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Expectations and Attitudes of Individuals With Type 1 Diabetes After Using a Hybrid Closed Loop System

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Abstract

Purpose—The first hybrid closed loop (HCL) system, which automates insulin delivery but requires user inputs, was approved for treatment of type 1 diabetes (T1D) by the US Food and Drug Administration in September 2016. The purpose of this study was to explore the benefits, expectations, and attitudes of individuals with T1D following a clinical trial of an HCL system.

Methods—Thirty-two individuals with T1D (17 adults, 15 adolescents) participated in focus groups after 4 to 5 days of system use. Content analysis generated themes regarding perceived benefits, hassles, and limitations.

Results—Some participants felt misled by terms such as “closed loop” and “artificial pancreas,” which seemed to imply a more “hands-off” experience. Perceived benefits were improved glycemic control, anticipated reduction of long-term complications, better quality of life, and reduced mental burden of diabetes. Hassles and limitations included unexpected tasks for the user, difficulties wearing the system, concerns about controlling highs, and being reminded of diabetes.

Conclusion—Users are willing to accept some hassles and limitations if they also perceive health and quality-of-life benefits beyond current self-management. It is important for clinicians to provide a balanced view of positives and negatives to help manage expectations.

Introduction

Type 1 diabetes (T1D) places a considerable physical and psychological burden on many individuals. Closed loop systems, also known as automated insulin delivery or artificial pancreas systems, hold great promise for improving self-management of T1D by mitigating the relentless array of tasks and decision making required of individuals to achieve normoglycemia. Although various paradigms exist, closed loop systems generally measure glucose levels continuously, infuse insulin via a pump, and use an algorithm to automate and optimize insulin dosing,¹ thus in theory reducing the number of physical and mental tasks expected for T1D management. The first of these systems, the Medtronic MiniMed 670G hybrid closed loop (HCL) system, was approved by the US Food and Drug Administration² for treatment of T1D in September 2016. Hybrid closed loop systems automate insulin delivery but require user inputs. Despite the potential of closed loop systems to improve diabetes management and quality of life, their uptake, as with any technology, depends on expectations and attitudes and the degree to which the actual technology is compatible with these perceptions. The current study examined the perceptions of a group of adults and adolescents with T1D following 4 to 5 days of 24-hour use of an experimental HCL system.

Closed Loop Systems: Promise and Limitations

The past decade has seen an acceleration of efforts to develop a closed loop system, which has been made possible by the wider availability and increased accuracy of diabetes devices, especially continuous glucose monitoring (CGM) systems. Thus, the expectations of the T1D community have shifted and closed loop therapy is seen no longer as just a theoretical possibility but as a clinical certainty.¹ Clinical trials of closed loop systems using a variety of algorithms and configurations have shown positive effects such as increased time when glucose values are in range and reduced hypoglycemia.^{3–8}

There are, however, various limitations inherent to the technology, which may interfere with uptake of systems. At present, closed loop systems depend on multiple components that are physically or wirelessly connected to the body. Users must accept being connected at all times to devices and the need to change and rotate pump infusion and sensor sites. And, as with any machine, components may fail. There are also challenges posed by the limitations of exogenous insulin to be rapidly absorbed.⁹ Algorithms that err on the side of being conservative may lead to hyperglycemia, whereas aggressive algorithms may cause hypoglycemia. Alternate systems that balance the effects of insulin with glucagon are being developed, but the safety of long-term daily delivery of subcutaneous glucagon needs to be assessed.¹ Hybrid closed loop systems, such as the one used in the present study, require user input to improve glucose control around events such as meals and exercise. The specific system tested here provided adjustments to the insulin delivery rate every 5 minutes, which is particularly effective overnight and replaces the usual “basal” insulin delivery programmed into insulin pumps.¹⁰ However, it required periodic blood glucose checks for calibration of the sensor, for correction doses, and before meals and exercise.¹¹ How individuals weigh the demands and benefits of closed loop and HCL systems may affect their likelihood to adopt this technology.

Closed Loop Expectations and Attitudes

Theories of technology uptake and health behavior decision making emphasize the importance of users’ expectations and attitudes in predicting their eventual adoption of health-related technologies.^{12–15} With regard to diabetes devices such as the insulin pump and CGM, users’ perceptions are associated with the uptake and subsequent use of devices.^{16,17} Some research has assessed expectations of closed loop systems from the perspective of individuals who lack prior system experience, and perhaps it is not surprising that those without experience tend to have very high expectations regarding the technology’s accuracy, trustworthiness, ease of use, and benefits to diabetes management.^{18–20} Although many of these hopes could ultimately be borne out, there is a danger that overly high expectations may lead to disappointment and rejection of diabetes devices and technologies.¹⁶ One reason for underuse and discontinuation of CGM, for example, has been a mismatch between overly optimistic expectations prior to use and perceived limitations of the device once used.²¹ It may also be natural to assume that newer technologies will improve on the limitations of prior systems even if similar challenges continue to apply. In one study of adults with T1D, most participants endorsed minimal barriers to starting on a closed loop system despite most also being reluctant to start on pump therapy, which is a major component of these systems.²⁰ More understanding is needed of how prior expectations of closed loop or HCL are met once users actually try out such systems.

Data are needed to determine the alignment between expectations and experience with closed loop systems to further inform device development and to proactively mitigate barriers to adherence once these devices are launched in clinical care. Users are more likely to accept technologies if systems are seen as useful and easy to use¹² and if their anticipated benefits outweigh perceived hassles and limitations.¹³ Users’ perceptions also undergo a process of evaluation and re-evaluation as users gain more experience with a system.¹⁴ If the system greatly helps the user, hassles that produce annoyance may be forgiven. These

perceptions are likely to be balanced against limitations related to health and safety. Individuals may have concerns about the accuracy of the system to correctly monitor glucose and to administer insulin in the right doses at the right time, and they may worry that if a system component breaks, they will be left unprepared to resume treatment tasks manually. To date, only a few studies have examined individuals' perceptions of the benefits, hassles, and limitations of closed loop systems. In these studies, adolescents and adults who had recently participated in an overnight HCL clinical trial noted benefits for peace of mind, enhanced glycemic control, improved control at night, better daytime functioning in life tasks, and perceived safety but also hassles related to alarms, calibration, device size, and technical difficulties.^{22,23} Although participants used these systems for 3 to 4 weeks, there was no daytime or mealtime use of closed loop. The purpose of this study was to explore the benefits, expectations, and attitudes of individuals with T1D following a clinical trial of an HCL system.

Methods

Participants

The sample included 17 adults (age = 28.2 ± 6.1 years) and 15 adolescents (age = 16.6 ± 0.9 years) participating in a multisite HCL (Medtronic, Northridge, CA) clinical trial of a prototype of the 670G pump. To be eligible, participants were required to be 14 to 40 years old. This age range was based on past clinical trials where the system was used in adolescents as young as 14 years old in a diabetes camp.²⁴ Additional inclusion criteria were diabetes duration of at least 12 months and a total daily insulin requirement of more than 0.4 units per kilogram. Participants were not included if they were pregnant, had diabetic ketoacidosis in the past month, had a hypoglycemic episode with seizure or loss of consciousness in the past 3 months, or had medical or psychiatric conditions that would interfere with protocol completion (Table 1).

Procedures

HCL trial—Nine groups of participants (6 adult and 3 adolescent groups) were run simultaneously at 3 different study sites across the United States. They were trained to use the study pump and CGM system during an initial enrollment visit, followed by 4 to 5 days wearing these devices while not in HCL mode. All participants took part in an outpatient run-in period of wearing the system. This allowed for the system to gather data on participants' insulin requirements and glucose control, and these data were used to initialize some of the HCL settings. Each day while wearing the system in HCL mode, the system made additional adjustments to tuning parameters based on the participants' glucose levels and insulin requirements. After this run-in period, a multiday-and-night trial of the HCL system began (5 days 4 nights for adults, 4 days 3 nights for adolescents). All participants met requirements of a meter glucose reading between 70 and 350 mg/dL and ketones < 0.6 mmol/L prior to beginning the HCL trial.

Participants were placed on 1 of 2 HCL systems. System A (used by the first 3 adult groups consisting of 8 total participants) used a Medtronic MiniMed Paradigm[®] Revel[™] 2.0 pump, a Medtronic third generation Enlite[®] sensor with MiniLink[®] transmitter, controller software

on an Android phone, and a translator to allow communication between pump and phone. System B, which was used by the remaining 3 adult groups (9 individuals) and all 15 adolescents, consisted of the Medtronic HCL system (in which the sensor communicated directly with the pump, within which the controller was embedded) and used a Medtronic fourth generation Enlite[®] sensor.¹¹

Both systems relied on a proportional-integral-derivative-based algorithm with insulin feedback, which modulates basal insulin delivery using commands every 5 minutes. For the purposes of the trial, tasks required of participants were calibration of the sensor every 12 hours; glucose monitoring using fingerstick and meter at least 4 times per day; meter tests for glucose values below 70 mg/dL or above 300 mg/dL; treatment of low glucose levels with fast-acting carbohydrate; management of high glucose levels with ketone testing and correction insulin; announcement of planned exercise; entry of meal bolus information; and confirmation of bolus doses prior to delivery by the system. For meals, participants were allowed to choose when, what, and how much to eat, without input from the study team about carbohydrate quantities. Participants were encouraged to exercise regularly according to their own routines. Participants were closely monitored by the clinical trial research team 24 hours a day throughout the study. At night, study groups stayed together at a hotel or guesthouse, with members of the research team in attendance. For the adults on System A and System B, there was no change in percentage time in target range after entering HCL mode. However, adults on System B had more aggressive parameter settings. In contrast to the adults, adolescents saw an increase in percentage time in target range. For more details about System B's performance, see Ly et al.¹¹

Focus groups and data analysis

At the end of the system trial, the 9 study groups gathered to participate in focus groups conducted by a psychologist who was not previously familiar to participants. Focus groups did not blend participants from different systems or age groups. An interview guide was used to maintain consistency across the 3 sites. Groups were asked to describe their prestudy expectations of the CL system and to provide feedback on the quality of their experiences. Discussions ranged from 40 to 75 minutes in length. Audio recordings were transcribed by a medical transcription company. All study protocols were approved by the institutional review board at each center.

Themes were extracted using a content analysis approach.²⁵ In an initial open coding phase, 2 raters (E.I. and M.L.T.) separately generated a set of codes, which formed the basis of a codebook. E.I. and M.L.T. then applied these codes to the remaining transcripts using NVivo qualitative analysis software.²⁶ A randomly selected 25% of transcript material was coded by E.I. and M.L.T. to allow for comparison across raters and facilitate refinement of the coding approach. Rater agreement on these double-coded segments was very good, with 86% average agreement on codes. (Agreement was counted when both raters identified the same code in a given segment or judged the same code as absent in a given segment.) In weekly meetings, the 2 raters met with a third researcher (D.N.) to reconcile discrepancies and modify codes as needed. Iterative changes to the coding system were applied to previously coded transcripts.

Results

Expectations

Participants' expectations ranged along a spectrum from anticipating a system that would handle virtually all diabetes tasks to a more limited view of an experimental system with modest benefits for glycemic control and reduced burden on the user (Table 2).

High expectations

Some participants, who generally described having low knowledge about HCL systems beforehand, expected the trial system to behave much like a real pancreas. They hoped for a “hands-off” experience that would provide a respite from diabetes management. Some anticipated being able to eat foods that would be difficult to manage under usual therapies due to high carbohydrate or fat content. Many participants remarked that calling it a “closed loop” system or the commonly used term “artificial pancreas” led them to have overly high hopes about its capabilities. These terms suggested that the system would manage everything for the user and require no additional tasks, approximating their views of a “normal” biological pancreas.

Modest expectations

Individuals who were knowledgeable about the current state of closed loop systems expressed modest expectations. They were less surprised by hassles of the system such as bolusing requirements, and they expected some “kinks” due to the system being in a testing stage. Other participants reported having little knowledge of the technology prior to the trial but wanting to maintain an open mind. They planned to watch how the system handled challenges before they allowed themselves to relax their own mental or physical control over diabetes.

Experiencing the System

As participants tested the system, they became aware of how it performed in real-life situations such as during and after meals, while sleeping, and during exercise. They made comparisons with their current management, noting many advantages of the HCL system for glycemic control and quality of life. Many also recognized hassles inherent to the system that were similar to or worse than current management. Some were disappointed by limitations in the system to handle mealtime and exercise challenges (Tables 3 and 4).

Benefits

Participants noted many ways in which the system helped to improve their diabetes management and to reduce worry about out-of-range numbers. Of importance was the algorithm's ability to prevent lows and to keep numbers from fluctuating. Users were particularly impressed by how stable they observed glucose values to be while on the system, and some observed that the system managed their diabetes better than they could themselves. Sleep was an area of particular benefit; users noticed improved sleep due to fewer glucose values being out of range and thus fewer interruptions from alarms.

Study participants also anticipated ways that the HCL system and future closed loop systems could improve their quality of life. They expressed optimism that systems could minimize long-term health complications. In the short term, steadier glucose levels were expected to lead to day-to-day benefits such as improved concentration, reduced fear of hypoglycemia, and better interactions with loved ones. The system allowed participants to eat and exercise more freely, and they noted eating foods such as pizza that have ordinarily been hard to manage. Participants expressed that using the system changed the role that diabetes played in their lives and made it less burdensome in profound ways. They described reduced worry, greater peace of mind, a burden being lifted, and being able to “put diabetes in a box.”

Hassles and limitations

Now having used the technology, participants drew contrasts between the promise of closed loop and the realities they observed regarding hassles and limitations of the trial HCL system. They expressed surprise that the system required user input for meals and exercise instead of using only sensor values to calculate insulin doses. Required tasks perceived as burdensome included responding to alarms, entering in meal information, confirming boluses, providing corrective insulin doses, calibrating CGM, and taking meter readings, sometimes in excess of what would happen in usual care. Carrying system parts (especially for System A) and keeping components such as the CGM sensor from falling off were described as challenges. Because of these tasks and hassles, several participants reported thinking about diabetes more while in the study than in their normal lives.

Participants in several of the focus groups were disappointed by what they saw as the HCL system not managing hyperglycemia aggressively enough. These participants tended to be adults who described themselves as maintaining good glycemic control. They characterized the system as biased toward preventing dangerous lows while tolerating more highs than they would prefer. Some observed that the system did not meet their expectations regarding time within a target glucose range. A few users described inputting higher carbohydrate quantities than they had actually consumed to cheat the algorithm and produce an effect that was close to what they would achieve on their own.

Some participants concluded that the HCL system was less a paradigm shift and more an incremental improvement to existing therapy with an insulin pump and CGM. Several participants were concerned that potential users would become disappointed if systems were called “artificial pancreas” or “closed loop” because the actual experience was not as automatic as those terms suggest. Some provided alternate labels such as “pump upgrade” or “smart basal.”

Future use

When asked if they would continue to use the HCL system after the study if given the option, most participants answered affirmatively. In some focus groups, participants reported sadness about the trial ending because they would have to return the system. On the whole, participants stated that even though the system was not perfect, it would be worth using because of benefits to glycemic control, long-term health, or quality of life.

In contrast, some participants stated that they would prefer to wait for the technology to advance further. These individuals tended to be relatively satisfied with their own management and saw the benefits of the HCL system, whether to glycemic control or quality of life, as insufficient to justify adopting this therapy. Several expressed concern that their hemoglobin A1C would increase if they relied on this system with its current settings. These participants noted that they would be more likely to want to use the HCL system if the algorithm had a more “aggressive basal” and if it allowed the user to have more opportunities to guide or override the system.

Discussion

The current study examined expectations and attitudes among a group of adults and adolescents with T1D following a multiday clinical trial of an HCL system. Many of the positives and negatives cited by participants in the current study echo what has been reported during interviews with other clinical trial participants, especially findings related to glycemic control, mental relief, overnight benefits, and hassles.^{22,23} Of note, these previous trials, although over 3 to 4 weeks, were for overnight systems only. The current study’s findings on daytime-specific benefits (eg, for meals and exercise) build on this prior work. The present study also highlights an additional concern, especially among users who already achieve target glycemic control, that the system does not prevent and manage hyperglycemia better than they can. These new insights are important given that planned closed loop and HCL systems are designed for 24-hour use and will continue to face algorithm design challenges for how to anticipate users’ insulin needs.⁹

Attitudes about the HCL system were wide ranging and even contradictory. For example, some found that the HCL system achieved a desirable amount of time in target glucose range, whereas others felt that their usual glycemic control was superior to that achieved by the system. Similarly, some experienced a sense of relief from diabetes burden during system use, whereas others found that their worry actually increased. Multiple factors are likely to contribute to this variation in attitudes, including personal characteristics, health history, pre-existing beliefs regarding one’s diabetes self-management, and attitudes toward technology, in general, and within the diabetes domain, in particular. In the current study, adults were more likely than adolescents to worry about the system’s ability to manage hyperglycemia, and this may be related to differences between these groups in baseline glycemic control. Adolescents, who on average were already experiencing more hyperglycemia than adults and were the only group to see more time in target range on the system, would likely have a more favorable view of the system’s response to high values. Future research should continue to investigate what factors predict users’ attitudes to help diabetes care providers tailor their education approach to the needs of particular patient types.

The current study design presented some limitations. Efforts were made to simulate natural living conditions, for example, by allowing participants to attend school or jobs, having them stay in a house or hotel rather than a clinical facility, and encouraging them to eat or exercise according to their preferences. However, the fact that participants were in a trial being monitored by study personnel may have affected their experiences. Difficulties using the

system may have been reduced due to the around-the-clock availability of guidance from study staff. An added consideration is that certain features of the system were restricted for testing purposes. This may have affected participants' appraisal of system performance or may have disguised the level of complexity involved in using the system. As these systems are not yet commercially available, it would be beneficial to consider the current findings alongside data from longer clinical trials where individuals are wearing a closed loop system for extended periods in normal living conditions. Sample size limited inferences that could be drawn about differences between adolescents and adults, or between users of System A and System B; however, it is likely that attitudes were shaped by developmental and system issues, such as the higher baseline hemoglobin A1C for adolescents and the more aggressive algorithm parameters of System B. Systems used for study purposes included additional components (such as the translator on System A) that may have contributed to hassles for users; these research components would not be present in commercial systems.

A strength of the current study was that it captured the perspectives of adults and adolescents with T1D after spending multiple days and nights living with an HCL system, thus offering novel insights into how users are likely to react to these systems when they become available. Unlike in prior studies using phone interviews, focus group methodology was used to obtain qualitative data from groups of participants, which stimulated candid discussions. The current study was unique in exploring not only individuals' expectations but also their experiences with an HCL system, which highlighted perceptions that may be relevant to technology acceptance.

Clinical Implications

How individuals weigh the pluses and minuses of closed loop technology and the alignment between expectations and experiences are likely to affect the degree to which they embrace these systems. The expectations that participants brought into the study may have affected their subsequent reactions to the system. Individuals who expected a more hands-off system expressed surprise and some disappointment about how much user input was required. Data suggest the importance of managing individuals' expectations of diabetes technologies to prevent disappointment due to overly high expectations.¹⁶ However, there is a possible down-side to overmanaging expectations: if expectations are set too low, individuals with T1D may decide not to try the technology and may not experience its benefits.

Even when using identical systems, individuals may have strikingly different perceptions of how well the system works for them. In the current study, participants were willing to accept some hassles and limitations of the HCL system if they also perceived benefits to health or quality of life and if the system provided value beyond what they could achieve prior to the trial. The current findings suggest that an optimal education approach would provide information about both the benefits and challenges of using a closed loop system. It should also be noted that future users of closed loop systems will not benefit from constant monitoring by research study staff. Participants here noted that a high level of education support would be essential to help individuals become comfortable with an HCL system. To help manage expectations and increase the likelihood of technology acceptance among

individuals with T1D, system developers and providers should articulate a balanced and transparent view of the positives and negatives of closed loop systems.

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References

1. Kowalski A. Pathway to artificial pancreas systems revisited: moving downstream. *Diabetes Care*. 2015;38(6):1036–1043. [PubMed: 25998296]
2. US Food and Drug Administration. The 670G System—P160017. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-Approved_Devices/ucm522764.htm. Accessed October 19, 2016.
3. Buckingham BA, Cameron F, Calhoun P, et al. Outpatient safety assessment of an in-home predictive low-glucose suspend system with type 1 diabetes subjects at elevated risk of nocturnal hypoglycemia. *Diabetes Technol Ther*. 2013;15(8):622–627. [PubMed: 23883408]
4. Kovatchev BP, Renard E, Cobelli C, et al. Safety of outpatient closed-loop control: first randomized crossover trials of a wearable artificial pancreas. *Diabetes Care*. 2014;37(7):1789–1796. [PubMed: 24929429]
5. Russell SJ, El-Khatib FH, Sinha M, et al. Outpatient glycemic control with a bionic pancreas in type 1 diabetes. *N Engl J Med*. 2014;371(4):313–325. [PubMed: 24931572]
6. Russell SJ, Hillard MA, Balliro C, et al. Day and night glycaemic control with a bionic pancreas versus conventional insulin pump therapy in preadolescent children with type 1 diabetes: a randomised crossover trial. *Lancet Diabetes Endocrinol*. 2016;4(3):233–243. [PubMed: 26850709]
7. Thabit H, Elleri D, Leelarathna L, et al. Unsupervised overnight closed loop insulin delivery during free living: analysis of randomised cross-over home studies in adults and adolescents with type 1 diabetes. *Lancet*. 2015;385(suppl 1):S96. [PubMed: 26312919]
8. Thabit H, Tauschmann M, Allen JM, et al. Home use of an artificial beta cell in type 1 diabetes. *N Engl J Med*. 2015;373(22):2129–2140. [PubMed: 26379095]
9. Skyler JS. T1DM in 2014: progress towards a bionic pancreas. *Nat Rev Endocrinol*. 2015;11(2):75–76. [PubMed: 25534194]
10. Ly TT, Roy A, Grosman B, et al. Day and night closed-loop control using the integrated Medtronic hybrid closed-loop system in type 1 diabetes at diabetes camp. *Diabetes Care*. 2015;38(7):1205–1211. [PubMed: 26049550]
11. Ly TT, Weinzimer SA, Maahs DM, et al. Automated hybrid closed-loop control with a proportional-integral-derivative based system in adolescents and adults with type 1 diabetes: individualizing settings for optimal performance [published online May 18, 2016]. *Pediatr Diabetes*. doi:10.1111/peci.12399.
12. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Quarterly*. 1989;13(3):319–340.
13. Janz NK, Becker MH. The health belief model: a decade later. *Health Educ Behav*. 1984;11(1):1–47.
14. Rogers EM. *Diffusion of innovations*. New York, NY: Simon & Schuster; 2010.
15. Venkatesh V, Davis FD. A theoretical extension of the technology acceptance model: four longitudinal field studies. *Manage Sci*. 2000;46(2):186–204.

16. Gonder-Frederick L, Shepard J, Peterson N. Closed-loop glucose control: psychological and behavioral considerations. *J Diabetes Sci Technol*. 2011;5(6):1387–1395. [PubMed: 22226256]
17. Gonder-Frederick LA, Shepard JA, Grabman JH, Ritterband LM. Psychology, technology, and diabetes management. *Am Psychol*. 2016;71(7):577–589. [PubMed: 27690486]
18. Elleri D, Acerini CL, Allen JM, et al. Parental attitudes towards overnight closed-loop glucose control in children with type 1 diabetes. *Diabetes Technol Ther*. 2010;12(1):35–39. [PubMed: 20082583]
19. van Bon AC, Brouwer TB, von Basum G, Hoekstra JB, DeVries JH. Future acceptance of an artificial pancreas in adults with type 1 diabetes. *Diabetes Technol Ther*. 2011;13(7):731–736. [PubMed: 21504332]
20. van Bon AC, Kohinor MJ, Hoekstra JB, von Basum G, DeVries JH. Patients' perception and future acceptance of an artificial pancreas. *J Diabetes Sci Technol*. 2010;4(3):596–602. [PubMed: 20513325]
21. Chase HP, Beck RW, Xing D, et al. Continuous glucose monitoring in youth with type 1 diabetes: 12-month follow-up of the Juvenile Diabetes Research Foundation continuous glucose monitoring randomized trial. *Diabetes Technol Ther*. 2010;12(7):507–515. [PubMed: 20597824]
22. Barnard KD, Wysocki T, Allen JM, et al. Closing the loop over-night at home setting: psychosocial impact for adolescents with type 1 diabetes and their parents. *BMJ Open Diabetes Res Care*. 2014;2(25):1–7.
23. 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. [PubMed: 25615888]
24. Ly TT, Roy A, Grosman B, et al. Day and night closed-loop control using the integrated Medtronic hybrid closed-loop system in type 1 diabetes at diabetes camp. *Diabetes Care*. 2015;38(7):12051211.
25. Pope C, Ziebland S, Mays N. Analysing qualitative data. *BMJ*. 2000;320(7227):114–116. [PubMed: 10625273]
26. NVivo 11 for Mac [computer program]. Burlington, MA: QSR International; 2015.

Table 1

Participant Characteristics

	Adults	Adolescents
Participants, No.	17	15
Age, y	28.2 ± 6.1	16.6 ± 0.9
Duration of diabetes, y	18.3 ± 6.9	8.2 ± 3.9
Total daily dose/weight, units/kg/day	0.6 ± 0.2	0.9 ± 0.2
A1C, %	6.9 ± 0.7	9.0 ± 1.1
Duration of study	5 days 4 nights	4 days 3 nights

Table 2

Expectations of the Hybrid Closed Loop System

Expectation Level	Theme	Participant Examples
High	Expected more hands-off	<p>“I’ve never done any trial before and I think that my expectations coming in were probably way too high. I thought it was going to be way more hands-off and I could eat whatever I wanted. . . . A lot more pancakes for breakfast and not being 220 after.” (adult, System A)</p> <p>“I thought I was getting a natural machine that did everything for me.” (adolescent, System B)</p>
	Was not as advertised	<p>“When I started telling other people about it initially I said, ‘artificial pancreas study,’ and then I kind of toward the end was like, ‘It’s kind of a pump upgrade.’” (adult, System A)</p> <p>“If you just call something a closed loop system, you kind of assume that it would give you insulin for, like, everything. It would just do it.” (adolescent, System B)</p> <p>“‘Hybrid closed loop,’ I don’t like it, and it’s misleading. . . . It feels like marketer speak. . . . It feels like they are trying to sell me a dream and it doesn’t live up. I think if it is re-positioned, you don’t have as many disappointed users.” (adult, System B)</p>
Modest	Expected some hassles or limitations	<p>“I’ve done two closed loop studies before in the hospital. . . . I expected to be calibrating and checking and I knew it wouldn’t be hands off.” (adult, System A)</p> <p>“I actually went into it with fairly low expectations because it was an investigational device that they probably hadn’t worked out a lot of the kinks, but I was overwhelmingly surprised by how well it did.” (adult, System B)</p>
	Open expectations	<p>“[I have been wondering] where are we on artificial pancreas and where are we on closed loop and what are we looking to expect? And so I thought maybe I could get some insight as to, hey, we’re getting there or we’re way off.” (adult, System B)</p> <p>“It was more about the experience, to see what it’s all about.” (adult, System B)</p>

Table 3

Benefits of the Hybrid Closed Loop System

Theme	Participant Examples
Steady glucose levels	"I tend to run higher at home and maybe 220 was the highest I went [in the study] and I've only had 3 lows, and none of those were below 60 . . . I don't want to give the pump back tomorrow." (adolescent, System B) "For me it was nice to not have those high spikes." (adult, System B)
Overnight benefit	"It was really nice to see that I was in range every morning when I woke up to go to breakfast and I didn't have to just eat protein for breakfast." (adolescent, System B) "It can prevent you from waking up dangerously low." (adolescent, System B)
Mealtime benefit	"I had so many dinners where I started at 130, and 3 hours later, it was 130, which I loved." (adult, System A) "I mean typically I don't eat burgers and pizza for dinner . . . but I was like, 'Nah, why not? Let's see how the system can handle it,' and I was pleasantly surprised." (adult, System B)
Exercise benefit	"I felt freer when I was exercising. I felt like I wasn't as worried about getting low because I felt like it was going to take care of it for me." (adolescent, System B) "I did extremely well with the runs and the blood sugar management before, after, and during was really good." (adult, System B)
Fewer long-term complications	"That little variability—that is so much healthier for my body." (adult, System B) "I think in the long run it's going to minimize complications for people, because you are so stable and I felt like I had more energy. I don't know if you guys did too, just because I feel like I get exhausted just from the swing from high low high low. I was so steady I felt more energized." (adult, System A)
Better quality of life	"Have you ever put 2 diabetic women who are on a high next to each other? That's me and my mom. It improves relationships, people. Being in range, oh my goodness." (adolescent, System B) "When you wake up with a better number in the morning psychologically you have a better day." (adult, System B)
Mental relief	"We are all afraid of having that bad low when we are driving or sleeping or having complications when we are in our 30s or 40s or 50s. Having something where you know your A1C is going to be good, you know your blood sugars are level removes that fear. These four days were the first time I actually started thinking I might not have to always worry about that." (adult, System B) "I felt again from an emotional standpoint, I felt like diabetes was less of a burden, like I was doing it right or even though it wasn't me doing anything, I didn't feel guilty about that." (adult, System B)
A break from diabetes	"You can put it in this neat little black box and just set it aside and it would be taken care of for a little while. That was so nice." (adolescent, System B) "I just didn't want to give [the system up after the study]. . . . I don't think it is a cure for diabetes by any means, but for me, 28 years of never having a second of a break from this disease state. . . . I'd rather spend time thinking about my children and being with my children or planning a date for my husband." (adult, System B)

Table 4

Hassles and Limitations of the Hybrid Closed Loop System

Unexpected tasks	<p>"I checked way, way more than I normally do at home." (adult, System B)</p> <p>"I thought I had a lot of input on this closed loop. Just like responding to the alerts and the meal boluses and I didn't really like that." (adult, System A)</p>
Hard to wear	<p>"The taping method on this is intense. There's a lot of tape going on your skin. I would think even on a little kid you're not going to have that much space, or on somebody that's just smaller." (adult, System B)</p> <p>"It wasn't such a big deal for me to carry [extra devices] for the study, but I think for home use and personal use, it would be a little tough to keep with you or on your person." (adult, System B)</p>
Not responsive enough to highs given what I can achieve on my own	<p>"I'm not worried about lows, I'm worried about highs. So having those highs is what frustrated me. . . . given what I keep such tight control." (adult, System A)</p> <p>"Only 30% of people are at the target A1C. That means for the bigger picture of diabetics in the world, [this system] would be good. But for me personally, maybe not." (adult, System B)</p>
Being reminded of diabetes	<p>"I think I still thought about everything just as much or more. It didn't really take away from the diabetes burden." (adult, System B)</p> <p>"I was still feeling my diabetes. I still thought about it constantly. I felt just as much or more burden. It wasn't any easier in that way." (adult, System B)</p>