announcements, difficult	7 (43.8)
Study insulin pump	Old school, annoying, casing cracked, backwards, fiddly, noisy	7 (43.8)
System visibility	Unattractive, visible, odd looks, cyborgs, annoying, hiding	7 (43.8)
Adhesive problems	Hurts, irritation, annoying	5 (31.3)
Challenges of surrendering control to technology	Frustrating, apprehensive, inflexible, controlled, odd, frightening, weird	5 (31.3)
Anxiety arising from system use	Panic, lack of freedom	4 (25)
Exercise	Frustrating, hard work, stopped exercise	3 (18.8)
Addiction to system	24 hours a day	1 (6.3)
Deskilling	Reliant	1 (6.3)
Smartphone interface experiences	Slow, frustrating	1 (6.3)

in Table 2). 100% of participants highlighted technical glitches with the closed-loop system in general, such as connectivity problems and reversion to "open-loop" (nonalgorithmic sensor-augmented pump therapy), while 87.5% (n = 14) of participants emphasized technical challenges experienced specifically with CGM-related parts of the system, such as sensor insertion challenges, calibration difficulties, and inaccuracy: "For more than half of the time the CGM has been slightly out of synch with the reality of my blood glucose levels" (P2).

A number of women who mentioned particular benefits also mentioned countervailing burdens. In addition to technical glitches (both CGM and non-CGM) weighing against general perceptions of (eg) peace of mind and excitement at new technology, women's specific complaints such as those regarding system bulk (n = 13), onerous maintenance requirements (n = 12), system alarms (n = 11), and the need for preprandial bolusing (n = 7) seem to work against widely shared perceptions of flexible lifestyles, improved sleep, and the utility of system alarms. Despite 75% of women also identifying good control as one of the perceived benefits of closed-loop (Table 1), 50% of participants criticized the system algorithm as being overly cautious and leading to suboptimal glycemic control, such as,

> When you're on that phone system, like, it won't let you correct as easily. So sometimes if you are high, you just have to sit there and wait for the phone to realize and then bring you down, which may take two hours. (P9)

Additional perceived burdens included difficulties arising from system pump usage (n = 7), system visibility (n = 7), adhesive problems (n = 5), and anxiety arising from system use (n = 4), as well as smaller numbers of women identifying challenges relating to exercise, addictiveness, "deskilling" as a consequence of system usage, and dislike of the smartphone interface. Five interviewees also discussed initial challenges associated with surrendering control of diabetes to technology, with one woman remarking that "it was really scary, the idea of handing [control] over to something else was quite frightening" (P13).

Levels of Trust

These complex experiences of closed-loop therapy led to varied levels of trust in closed-loop therapy. When asked to estimate the level of trust they placed in the system, seven women gave percentage figures ranging between 80% and 100% with a mean of 89.9%, indicating high levels of trust in closed-loop therapy. The remaining women gave verbal answers (ie, answers without a percentage figure) that encompassed a range of opinions, with four participants expressing similarly high levels of trust to the women mentioned above (eg, "I would say [I trusted it] totally"; P12) and five participants framing their responses with a range of caveats. These included the view that trust has to be accompanied by continued vigilance ("You can't just leave it. . . . I do trust it but . . . you do have to keep checking"; P11); the view that trust developed only during the poststudy period

("Now I do [trust it] but during the four-week [study] period I didn't"; P2); and the view that system inaccuracy means that "reliability" may be a more appropriate term than "trust": "I might talk about reliability more than trust? It is really good. It's just, not as accurate as you'd like it to be" (P1).

Discussion

Building on a previous study of overnight closed-loop therapy in pregnancy,[17] our findings provide the first insights into the complex psychosocial experiences of women using day-and-night closed-loop therapy in pregnancy. Our findings indicate a range of perceived benefits, reflected by all participants opting to continue using closed-loop for at least some of the time after the randomized trial and 12 of 16 participants continuing to use closed-loop postpartum.[16] While our data indicate that closed-loop is in many ways a positive technological experience with potential to mitigate the significant burdens of self-care in pregnancy, they also show that users' positive perceptions were counterbalanced by a range of less positive experiences, leading to an overall picture of complexity and ambivalence.

Our key findings relate, first, to the balance between perceived benefits (eg, peace of mind, excitement at new technology, and impressions of superior glycemic control) on the one hand, and perceived burdens (eg, technical glitches, system bulk, and suboptimal algorithmic control) on the other. We thus confirm the findings of several previous psychosocial studies of closed-loop systems that have reported the coexistence of multiple perceived benefits and burdens in a range of populations and study contexts.[17,21-25] Our data also echo the coexistence of perceived benefits and burdens reported in our previous study of overnight usage, although some perceived burdens identified in that study (eg, obsessive checking of system readouts, concerns regarding "deskilling" arising from loss of bodily sensation or "outsourcing" sensation to system devices) did not emerge as strongly in the present study. It is possible that the more extended usage entailed by day-and-night usage may have led to a decline in obsessiveness as the novelty of the system wore off over time (as is common with wearable technologies in general).[26] It is unclear why deskilling concerns should have been more prominent in the previous study, although the broader population enrolled in this study (with concomitant variations in booking HbA1c and prior technology usage) may have included fewer women who were highly aware of diabetes-related bodily sensations and therefore the related possibilities of technology-related deskilling and "outsourcing."

A second key area of our findings relates to users' views regarding the level of trust they placed in the study closed-loop system. Despite enumerating more perceived burdens than perceived benefits, participants generally expressed high levels of trust in the system. This finding was surprising in light of women's widely shared concerns about perceived burdens arising from technical glitches and other challenges, but could be related to prominent feelings of excitement at using new technology, superior glycemic control, and peace of mind. A minority of women, however, expressed more qualified views, suggesting for instance that trust has to be counterbalanced with constant vigilance to ensure that the system is operating correctly. This variation in terms of women's level of trust, and varied experiences more widely, may arise in part from the fact that contemporary closed-loop systems incorporate multiple interconnected devices: insulin pump, CGM sensor and transmitter, and smartphone. Each of these has its own distinct attributes and "affordances" which may interact with individual users' preferences and experiences in varied ways.[27] For example, participants were divided in terms of whether they regarded the DANA study pump in terms of perceived benefit (n = 6) or perceived burden (n = 7).

The strengths of this study include our use of semistructured interviews to generate rich qualitative psychosocial data regarding experiences of technology use within a broad patient population, as part of a wider study generating detailed biomedical data about women's response to closed-loop therapy in type 1 diabetes pregnancy.[16] We are of course limited by the small number of participants and the fact that this was the first home study of day-and-night closed-loop therapy in pregnancy, which may have contributed to women's excitement and positive perceptions.

Conclusion

While future technological progress may alleviate specific concerns regarding technical glitches and physical bulk of closed-loop systems, other potential challenges such as maintenance requirements, human input needs (in terms of, eg, prandial bolusing), and surrendering control to technology may be more enduring features of automated diabetes technologies. When engaging with users who may exhibit both positive and negative impressions of new technologies, clinicians will need to take account of these psychosocial 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 potentially varied impact in the complex and varied contexts of individual users' lives. New diabetes technologies should not be introduced without appropriate innovations in terms of surrounding clinical care. Significant clinical training, engagement, and investment may be necessary to minimize the burdens and maximize the benefits of future closed-loop systems in mainstream diabetes care.

Abbreviations

CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; HbA1c, glycated hemoglobin.

Acknowledgments

The authors are grateful to the women who participated and to the NHS antenatal diabetes health care teams.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: HM reports having received speaker honoraria from Medtronic, Abbott Diabetes Care, Eli Lilly, and Novo Nordisk and serves on a scientific advisory board for Medtronic. RH 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.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This project is supported by grants from Diabetes UK (BDA 07/0003551), National Institute for Health Research (NIHR CDF 2013-06-035), Gates Cambridge Trust, and Jean Hailes for Women's Health. CF is funded by JDRF. RH receives additional support for the artificial pancreas work from JDRF, National Institute for Health Research Cambridge Biomedical Research Centre and Wellcome Strategic Award (100574/Z/12/Z). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the UK Department of Health.

Supplementary Data

Interview topic guide; Benefits of Closed-Loop Therapy; Burdens of Closed-Loop Therapy.

Supplemental Material

Supplemental material for this article is available online.

References

1. Persson M, Norman M, Hanson U. Obstetric and perinatal outcomes in type 1 diabetic pregnancies: a large, population-based study. *Diabetes Care*. 2009;32(11):2005-2009.
2. Klemetti M, Nuutila M, Tikkanen M, Kari MA, Hiilesmaa V, Teramo K. Trends in maternal BMI, glycaemic control and perinatal outcome among type 1 diabetic pregnant women in 1989-2008. *Diabetologia*. 2012;55(9):2327-2334.
3. Tennant PW, Glinianaia SV, Bilous RW, Rankin J, Bell R. Pre-existing diabetes, maternal glycated haemoglobin, and the risks of fetal and infant death: a population-based study. *Diabetologia*. 2014;57(2):285-294.
4. Macintosh MC, Fleming KM, Bailey JA, et al. Perinatal mortality and congenital anomalies in babies of women with type 1 or type 2 diabetes in England, Wales, and Northern Ireland: population based study. *BMJ*. 2006;333(7560):177.
5. Yamamoto J, Murphy HR. Emerging technologies for the management of diabetes in pregnancy. *Curr Diab Rep*. 2018;18(4).
6. Maresh MJ, Holmes VA, Patterson CC, et al. Glycemic targets in the second and third trimester of pregnancy for women with type 1 diabetes. *Diabetes Care*. 2015;38(1):34-42.
7. Murphy HR, Bell R, Cartwright C, et al. Improved pregnancy outcomes in women with type 1 and type 2 diabetes but substantial clinic-to-clinic variations: a prospective nationwide study. *Diabetologia*. 2017;60(9):1668-1677.
8. Damm P, Mersebach H, Rastam J, et al. Poor pregnancy outcome in women with type 1 diabetes is predicted by elevated HbA and spikes of high glucose values in the third trimester. *J Matern Fetal Neonatal Med*. 2014;27(2):149-154.
9. Farrington C. Data as transformational: constrained and liberated bodies in an "artificial pancreas" study. In: Lynch R, Farrington C, eds. *Quantified Lives and Vital Data: Exploring Health and Technology Through Personal Medical Devices*. London: Palgrave Macmillan; 2017:127-154.
10. Feig DS, Asztalos E, Corcoy R, et al. CONCEPTT: continuous glucose monitoring in women with type 1 diabetes in pregnancy trial: a multi-center, multi-national, randomized controlled trial - study protocol. *BMC Pregnancy Childbirth*. 2016;16(1):167.
11. Law GR, Ellison GT, Secher AL, et al. Analysis of continuous glucose monitoring in pregnant women with diabetes: distinct temporal patterns of glucose associated with large-for-gestational-age-infants. *Diabetes Care*. 2015;38(7):1319-1325.
12. Kallas-Koeman MM, Kong JM, Klinke JA, et al. Insulin pump use in pregnancy is associated with lower HbA1c without increasing the rate of severe hypoglycaemia or diabetic ketoacidosis in women with type 1 diabetes. *Diabetologia*. 2014;57(4):681-689.
13. Abell SK, Suen M, Pease A, et al. Pregnancy outcomes and insulin requirements in women with type 1 diabetes treated with continuous subcutaneous insulin infusion and multiple daily injections: cohort study. *Diabetes Technol Ther*. 2017;19(5):280-287.
14. Murphy HR, Stewart ZA. Automated insulin delivery: what's new, needed, and next? *Lancet*. 2017;389(10067):333-334.
15. Stewart ZA, Wilinska ME, Hartnell S, et al. Closed-loop insulin delivery during pregnancy in women with type 1 diabetes. *N Engl J Med*. 2016;375(7):644-654.
16. Stewart ZA, Wilinska ME, Hartnell S, et al. Day-and-night closed-loop in a broad population of pregnant women with type 1 diabetes: a randomized controlled crossover trial. *Diab Care*. 41(7):1391-1399.
17. Farrington C, Stewart ZA, Barnard K, Hovorka R, Murphy HR. Experiences of closed-loop insulin delivery among pregnant women with type 1 diabetes. *Diab Med*. 2017;34(1):1461-1469.
18. Francis JJ, Johnston M, Robertson C, et al. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. *Health Psychol*. 2009;25(10):229-1245.
19. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101.
20. Weick K. *Sensemaking in Organizations*. Thousand Oaks, CA: Sage; 1995.
21. Barnard KD, Wysocki T, Thabit H, et al. Psychosocial aspects of closed- and open-loop insulin delivery: closing the loop in adults with type 1 diabetes in the home setting. *Diabet Med*. 2015;32(5):601-608.
22. Barnard KD, Wysocki T, Allen JM, et al. Closing the loop overnight at home setting: psychosocial impact for adolescents with type 1 diabetes and their parents. *BMJ Open Diabetes Res Care*. 2014;2(1):e000025.

23. Ziegler C, Liberman A, Nimri R, et al. Reduced worries of hypoglycaemia, high satisfaction, and increased perceived ease of use after experiencing four nights of MD-logic artificial pancreas at home (DREAM4). *J Diabetes Res*. 2015;2015:590308.
24. Kropff J, DeJong J, del Favero S, et al; AP@home consortium. Psychological outcomes of evening and night closed-loop insulin delivery under free living conditions in people with type 1 diabetes: a 2-month randomized crossover trial. *Diabet Med*. 2017;34(2):262-271.
25. Farrington C. Psychosocial impacts of hybrid closed-loop systems: a review. *Diabet Med*. 2018;35(4):436-449.
26. Neff G, Nafus D. *Self-Tracking*. Cambridge MA: MIT Press; 2016.
27. Hutchby I. Technologies, texts and affordances. *Sociology*. 2001;35(2):441-456.