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## Research: Treatment

# Psychosocial aspects of closed- and open-loop insulin delivery: closing the loop in adults with Type 1 diabetes in the home setting

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## Abstract

**Aims** To explore the psychosocial experiences of closed-loop technology and to compare ratings of closed- and open-loop technology for adults with Type 1 diabetes taking part in a randomized crossover study.

**Methods** Adults (aged > 18 years) on insulin pump therapy were recruited to receive a first phase of either real-time continuous glucose monitoring with overnight closed-loop or real-time continuous glucose monitoring alone (open-loop) followed by a second phase of the alternative treatment in random order, at home for 4 weeks, unsupervised. Participants were invited to share their views in semi-structured interviews. The impact of the closed-loop technology, positive and negative aspects of living with the device overnight, along with the hopes and anxieties of the participants, were explored.

**Results** The participants in the trial were 24 adults with a mean (SD) age of 43 (12) years, of whom 54% were men. The mean (range) interview duration was 26 (12–46) min. Content and thematic analysis showed the following key positive themes: improved blood glucose control ($n = 16$); reassurance/reduced worry ($n = 16$); improved overnight control leading to improved daily functioning and diabetes control ($n = 16$); and improved sleep ($n = 8$). The key negative themes were: technical difficulties ($n = 24$); intrusiveness of alarms ($n = 13$); and size of equipment ($n = 7$). Of the 24 participant, 20 would recommend the closed-loop technology.

**Conclusions** Closed-loop therapy has positive effects when it works in freeing participants from the demands of self-management. The downside was technical difficulties, particularly concerning the pump and 'connectivity', which it is hoped will improve. Future research should continue to explore the acceptability of the closed-loop system as a realistic therapy option, taking account of user concerns as new systems are designed. Failure to do this may reduce the eventual utility of new systems.

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## Introduction

Closed-loop technologies, sometimes referred to as an artificial pancreas, are developing rapidly with successful 'diabetes camp' [1] and at-home/outpatient trials [2–6]. Closed-loop systems have been found to have clinical efficacy, resulting in tighter overnight glycaemic control without increased frequency or severity of hypoglycaemia [3,4]. Such systems have the potential to provide a realistic

**What's new?**

- Closed-loop technology has specific psychosocial benefits supporting optimum self-management in adults with Type 1 diabetes.
- Advances in technology are associated with greater usability, but further development work is necessary to improve connectivity.
- Future research is required to determine the holistic impact of closed-loop as a realistic therapy choice for people with Type 1 diabetes.

treatment option for people with Type 1 diabetes, but the usability and impact on psychosocial outcomes will be crucial factors in the realization of benefits from the use of this technology [7].

Maintenance of optimum glycaemia overnight is particularly challenging for people with Type 1 diabetes, with nocturnal hypoglycaemia being common and representing a critical problem in the management of the condition. Nocturnal hypoglycaemia can cause heightened anxiety, which affects psychosocial functioning [8]. The risk of hypoglycaemia represents a major obstacle to the achievement of optimum blood glucose levels [9]. Early research into overnight closed-loop therapy has shown positive results in achieving optimum glycaemia without increased risk or frequency of hypoglycaemia for adolescent participants [3,4].

The current open-label, multicentre, randomized crossover study recruited participants from three centres in the UK. Participants aged ≥ 18 years with Type 1 diabetes were randomly assigned to receive 4 weeks of overnight closed-loop insulin delivery (using a model-predictive control algorithm to direct insulin delivery), then 4 weeks of insulin pump therapy with real-time continuous glucose monitoring (open-loop phase) or vice versa. The primary outcome was time spent in the target glucose range of 3.9–8.0 mmol/l between midnight and 0700 h. Analyses were conducted on an intention-to-treat basis [4].

The aims of the present sub-study were to explore the psychosocial experiences with the use of closed-loop technology and to compare ratings for the closed-loop with those for the open-loop technology in adults with Type 1 diabetes taking part in a randomized crossover study.

## Participants and methods

The main aims and methodology of the trial have been reported in detail elsewhere [4]. In brief, in addition to the efficacy and safety outcomes of closed-loop technology in this open-label, single-centre, randomized two-period crossover study (with 12 participants completing the closed-loop phase first), the utility of the technology was evaluated. Inclusion criteria were: Type 1 diabetes (WHO criteria); C-peptide-negative; age ≥ 18 years; receiving insulin-pump therapy for at least 3 months; knowledge of insulin self-adjustment; undertaking of glucose self-monitoring at least four times daily; and an $HbA_{1c}$ concentration of ≤ 86 mmol/mol (10%). Exclusion criteria were: established nephropathy; neuropathy or proliferative retinopathy; total daily insulin dose of ≥ 2.0 U/kg; regular use of continuous glucose monitoring within 1 month before enrolment; severe visual or hearing impairment; and pregnancy or breastfeeding. The study protocol was approved by the East of England Central Cambridge Ethics Committee. The study included a mixed-methods approach, using psychosocial questionnaires and semi-structured interviews to evaluate participants' perceptions of lifestyle change, diabetes management and fear of hypoglycaemia.

## Questionnaire data

At study entry, and again at the end of two interventions (closed- and open-loop therapy), each participant completed the Diabetes Technology Questionnaire (DTQ). This is a 30-item measure of the impact of, and satisfaction with, technological tools that may be used in the management of Type 1 diabetes [8]. Participants were asked to rate their agreement or disagreement with statements regarding the specific diabetes technology in use at that measurement point [i.e. open-loop (real-time continuous glucose monitoring) alone or closed-loop with real-time continuous glucose monitoring]. Individual items were scored separately for each of the two columns of response options, yielding separate total scores for 'Is this a problem now?' (current) and 'How has it changed compared to your treatment before the study?' (change). The DTQ was administered at baseline and at the end of the two 28-day crossover periods. Analysis was conducted using paired-sample *t*-tests. Statistical analysis was conducted using SPSS (version 21).

The DTQ yields separate scores for the 'current' (How much is this a problem now?) and 'change' (How has it changed compared to before the study?) subscales. At baseline, only the 'current' items were administered, while at the conclusion of each crossover period both the 'current' and 'change' items were administered. After reverse scoring of some items, higher scores were indicative of more favourable satisfaction with and impact ratings for the technology. Based on participant responses in the present study, internal reliability (Cronbach's α coefficient) remained > 0.91 for the DTQ 'current' items and > 0.94 for the DTQ 'change' items throughout the study. Previous unpublished data from a sample of 115 adolescents and parents yielded similar psychometric data.

For the present study, the DTQ was modified to include a nine-item 'user friendliness' section for each of four possible technological components of the participants' diabetes regimens (glucose meter, insulin pump, continuous glucose monitor, closed-loop insulin delivery system). Participants rated the complete package of technology they had been using and each component that was part of their current regimen, in addition to each dimension of user friendliness, on a five-point scale, where 1 = 'terrible' and 5 = 'excellent'.

## Semi-structured interviews

Semi-structured interviews to explore participants' perceptions of the impact of the technologies on their experiences were designed in collaboration with the clinical research team. Factors including lifestyle change, diabetes management, safety and impact on their ability to carry out their usual daily routines were discussed. The interview schedule was then piloted on four potential participants, with questions on usability, relevance and acceptability. These participants were not included in the study. The feedback was positive, with minor revisions suggested, and the interview schedule was revised in line with these. All participants in the study were invited to participate in the interview study and all elected to do so.

On completion of each intervention, participants were invited to partake in an audio-recorded telephone interview conducted by K.D.B. All interviews were conducted within 2 weeks of the end of the trial. Audiotapes were transcribed with all identifying details removed. Following transcription, K.D.B. and A.J.Y. performed independent thematic analyses, reading each participant's interview in full before performing cross-comparisons to identify continuities and differences between accounts. This analysis was used to develop a coding framework, which captured original research questions and emerging findings [11].

Content analysis focused on the number/frequency of 'instances', their context, meaning and whether they were common across participants. Free text analysis concentrated on identifying the key themes arising, with a view to understanding the experiences of participants, exploring connections between themes and identifying how the technology affected everyday living and factors affecting quality of life in ways that were important to participants.

## Results

A total of 24 adults, 54% of whom were men, with a mean (SD) age of 43 (12) years, $HbA_{1c}$ concentration of 65 (9) mmol/mol [8.1 (0.8) %], BMI of 26.0 (3.5) kg/m$^2$, and duration of diabetes of 29 (11) years, participated in the interviews. The mean (range) interview duration was 26 (12–46) min. A total of 22 participants completed the trial. Two participants were classified as having a shortened study period (where the closed-loop technology safety mechanism instigated reversion to routine insulin pump therapy), one of whom would have preferred to continue the trial. All data are reported collectively.

## Questionnaire data

The DTQ data at one or more measurement points were missing for three participants. The mean DTQ item scores during each phase of the study [at baseline (DTQ 'current' items only) and after the closed-loop and open-loop phases (DTQ 'current' and 'change' items)] are shown in Table 1. The mean item scores were all > 3.0, indicating overall favourable ratings for the impact of and satisfaction with the diabetes technology just recently used by the participants. Although the DTQ current item scores appeared to be higher (more favourable) after the open-loop phase, these scores did not differ significantly. The same was true of the comparison of DTQ 'change' scores between the closed-loop and open-loop conditions (all $P > 0.16$).

The user friendliness ratings of each technological component of participants' current diabetes regimens were evaluated by examining the percentages of responses in the 'good' or 'excellent' categories. The most important of these results, shown in Table 2, concern participants' ratings of the closed-loop insulin delivery system after the closed-loop phase of the study. The results show that participants were least satisfied with the use of the closed-loop system during physical activity and bathing and with regard to appearance issues that were created by use of the system (mean ratings were in the 'poor' range). The participants were most satisfied with the closed-loop system regarding its ease of start-up and calibration, the instructions, manual and technical support that were provided, and performance accuracy/reliability (mean ratings were in the 'good' range). None of the items yielded a mean rating > 4 (good) on the five-point response scale.

The results also indicated fewer 'good' or 'excellent' ratings of the insulin pumps used during the open- (27.8%) and closed-loop (29.4%) phases compared with baseline (77.2%).

Eight participants spoke about their improved sleep as a consequence of using the closed-loop system. The reassurance and peace of mind associated with the closed-loop technology were frequently cited as benefits ($n = 16$). Worrying less about diabetes and blood glucose levels, as

**Table 1** Diabetes Technology Questionnaire scores for the current and change subscales at baseline and following the closed- and open-loop phases of the study

| | Baseline | Open-loop therapy | Closed-loop therapy |
|---|---|---|---|
| No. of participants | 22 | 19 | 20 |
| DTQ subscale, mean (SD) score | | | |
| Current | 3.66 (0.53) | 3.89 (0.52) | 3.63 (0.64) |
| Change | | 3.22 (0.44) | 3.24 (0.63) |

DTQ, Diabetes Technology Questionnaire.
Possible range of mean item scores is 1.0 to 5.0. Higher scores indicate more favorable impact of and satisfaction with the rated diabetes technology.

**Table 2** Participants' ratings of the closed-loop insulin delivery system

| User friendliness item | Mean rating | SD |
|---|---|---|
| System size, weight, appearance, fashion issues | 2.29 | 0.72 |
| Ease of start-up, calibration, etc. | 3.95 | 1.02 |
| Battery life and ease of replacement | 3.05 | 1.39 |
| Variety and flexibility of functions | 3.44 | 1.29 |
| Instructions, manual and technical support | 3.95 | 0.81 |
| Screen information and reports | 3.35 | 1.14 |
| Alarm functions | 3.38 | 1.20 |
| Use during sports, exercise, bathing | 2.00 | 1.28 |
| Accuracy and reliability of performance | 3.79 | 1.03 |

Possible range of mean item scores is 1.0 to 5.0. Higher scores indicate more favorable impact of and satisfaction with the rated diabetes technology.

well as the security of knowing that the technology was 'taking over for a while' contributed to this reassurance.

Sixteen participants commented on having improved blood glucose levels as a result of using the closed-loop system, reporting that 'waking up on a good number' contributed to improved blood glucose control during the following day, providing a 'better start' to the day rather than waking up and immediately having to deal with a 'hypo' or hyperglycaemia.

In response to the question 'What would you change about the closed-loop system?', 13 participants said 'the equipment'; specifically, six would make it smaller and seven would make it more portable, including increasing the bluetooth range, i.e. improving connectivity.

In response to 'What was the impact on your daily life?', eight participants reported the closed-loop system could 'do a better job than I could', reporting that having improved nocturnal glycaemic levels meant they had a better day. Five reported the positive impact of improved blood glucose control, saying they 'felt better', 'worried less' and 'had increased confidence'. Negative impacts reported were the system being 'inconvenient' ($n$ = 4) and it 'restricting movement' ($n$ = 1), with another participant saying the whole experience was 'really hard'.

Twenty participants would recommend the closed-loop technology to a friend with Type 1 diabetes, one participant could not answer this question and three would not recommend it.

When asked for their preference between closed-loop and continuous glucose monitoring, 12 participants chose the closed-loop system, four the continuous glucose monitoring, two did not answer and six participants were unable to provide a preference for a number of reasons:

'No preference – closed-loop took a little more effort';

'Closed-loop isn't quite there yet…it required more time';

'Open-loop [continuous glucose monitoring] you are still controlling yourself…closed-loop took more effort';

'Open-loop [continuous glucose monitoring] is a useful system…takes more time. Closed-loop takes control away…it was quite liberating'.

These responses demonstrate the difference in views regarding the amount of effort required by the closed-loop system with one person finding this problematic and the other really liking it.

## Key positive experiences

Table 3 shows the positive comments received. The enthusiasm and strength of feeling expressed by some participants about their experience of the closed-loop system were significant. Comments included: 'Brilliant'; 'Sad to finish'; 'Felt halfway human'; 'I was a nicer person to be around'; 'I was more effective, more productive'; and 'I felt normal'. None of the participants regretted taking part in the trial and all had something positive to say about their experience of being involved; however, three participants who completed the trial felt that participation had been challenging at times, saying, 'It took over my life' (005), 'I was sick to death of it' (018) and 'It was fragile, laborious and had a major impact on my routine' (023).

Potential reduction of long-term complications (via improved blood glucose control overnight) were reported by three participants. 'Improved health', 'more energy', feeling 'liberated' and 'generally feeling better' were cited as benefits by participants. Similarly, 'improved sleep' was reported by six participants, contributing to general feelings of well-being. One participant commented on the change in their partner's attitude towards their diabetes saying 'it made him much more aware of how difficult it is controlling diabetes …. made him much more caring' (018).

Furthermore, reassurance, reduced worry and peace of mind were associated with using the closed-loop system ($n$ = 16), with a better understanding of diabetes ($n$ = 3) and seeing how 'it' responded to different situations was helpful ($n$ = 1). Nineteen participants felt safe with the device, particularly once their initial anxiety about whether it would perform on the first day or two had gone, and were confident that it 'was OK' (Table 3).

The concept of the technology and the prospect of 'how good it could be' in the not too distant future, with advances towards a fully automated system and the associated possibilities, was reported as a benefit by nine participants, something that was also expressed by parents of adolescents taking part in the previous study. Several participants said that they had taken part to help 'further the cause' of diabetes research and hoping to benefit other people as well as themselves in the future. There was also widespread acknowledgement that this is cutting-edge research and so some teething difficulties were inevitable.

## Key negative experiences

Table 4 shows the key negative experiences reported. All participants reported having experienced some technical or usability difficulties with the equipment, but these were most

**Table 3** Key positive themes

| Theme and participants' comments | Participant identifier code |
|---|---|
| Reassurance/peace of mind | |
| 'The reassurance, it was comforting knowing it was there' . . . 'My blood sugars were more stable than they normally are'. | 022 |
| 'I went to bed confident that they were better than they normally would be'. | |
| 'Not worrying about my blood sugars and feeling it was its responsibility, not mine'. | |
| 'I didn't have to worry' | 010 |
| 'I didn't go to sleep worrying about a hypo' | 014 |
| 'I didn't need to worry as it looked after you' | 016 |
| 'You could wake up, look at this diagram of the profile of your blood sugar and it would be dead level, . . .absolutely constant throughout the night and that makes you feel better'. | 006 |
| 'It was pretty good . . .. It was the best I have had for several years'. | 014 |
| 'I didn't go to sleep worrying about having a hypo or not waking up'. | |
| 'I knew that it would correct this, it was like a break'. | |
| 'It was brilliant . . . it allowed me to stop worrying about a lot of things . . .' | 013 |
| General positive comments | |
| 'In the 2 weeks I was using it, it was brilliant'. | 017 |
| 'The principle of it is wonderful [if it lived up to expectations]'. | |
| 'I didn't realize how much better I could feel'. | 003 |
| 'I've never felt better in my adult life . . .. I felt normal, more fund to be around'. | |
| 'It made me much more effective, more productive and much nicer to be around'. | |
| 'I felt really emotional . . . like I was on the brink of something'. | |
| 'The whole thing was brilliant'. | 012 |
| 'When it finished I was really sad'. | |
| 'Very impressed, I enjoyed it very much and wish it hadn't stopped'. | |
| 'If I could get over my dislike of the pump, that would be the worse thing about it, it would be coming off it and giving the system back'. | 004 |
| 'Once you got used to it, it was really good'. | 007 |
| Better sleep | |
| 'It did away with the intrusiveness and not having to wake up and check blood glucose levels' | 017 |
| 'Better sleep pattern . . .When it worked it was fantastic . . . I had 8 hours uninterrupted which is fantastic'. | 009 |
| 'Better sleep' | 011 |
| 'You were in the morning at a good level to start with'. | 016 |
| 'You didn't worry when you went to sleep because you knew it was going to look after you'. | |
| Wake up in the morning feeling normal | 020 |
| Improved blood glucose control | |
| 'Better insight into controlled whole diabetes' | 018 |
| 'It managed to maintain blood glucose levels' | 004 |
| 'I only had one overnight hypo' | 010 |
| 'It was brilliant! All conversations are 'we don't know what's happening at night . . .. Now it's good overnight and we don't have to think about it. I slept so much better.' | 001 |
| 'Knowing that for 8 hours a day, you have good control.' | |
| 'There was nothing bad about the algorithm [but the equipment was still quite raw].' | |
| 'My blood glucose was perhaps better controlled'. | 005 |
| 'I was really impressed with how it stabilized my blood sugar, it was pretty much spot on'. | 011 |
| 'Waking up in the morning and seeing your blood sugars in a straight line for about 12 hours which was fantastic'. | 019 |
| 'I can't describe that feeling but it was brilliant. It really is amazing'. | |
| 'My sugars were a lot better in the morning . . . it does what it says on the tin'. | 008 |
| 'The technology is coming forward and research is coming forward . . .. There will be solutions to the issues'. | |
| 'The concept.. moving towards an artificial pancreas optimizing people's sugar controls to improve the levels to avoid high readings'. | 002 |
| 'It was generally doing at least as good if not a better job than I would be doing myself'. | |
| 'Wake up with perfect blood glucose levels, good start to the day' | 021 |
| Improved blood glucose control overnight led to improved daytime control | |
| 'I was impressed how it controlled things during the day' | 013 |
| 'Better during the day as it's being controlled better' | 015 |
| 'Feeling better in the morning' | 011 |
| 'My control overnight almost all of the time was excellent.' | 021 |
| 'I would pretty much always wake up with a perfect blood sugar which was then a really good way to start your day'. | |

often associated with the insulin pump and continuous glucose monitor than with the closed-loop technology itself. Common problems included connection difficulties, poor battery life, sensors not sticking very well or getting in the way/being too large.

The alarms were also a problem for several participants ($n$ = 13), particularly when they became intrusive by waking up other family members or causing repeated sleepless nights. Feelings of powerlessness were reported in terms of the alarm sounding, corrective action being taken promptly, but then the

**Table 4** Key negative themes

| Theme and participants' comments | Participant identifier code |
|---|---|
| Alarms beeping frequently | |
| 'absolutely dreadful ... sick to death of it' | 018 |
| 'It bleeped a lot at night, the alarms' | 015 |
| 'Alarming all the time' | 021 |
| 'Problems with the companion waking me up' | 005 |
| 'The alarms .... Everybody knows'. | 001 |
| 'There were so many times when for a variety of reasons it kept me awake all night because it was alerting or it didn't seem to work'. | 009 |
| 'The worst thing for me was not knowing whether what was happening was down to operator incompetence or the technology'. | |
| 'There were a couple of stressful moments ... it was not as robust or resilient as I thought it would be'. | 003 |
| 'The alarms were very intrusive'. | |
| 'The alarms would go off [when setting up the system]'. | 008 |
| 'The alarms'. | 007 |
| 'The whole system is too big ... you couldn't walk around with it'. | |
| 'The alarms ... connecting them altogether was a problem really' | 015 |
| 'I found it difficult with my shift patterns' | |
| 'The equipment really ...' | |
| 'It was awful ... it wasn't for me at all'. | 020 |
| 'The inconvenience in the evening, the bleeping just going off ... its sleep deprivation for me' | |
| 'It got a bit confused.. it bleeped at night a couple of times and kept losing contact'. | 012 |
| Technical/Usability difficulties | |
| Problems with the hardware | 018 |
| Connecting the devices together was a problem | 015 |
| It kept losing contact | 012 |
| 'The calibration at night'. | 007 |
| It's noisy, technical setting it up and the range is too short | 016 |
| 'It's too easy to turn off by mistake'. | 004 |
| 'I had a lot of trouble with the transmitter'. | 005 |
| 'The terrible row ...' | |
| 'The first week I felt sleep deprived'. | |
| 'The equipment wasn't very easy to use' [talking mostly about CGM and pump] | 006 |
| 'The noise from the hardware ... the fan.. next to the bed'. | 010 |
| 'I was wary of it losing its connection'. | |
| 'I had to sleep very close to the thing which meant I didn't have much room to move' | 016 |
| 'If I turned over the sensor was too far away from the CAD and it got detached which was the worse thing' | |
| 'It's quite restrictive' | |
| 'The connectivity.. the blue tooth' | 013 |
| 'You feel a bit battered by the end of it ... fit your whole life around a machine that isn't working that well'. | 019 |
| Night-time 'hypos' | |
| 'Absolutely dreadful'. | 018 |
| 'I was really angry by the end of it ... I had a lot of problems with the hardware'. | |
| 'The whole thing overwhelmed me I have to say'. | |
| 'You couldn't image what was going to go wrong next' | |
| 'Whilst I was on the closed loop ... I was really worried because I kept going hypo' | |
| 'I found it made me really anxious' | |
| More night hypos on the closed loop | 005 |
| Too big | |
| 'Not very portable .... So much equipment you need to be using for the Closed Loop' | 011 |
| Needs to be smaller | 014 |
| It's bulky | 016 |
| '.. limited by the actual technologies available ...' | 002 |
| 'You have to be within reasonable range for the transmitter to work ...' | |
| 'All the communication between the algorithm and equipment ...' | |
| 'Making it smaller would be the biggest thing' | 014 |

alarms continuing to sound approximately every 20 min as blood glucose levels were returning to a safe range. Interestingly, participants did not distinguish between 'real' alarms or 'false' alarms, so it is not possible to know whether the alarms were always appropriate. Two participants did, however, report that the alarms were a positive aspect of the technology because they gave them a greater awareness of hypo- and hyperglycaemia and they were able to act quickly to treat them.

Seven participants commented on the size of the equipment, specifically the lack of portability of the laptop, the size of the sensors, having to carry so many things but lacking somewhere to put them. For those participants who used both first-generation and second-generation sensors, the reduced size of the second-generation sensors was reported favourably.

Three participants reported the inconvenience of using the equipment, finding it hard to fit it into their lifestyles. Another participant reported increased anxiety because of the technology, with a further three participants reporting more episodes of hypoglycaemia than usual whilst on the closed loop. One of these participants said that it ‘knocked my confidence’.

## Discussion

The impact of the tested closed-loop technology was positive for most (21/24) participants, outweighing reported downsides, which were often described as ‘teething’ problems with the technology.

Closed-loop technology represents cutting-edge technological research in the treatment of Type 1 diabetes, with technological advancements facilitating a progression to home-based trials. There is scant evidence, however, on whether the technology will meet people’s needs in the context of usability and psychosocial functioning. In addition to having biomedical and cost-effectiveness benefits, the technology must be usable, safe and beneficial from a psychosocial perspective if people are going to be able to embrace it as a realistic therapy option.

Participants’ impact and satisfaction ratings after the use of closed- or open-loop technology, as measured by the DTQ, showed that, overall, participants were moderately favourably disposed toward both insulin delivery systems. Of the 30 DTQ items, 20 difference scores favoured closed-loop, seven difference scores favoured open-loop and three difference scores were 0, favouring neither technology.

Analysis of the user friendliness of the closed-loop system showed moderately positive opinions of the technology except for items measuring appearance concerns and difficulties using the system during physical activity and bathing. Otherwise, the usability ratings were moderately positive (in the ‘good’ range), showing aspects of the closed-loop system that need further improvement. This was also reflected in the interviews, where participants reported challenges transferring to the study insulin pump, which was different from the one they usually wore.

The key themes, both positive and negative, were similar to those reported for adolescents with Type 1 diabetes [11], with widespread optimism for future technological developments and potential availability commercially in the near future. Usability challenges perhaps had a greater impact on daily living than those reported by adolescents, contributing to less enthusiasm for the technology than was reported by parents in previous research. Participants in the present study reported hoping the closed-loop system would be available for younger generations with Type 1 diabetes and were thinking about potential availability as their own children grew up.

Technological advances in diabetes management have been rapid over recent years and have been met with mixed reviews. Insulin pump therapy and continuous glucose monitoring devices have been both positively and negatively associated with quality of life [12,13]. Whilst the benefits of these technologies are widely reported, the reality of having to live with a device constantly over a period of time can be challenging. It could be argued that participants in closed-loop research are ‘highly motivated’ [2] and perhaps not representative of the wider population with Type 1 diabetes; it is important, therefore, to consider that interruptions to daily living and the requirement to dedicate more time than desired on diabetes self-management take their toll on the lived experience and quality of life. Technological development should ensure the psychosocial impact of devices is fully considered.

Limitations of the present study include the low participant numbers and the fact that the trial was powered on time spent in the target glucose range, so lacked statistical power to detect significant differences in psychosocial functioning between the two arms. Similar challenges have been found in previous research [5], where anxiety and quality of life were not assessed because of the short duration of the intervention. The interviews were designed to add depth and psychosocial context to the biomedical results of the main trial and, as such, were not designed as a detailed qualitative evaluation that would have required considerably longer interviews and phenomenological analysis.

In conclusion, the development and refinement of closed-loop technology is moving apace. Representing cutting-edge therapy for the treatment of Type 1 diabetes, the biomedical benefits are matched by psychosocial outcomes. Participants liked the additional information provided by the open-loop technology, but technical glitches were reported drawbacks. The closed-loop device has major positive effects when it works in freeing patients from some of the demands and challenges of self-management. The downside for those who had more negative views was generally the technical difficulties, particularly concerning the pump and the ‘connectivity’ which it is hoped will improve. Future research should continue to explore the holistic acceptability of closed-loop therapy as a realistic option and take account of user concerns as new systems are designed. Failure to do this may reduce the eventual utility of new systems.

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### Competing interests

None declared.

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