The impact of using a closed-loop system on food choices and eating practices among people with Type 1 diabetes

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The impact of using a closed-loop system on food choices and eating practices among people with Type 1 diabetes: a qualitative study involving adults, teenagers and parents

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Abstract

Aims We explored whether, how and why moving onto and using a hybrid day-and-night closed-loop system affected people’s food choices and dietary practices to better understand the impact of this technology on everyday life and inform recommendations for training and support given to future users.

Methods Twenty-four adults, adolescents and parents were interviewed before commencing use of the closed-loop system and following its 3-month use. Data were analysed thematically and longitudinally.

Results While participants described preparing and/or eating similar meals to those consumed prior to using a closed-loop, many described feeling more normal and less burdened by diabetes in dietary situations. Individuals also noted how the use of this technology could lead to deskilling (less precise carbohydrate counting) and less healthy eating (increased snacking and portion sizes and consumption of fatty, energy-dense foods) because of the perceived ability of the system to deal with errors in carbohydrate counting and address small rises in blood glucose without a corrective dose needing to be administered.

Conclusions While there may be quality-of-life benefits to using a closed-loop, individuals might benefit from additional nutritional and behavioural education to help promote healthy eating. Refresher training in carbohydrate counting may also be necessary to help ensure that users are able to undertake diabetes management in situations where the technology might fail or that they take a break from using it.

Diabet. Med. 00: 1–8 (2019)

Introduction

A closed-loop system is a rapidly evolving technology for people with Type 1 diabetes which is still under development, although it is used in clinical practice in the USA. A closed-loop system comprises a real-time continuous glucose monitor, an insulin pump and an algorithm which translates, in real time, information received from the continuous glucose monitor and computes the amount of insulin delivered by the pump. These systems need varying levels of user input, with most requiring users to count carbohydrates and announce this information prior to snacking or eating a meal [1]. While the intended purpose of a closed-loop system is to improve glycaemic control and lessen the burden of diabetes self management [2], concerns have been raised that there may be unintended behavioural consequences to using this technology [3]. Specifically, it has been hypothesized that the use of a closed-loop may result in a transition from what has been termed ‘restrained’ to ‘non-restrained’ eating behaviour, prompting calls for further research [3]. While studies have previously consulted users of closed-loop systems, these have often focused on experiences of overnight systems [4–9] and/or systems used for very short
What’s new?

- This is the first study to explore how moving onto and using a closed-loop system may affect people’s food choices and eating practices.
- Using a closed-loop can help people to feel more normal, and less anxious and burdened by diabetes in dietary situations.
- While we did not find the level of unrestrained eating behaviour hypothesized by others, we did observe some potential slippage into increased snacking and unhealthier eating as a result of using a closed-loop.
- We support recommendations for people to be given tailored training and nutritional support to help promote healthy eating while using a closed-loop.

periods (typically ≤5 days) in supervised environments [10–12], with none focusing specifically on how the use of a closed-loop might affect users’ dietary practices.

We report findings from a longitudinal interview study undertaken with individuals who participated in the APCam11 trial, which assessed the effectiveness of a day-and-night closed-loop system combined with pump-suspend feature compared with sensor-augmented pump therapy in adults and youth (aged 6+ years) with Type 1 diabetes (Table 1) [13]. To be eligible for this 3-month trial, participants/caregivers needed to have a good knowledge of insulin self-adjustment; this was determined through a review of clinical records and pump downloads (e.g. to determine that individuals were carrying out at least 4 blood glucose finger-prick checks per day), and discussions with potential recruits and their clinical teams, who knew these individuals well.

Potential recruits also needed to have been using an insulin pump for at least 3 months [13]. A key aim of the interview study was to explore whether, how and why moving onto and using a closed-loop affected people’s food choices and dietary practices. This investigation was undertaken to better understand the impact of this technology on everyday life and help inform recommendations for dietary training and support given to future users.

**Participants and methods**

Qualitative approaches are recommended when little is known about the area of investigation as they enable findings to emerge from the data rather than testing predetermined hypotheses [14,15]. In this study, in-depth interviews informed by topic guides were used so that the discussion remained relevant to the study aims, while affording the flexibility needed for participants to raise issues they perceived as salient, including those unforeseen at the study’s outset (Table 2). Data collection and analysis took place concurrently so that findings from early interviews could be used to inform areas explored in later interviews. The study was informed by normalization process theory [16], an epistemological position which recognizes that there may be unintended consequences arising from using a new technology, and that technology use may be influenced by personal and contextual factors which need to be captured and explored as part of the data collection and analysis process.

We interviewed individuals aged ≥16 years, individuals aged 13–15 years and their parent(s), and the parents of those aged ≤12 years who had been randomized to the closed-loop arm of the trial. Individuals were recruited into the interview study by staff in the four participating UK sites using an opt-in procedure. Recruitment continued until there was adequate representation for each age group and data saturation had occurred.

Participants were interviewed just before commencing use of the closed-loop (baseline) and 3 months later, just after their participation in the trial had been completed. This design permitted us to explore and compare how people had managed their (or their child’s) diabetes and diet using an insulin pump (baseline) and using a closed-loop (follow-up) (Table 2). Hence, we were able to establish whether, how and why people’s dietary choices, attitudes towards food, and dietary-related diabetes management practices changed as a result of using a closed-loop. Interviews were conducted by M.B., an experienced qualitative (non-clinical) researcher, at a time and location of participants’ own choosing (mostly in their own homes), averaged 1–2 hours. Interviews were digitally audio-recorded and professionally transcribed in full.

Data were analysed by J.L. and D.R., two highly experienced qualitative (non-clinical) researchers, using a thematic approach informed by the method of constant comparison. Each individual undertook an independent analysis and wrote a separate report before meeting to compare interpretations and reach agreement on key findings. As part of the data analysis process, interviews were cross-compared to identify recurrent themes [17]. To establish whether, how and why participants’ food choices and eating practices changed as a result of using the closed-loop, J.L. and D.R.

<table>
<thead>
<tr>
<th>Table 1 Information about the study devices</th>
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<tbody>
<tr>
<td>The automated hybrid closed-loop system used in the APCam11 trial (FlorenceM) comprised:</td>
</tr>
<tr>
<td>• a modified next-generation sensor-augmented Medtronic insulin pump 640G (Medtronic Minimed, CA, USA) with pump-suspend feature;</td>
</tr>
<tr>
<td>• a Medtronic continuous glucose monitor transmitter with Enlite 3 sensor;</td>
</tr>
<tr>
<td>• an Android smartphone containing the Cambridge model predictive algorithm with a propriety translator to allow wireless communication with the insulin pump.</td>
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</table>

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also compared participants’ baseline and follow-up interviews. A coding framework was then developed which captured key themes and the contextual information needed to aid data interpretation, in line with our epistemological approach. Nvivo (version 10, QSR International Pty Ltd., Doncaster, Australia), a qualitative software package, was used to facilitate data coding and retrieval, and coded datasets were subjected to further analyses to enable more nuanced interpretations of the data.

Cambridge East Research Ethics Committee approved the study (REC ref. 15/EE/0324). To safeguard anonymity, unique identifiers are used throughout.

### Results

The sample comprised 12 participants aged 16+ years, 3 aged 13–15 years and 9 parents (Table 3). All adult participants reported having previously attended a structured education programme [e.g. a Dose Adjustment For Normal Eating (DAFNE) course] where they had received instruction in flexible intensive insulin therapy. Similar training in carbohydrate counting and insulin dose adjustment was reported by the parents and adolescents in the sample. Below, we begin by reporting how people managed their (or their child’s) diet and diabetes using an insulin pump before going on to consider their experiences while using a closed-loop. As we will show, while participants did not generally make major dietary changes as a result of using a closed-loop, many described feeling more normal and less burdened by their diabetes in dietary situations. In addition, while participants were very positive about their experiences, there was also potential for the use of this technology to lead to deskilling and unhealthier eating over time.

#### Managing food and diabetes using an insulin pump

Participants, at baseline, described the benefits of managing their diabetes and diet using an insulin pump. In particular, participants praised the pump for making snacking and eating out easier, because ‘with an injection you’ve got to go somewhere like a toilet and inject yourself, with the pump you just press a few buttons’ (participant 3). However, most also noted how, despite using a pump, their food choices and eating practices had tended to be fairly standardized: ‘day to day, we tend to stick to the basic things, pastas and rice and curries and chillies and things like that’ (participant 7). In some cases, food choices had been standardized or tailored to take account of diabetes. For instance, some participants described how they had eaten or prepared the same kinds of meals on a regular basis to facilitate carbohydrate counting: ‘I tend to stick to the same things because it’s what you know the carb values of, so that does factor into my decision making’ (participant 11). Others reported choosing to routinely consume low glycaemic index foods, such as porridge at every breakfast, to help minimize fluctuations in blood glucose, ‘because oats tend to have a very low GI and I find that helps keep things relatively stable blood sugar-wise’ (participant 14).

<table>
<thead>
<tr>
<th>Baseline interview:</th>
<th>Follow-up interview:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background information: who the participant/child lives with; everyday work/school and family life; who is involved in food purchasing and preparation, and why.</td>
<td>Experiences of managing diabetes using a closed-loop system; including, carbohydrate counting, use of corrective doses, strategies for preventing and/or managing hypoglycaemia and hyperglycaemia.</td>
</tr>
<tr>
<td>Experiences of managing diabetes using an insulin pump; including, carbohydrate counting and use of corrective doses, strategies for preventing and/or managing hypoglycaemia and hyperglycaemia.</td>
<td>Experiences of managing diabetes using a closed-loop system; including, carbohydrate counting, use of corrective doses, strategies for preventing and/or managing hypoglycaemia and hyperglycaemia.</td>
</tr>
<tr>
<td>Daily food choices; for example, kinds of meals consumed (and reasons for these meal choices), frequency of snacking, types of snacks consumed (and reasons for not snacking), reasons for avoiding/eating certain foodstuffs while using an insulin pump.</td>
<td>Perceived impact of using a closed-loop on food choices and eating activities.</td>
</tr>
<tr>
<td>Perceived benefits and burdens of using a pump in dietary situations.</td>
<td>Participants’ views about whether, how and why, their/their child’s food choices and diabetes self management practices (e.g. carbohydrate counting) have changed or remained the same as a result of using the closed-loop system.</td>
</tr>
<tr>
<td>Perceived impact of using a pump on self-perceptions relationships with others, everyday food choices and food-related activities.</td>
<td>Perceived benefits and burdens of using a closed-loop system in dietary situations; were these anticipated or unanticipated, and why?</td>
</tr>
<tr>
<td>Anticipated impact of using a closed-loop on food choices and eating activities.</td>
<td>Perceived impact of using this technology on self-perceptions, relationships with others and everyday work/school and family life.</td>
</tr>
<tr>
<td>Any other issues the participant would like to raise and discuss.</td>
<td>Any other issues the participant would like to raise and discuss.</td>
</tr>
</tbody>
</table>

**Note.** While the same general areas, as outlined above, were covered with all participants, tailored questions were also asked and probes used to encourage and enable a fuller elicitation of responses to particular questions. We also tailored some of the questions asked in each participant’s follow-up interview to take account of the kinds of information and experiences they had shared in their baseline interview.
Some also implicated behavioural and personality traits, for instance, participant 5, who described themself as ‘a creature of habit’, and participant 6, who observed how ‘I kinda do stick to the same foods, not because of the pump, just because I don’t really like changing’.

As part of their dietary routines, most participants described eating meals containing rice, pasta, potatoes and bread. To help optimize their blood glucose control when these kinds of foods were eaten, participants also described making an effort to count carbohydrates by consulting food labels, websites and/or using phone apps as well as weighing foodstuffs and using predetermined measures:

‘I do actually, I weigh pasta [laughter] and I also weigh rice … And, like cereal, I did, on the carbs course. They said: “Measure your cereal out and then stick it in your bowl, so you know what it looks like in your bowl”. And then they suggest like you put a mark—in permanent—which I’ve done.’ (participant 6)

Some, including participant 7, also noted how they had tried to control their portion sizes to help optimize blood glucose control:

‘If I have a massive meal, that’ll throw my control off slightly … So I tend to eat a similar-sized meal for most meals. So my evening meals tend to be between 70 and 80 g of carbs.’

Given the importance attached to carbohydrate counting and monitoring portion sizes, participants described how non-routine dietary situations, such as when they ate out or consumed buffets, could be very challenging and sometimes stressful:

‘If you go out for a meal with friends that can be a big drama. It just requires guesstimates, em, buffets are clearly a nightmare: that’s just, yeah. It’s just pick a number [laughing], kinda correct later.’ (participant 4)

Participants also noted the difficulties of achieving stable blood glucose control when they or their child ate high-fat, energy-dense foods such as curries, pizzas and Chinese foods, because of the delayed absorption of carbohydrates. Such individuals also reported the poor sleep they had experienced, even when the pump’s dual wave function had been used, wherein ‘I would wake up in the night feeling rotten. My sugars would be mid- or low-to-mid-twenties’ (participant 7). To help address or minimize these kinds of difficulties, most participants described eating out or consuming takeaway foods infrequently. Parents also described restricting foodstuffs such as pizza and popcorn to the weekends because, when these foods were consumed in the evenings, they needed to wake early or stay up in order to stabilize their child’s blood glucose:

‘Pizza is a nightmare . . . pizza and popcorn night, no sleep for us . . . So there is a rule, pizza is either Friday night or Saturday night or even Sunday lunchtime, but never on weeknights, cause it sends his sugars high.’ (parent 5)

To explain why they tended to eat/prepare the same kinds of meals, most participants, however, implicated factors and considerations which were not directly connected to their diabetes. These included ‘not having the time to think up new menus, so I tend to rotate the same kinds of meals from week to week’ (participant 6). Relatedly, some participants also noted how, because food shopping had become a routinized and non-reflexive process, this had resulted in the same items always being purchased:

‘[T]here’s nothing that I particularly avoid or prefer to eat, or anything else, but also you do eat the same things all the time. You eat the same types of cereal. You eat the same things in your sandwiches. And I don’t do that because it makes it [carbohydrate counting] easier . . . If you eat something all the time—you kind of, you do, you buy the same stuff in the supermarket—you don’t really think about it.’ (participant 6)

Table 3: Demographic characteristics of study participants

<table>
<thead>
<tr>
<th>Participants with Type 1 diabetes (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, female (n, %)</td>
</tr>
<tr>
<td>Age at recruitment (years)</td>
</tr>
<tr>
<td>13–15</td>
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<tr>
<td>16–20</td>
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<tr>
<td>21–30</td>
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<td>31–40</td>
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<td>41–50</td>
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<tr>
<td>51–60</td>
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<tr>
<td>60+</td>
</tr>
<tr>
<td>Occupation/education (n, %)</td>
</tr>
<tr>
<td>Professional</td>
</tr>
<tr>
<td>Semi-skilled</td>
</tr>
<tr>
<td>Retired</td>
</tr>
<tr>
<td>Higher education</td>
</tr>
<tr>
<td>Secondary school</td>
</tr>
<tr>
<td>Previous involvement in closed-loop trial(s)</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Parents of paediatric patients (n=9)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, female (n, %)</td>
</tr>
<tr>
<td>Age at recruitment (years)</td>
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<tr>
<td>31–40</td>
</tr>
<tr>
<td>41–50</td>
</tr>
<tr>
<td>51–60</td>
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<tr>
<td>Occupation (n, %)</td>
</tr>
<tr>
<td>Professional</td>
</tr>
<tr>
<td>Semi-skilled</td>
</tr>
<tr>
<td>Unemployed/</td>
</tr>
<tr>
<td>full-time carer</td>
</tr>
<tr>
<td>Child had previous involvement in closed-loop trial(s)</td>
</tr>
</tbody>
</table>

*This includes parents who represented children aged ≤12 years (n=5) and parents of children aged 13–15 years (n=4). In one instance, both parents of a child aged 13–15 years participated in an interview.
Managing food and eating using a closed-loop system

At follow-up, participants described preparing and eating very similar kinds of meals to those consumed previously. Most, however, also reported having felt more normal and less burdened by diabetes in dietary situations. For instance, because of the perceived ability of the closed-loop to ‘soak up’ (participant 3) errors and stabilize blood glucose if they miscalculated the carbohydrate content of meals, participants described having felt liberated from the requirement to weigh and measure foodstuffs or consult labels and websites:

‘If you’re a little off, the closed-loop always ends up sorting you out, so you don’t have to be as anal about it … You don’t have to measure out every individual gram … The closed-loop system will control it and keep your sugar levels at a better level without having to actually get the scales out and the jugs out to measure the carbs.’ (participant 1)

Participants also described how they had felt more confident and less anxious when eating out because they were less worried about the consequences of incorrectly estimating the carbohydrate content of the foods consumed.

‘Also, you got that confidence that your sugar levels aren’t gonna suddenly drop or suddenly go sky high if you miscalculated your carbs … So if I went out for dinner and I did miscalculate my carbs a little bit, it wouldn’t be a problem during the night while I’m asleep, where they [blood glucose levels] suddenly go up or they suddenly go down, because the algorithm would deal with that.’ (participant 5)

Individuals also noted how the closed-loop had permitted them to snack more easily because they no longer saw it as necessary to administer a corrective dose to address a small rise in their blood glucose, as the closed-loop would do this automatically:

‘So, if I was sort of doing the kids’ tea and I would sort of have a couple of chips, that I would probably think: Oh, I — you know — and I think it was quite subconscious that, you know: Oh, I don’t need to bolus for that because it’s not very much. It’s only gonna be sort of 10 g of carbs, and the … the artificial pancreas will be able to sort of, will deal with that, because it will see the sugars going up slightly and it’ll give it a bit more insulin.’ (participant 3)

The quality-of-life benefits of using a closed-loop were also noted, with participant 1, for instance, describing having felt more ‘normal’ because of being able to interact with peers in more spontaneous ways around food:

‘If somebody’s going round with a packet of biscuits and they offer you one, you can have a quick look and go, Oh yeah, go on then, yeah, I’ll have a biscuit. And you don’t have to worry about it as much as if you weren’t on a closed-loop, where it’d be like: Well, er, can I have a biscuit? Can’t I have a biscuit? Oh well, you know, maybe I shouldn’t … It just means you can go with the flow, go with everybody else.’

Additional benefits were reported by teenagers and their parents, who noted how the closed-loop had acted as a safety net at a point in the life course where, as participant 12’s parent, noted:

‘[H]e just struggles, because he likes to do the kind of things that his friends do—he treats himself as if he’s not a diabetic … He eats what he wants, when he wants. And, you know, sometimes he forgets to put insulin in.’

It was also noted how the closed-loop helped to protect a child from prolonged hyperglycaemia if they forgot to administer insulin prior to a meal or a snack:

‘I mean there was one occasion when she didn’t inject for her lunch at all school. She was just too busy playing … She went up to 15, and then within about 45 minutes then her numbers were normal again, because the closed-loop just picked it up and corrected and corrected and corrected.’ (parent 4)

Unintended consequences

While participants were extremely praiseworthy of the closed-loop, some also noted that there was potential for ‘bad habits’ (participant 1) and unhealthy eating to creep in over time. For instance, various individuals noted how, as a result of using the closed-loop and no longer feeling it was necessary to administer a corrective dose, they or their child had been inclined to snack more frequently:

‘[H]e might have been more complacent on the snacks knowing that the system responds, because in the past if you were to take small snacks and so forth you would have himself to look after them. But now with the confidence in the closed-loop system I think he probably just [feels] relaxed in getting snacks wherever he can get them from. So his alertness of what to eat and when might have quite relaxed as well, because of that rebut given by the new system.’ (parent 9)

Some individuals also noted how using the closed-loop could result in more frequent consumption of treats and takeaway meals, as they had found it was possible to eat high-fat, energy-dense foods without experiencing adverse consequences:

‘So I could pretty much just eat whatever I wanted … I felt like I didn’t have to watch what I was eating … I could go a little bit more luxury, and I could have things that I wouldn’t usually go for because I’d go: Oh, it’s got loads of sugar in, that. Sod it. It tastes nice.’ (participant 7)
‘[N]o child really should eat crap. But all children do, like we all have ice cream, we all have sweets. We all have things but [child’s name] can’t, because he has a disease. And if he does have this on a regular basis, it will have a massive effect on his later health. So I had to be mindful of that. Whereas with the artificial pancreas, you’re kind of so much more relaxed—I definitely was towards the end—as it copes with things like pizza and ice cream.’ (parent 7)

In addition, because the closed-loop could address errors in carbohydrate counting, some individuals noted having allowed their portion sizes to increase:

‘My portion size increased slightly, because like I say, I enjoy my food. I like cooking. I like eating … The first couple of weeks I was eating very carefully and doing everything as I should. And then I realized, I simply realized how good the closed-loop was, and went: Oh, slightly bigger portion sizes now.’ (participant 9)

Some participants also voiced concerns that because they had not found it necessary to count carbohydrates accurately in advance of a meal, there was a risk that this skill could be unlearnt over time:

‘I mean, yeah, the only other sort of thing is that there is this danger that you, if you were too used to closed-loop, then there’s a chance that I would have unlearnt in a way, some of the, some of those skills, like accurately counting your carbohydrates.’ (participant 14)

Hence, such participants suggested that, were individuals to stop using a closed-loop after prolonged use, they would need refresher training in carbohydrate counting to ‘avoid messing your blood glucose up.’ (participant 14)

Discussion

This study has explored people’s food choices and dietary practices while using a hybrid day-and-night closed-loop system over 3 months. While participants noted major benefits to using the closed-loop in dietary situations, in particular how it enabled them or their child to feel more normal and less burdened by diabetes, our findings go some way to alleviating the concerns raised by others [3] that the use of this technology, and the increased dietary permissiveness and flexibility it potentially allows, will necessarily lead to ‘unregulated’ and ‘unrestrained’ eating. Indeed, in keeping with findings from interviews undertaken with individuals using flexible intensive injection regimens [18], we found that participants’ food choices, including their tendency to always eat/prepare the same kinds of meals, were largely influenced by factors not directly connected to their diabetes. Such factors included habit and a need to keep food-related tasks simple by using ‘short cuts’ to help food-related activities fit into busy work and family lives [18–20].

Although we did not find the level of ‘unrestrained’ eating behaviour hypothesized by Kahkoska et al. [3], we did observe some potential slippage into unhealthier eating as a result of using the closed-loop. Specifically, some participants reported increased snacking and portion sizes and consumption of fatty, energy-dense foods (e.g. pizza) because of the perceived ability of the closed-loop to deal with errors in carbohydrate counting and automatically address small fluctuations in blood glucose resulting from snacking or delayed absorption of fatty foods. While, in the main trial from which our participants were recruited, weight change was not significantly different between the two arms, a 2.2 kg weight gain was observed in the closed arm (as compared with 1.4 kg in the control arm) [21]. In another 3-month trial of a hybrid closed-loop delivery system, weight gains of 1.4 and 1 kg were also observed among adult and adolescent users, respectively [22]. Although the reasons for this weight gain are likely to be complex, our findings, which suggest that people might increase their caloric intake as a result of using a closed-loop system, may have potential explanatory value. Given that our participants only used the closed-loop for three months, longer term follow-up, including investigation of whether the use of a closed-loop system leads to (further or sustained) weight gain, dyslipidaemia, fatty liver disease and other adverse cardio-metabolic outcomes, may be important to determine and quantify the clinical implications of our findings. In keeping with broader guidelines for supporting the self management of diabetes [23–25], our finding that use of a closed-loop may result is less healthy eating also offers potential empirical support to Kahkoska et al.’s recommendation that targeted nutritional and behavioural education should be provided to help promote healthy eating behaviour while using this technology [3].

Our finding that participants may become deskilled as a result of using a closed-loop system suggests that users may benefit from receiving ongoing training in carbohydrate counting to help ensure they are able to manage diabetes in situations where the technology might fail or they choose to have a break from using it. Consideration could also be given to offering refresher training at the end of trials of closed-loop systems, especially those of longer duration, to help participants revert to regimens where accurate carbohydrate counting may be imperative.

The teenagers and parents in the study particularly valued the closed-loop as it was seen to offer a safety net at a point in the life course where the self management of diabetes could be neglected as a result of individuals having other priorities and wanting to fit in with their peers [26,27]. Indeed, the particular benefits of closed-loop technology to this age group have been noted by others, who have shown that in scenarios mimicking ‘non-compliant’ behaviours among adolescents, closed-loop systems can be safe and effective because of the system’s...
ability to partly compensate for boluses being forgotten or underestimated [28,29].

A key study strength is that it involved a diversity of users (adults, adolescents and parents) who had used a closed-loop in real-life settings over several months. An additional strength is our flexible, open-ended approach, as this enabled us to identify erstwhile unrecognized benefits and unintended consequences arising from using the closed-loop. As is typical in studies investigating use of closed-loop technology, our sample was skewed towards educated and highly motivated individuals [4,6,7], which might limit the generalizability of our findings. An additional limitation is that we did not use a dietary assessment tool, and the use of such a tool could be considered in future (mixed methods) studies. Before the trial, participants were using an insulin pump and flexible intensive insulin therapy approach. Hence, we might have observed a greater impact of the closed-loop on food and eating practices had participants, for instance, been using fixed dose regimens, such as those involved in a recent Australian study [30]. Participants in the current study used a hybrid closed-loop system which required them to count carbohydrates and announce this information to the system. Hence, there may be greater potential for dietary change and/or quality-of-life benefits among people using fully automated systems that are currently under development [1], and which could be the focus of future qualitative and dietary research.

In conclusion, while closed-loop systems can make a significant difference to users’ lives by allowing them to feel more normal and less burdened by diabetes in dietary situations, there is potential for the use of this technology to result in unhealthier eating over time. Consideration should therefore be given to offering users nutritional and behavioural support to help ensure that the clinical and other benefits of using this technology are fully realized and sustained.

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Competing interests
R.H. reports having received speaker honoraria from Eli Lilly and Novo Nordisk, serving on advisory panels for Eli Lilly and Novo Nordisk, receiving licence fees from B. Braun and Medtronic. R.H. and M.E.W. report patent patents and patent applications. M.E.W. also reports receiving licence fees from Becton Dickinson and serving as a consultant for Becton Dickinson. M.T. reports having received speaker honoraria from Novo Nordisk and Medtronic. L.L. reports having received speaker honoraria from Minimed Medtronic, Animas, Roche, Sanoﬁ, Insulet and Novo Nordisk, serving on advisory panels for Abbott Diabetes Care, Roche, Sanoﬁ, Minimed Medtronic, Animas and Novo Nordisk, receiving grants to attend educational meetings from Sanoﬁ, Novo Nordisk and Takeda. F.C. reports receiving speaking fees from Medtronic, Eli Lilly and Abbott, and serving on Advisory Boards for Medtronic, Novonordisk, Insulet and Eli Lilly. H.T. reports receiving research support from Dexcom. J.L., M.B., J.A. and D.R. have no conﬂicts to report.

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References


24 National Institute of Clinical Excellence. NICE guideline [NG17]. Type 1 diabetes in adults: diagnosis and management. Available at https://www.nice.org.uk/guidance/ng17/chapter/1-Recommenda-


