1 Exercising with an automated insulin delivery system: Qualitative insight into the hopes

2 and e	xpectations	of peopl	le with t	vpe 1 d	liabetes
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21 Key Points:

- Perceived impact of using automated insulin delivery systems for people with Type 1
 Diabetes and their families was explored in four sites (US, UK)
- Hopes, expectations and impact on sports and exercise was a key theme
- Automated insulin delivery systems could improve confidence to exercise for people with Type 1 Diabetes and their families.
- 27
- 28 Keywords: Automated insulin delivery system; Type 1 Diabetes; Qualitative research;
- 29 Exercise; Physical activity
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- 31

1 Abstract

For people with type 1 diabetes (T1D), regular exercise can be highly beneficial. Although exercise has been shown to improve quality of life and health for people living with TID, there are common barriers. To examine such issues, we explored the perceived impact that automated insulin delivery systems could have on the person with T1D and their families. One common theme found was hopes, expectations and impact on sports and exercise. Four sites (3-United States, 1-UK) were involved in this study. 284 participants (children (8-11 years), adolescents (12-18 years), parents/caretakers of children and adolescents with T1D; adults with T1D and their significant others/partners) were recruited across all sites. Between May and December 2015, focus groups and structured interviews were conducted and analysed using content analysis. Three themes found related to the benefits of automated insulin delivery systems: (a) more freedom and spontaneity in the individual's ability to exercise; (b) relief from worry of hypoglycaemia as a result of exercise; (c) removing the "guesswork" of adjusting insulin for exercise. Two further themes emerged relating to potential concerns with regard to safely exercising while wearing automated insulin delivery systems. Further research is encouraged into providing accurate algorithms and increase confidence for those using automated insulin delivery systems and their loved ones.

1 Introduction

2 Regular exercise for people with type 1 diabetes (T1D) has been shown to benefit insulin sensitivity, reduce cardiovascular risk factors, improve quality of life, and reduce mortality 3 for people with T1D.¹ However, there are also common barriers to exercise for people with 4 T1D. The main barriers linked to TID and exercise were fear of hypoglycaemia and lack of 5 knowledge about managing diabetes and its complications around exercise^{1,2} Using an insulin 6 pump provides flexibility in controlling the timing and amount of insulin delivered, 7 addressing some of the barriers to exercise.³ The addition of a continuous glucose monitor 8 (CGM) offers greater control over blood glucose levels and may help make exercise more 9 feasible.⁴ Training is required to ensure effective use of these technologies, addressing bolus 10 doses pre and post exercise³ and managing post exercise hyperglycaemia.³ 11

The automated insulin delivery systems include an insulin pump and CGM device 12 along with an algorithm embedded in either the insulin pump or a separate handheld device 13 14 that coordinates insulin delivery by the pump based upon the CGM results. In safety and efficacy trials, automated insulin delivery systems have shown to decrease hypoglycaemia^{5, 6}. 15 However, no known research outside of clinical trials exists which focuses on the 16 expectations of such systems. To address this gap, we explored the perceived impact that 17 18 automated insulin delivery systems would have on the person with T1D and their families. 19 One common theme found was hopes, expectations and impact on sports and exercise.

20 Participants and Methods

21 Four sites (Stanford University School of Medicine, California; Bournemouth University, UK; the Joslin Diabetes Center, Boston; and the Lurie Children's Hospital, Chicago) were 22 23 involved in this study. Ethical approval was granted from each institution's Institutional Research Board prior to recruitment. 284 participants were recruited across all sites through 24 flyers posted in clinics and hospitals, social media, as well as current infrastructures (e.g. 25 support groups).^{7,8} (see Table 1). Participants with and without knowledge and/or experience 26 of automatic insulin delivery systems were recruited and no specific manufacturer details of 27 current or previous pumps and/or CGM were provided. Participants included: children (aged 28 29 8-11 years) and adolescents (aged 12-18 years) with T1D; parents/caretakers of children and adolescents with T1D; adults with T1D and their significant others/partners. (Insert Table 1 30 here) 31

1 Between May and December 2015, focus groups and structured interviews were 2 conducted. Subsets of participants using pumps, CGM, and automated insulin delivery systems were included, but separated according to method of treatment. For example, those 3 who had already experienced participating in a clinical trial of an AID system would be 4 5 interviewed separately to those who had yet to have any experience with an AID system. Each site used a team of experienced and qualified focus group/interview facilitators who 6 7 worked from the same structured topic guide and explored in depth key issues around expectations of the automated insulin delivery system, hopes, anxieties, reasons for uptake, 8 9 perceived benefits/barriers, impact on daily function, possible reasons for discontinuation and potential barriers to optimal engagement. An explanation of the automated insulin delivery 10 system was not provided to enable the participants to discuss what they knew of the 11 technology and their hopes and expectations of this new technology. Following transcription 12 of the audio files, the data was analysed using thematic analysis⁸. The full method (e.g., full 13 inclusion criteria, sample questions, analysis) of this study has been published^{7, 8}. 14

15 **Results**

Three overriding themes were commonly discussed related to benefits of automated insulin delivery systems that included: (a) more freedom and spontaneity in the individual's ability to exercise; (b) relief from worry of hypoglycaemia as a result of exercise, and, (c) removing the "guesswork" of adjusting insulin for exercise. There were also two further themes that emerged related to potential concerns with regard to safely exercising while wearing automated insulin delivery systems. First, we will present findings regarding the potential benefits, followed by participant concerns.

23 Freedom to exercise

With regards to exercise, one of the most commonly discussed beliefs about automated
insulin delivery systems was the possible freedom it would provide. One aspect of this
freedom was being able to partake in exercise without constantly checking blood sugar
levels:

- It'd be nice on long runs, not to have to worry about getting low blood sugar. That
 would be nice. As it is, I always carry sugar with me, but sometimes, when I'm on a
 long run, I just don't feel like eating sugar (Adult, Focus group).
- It would be useful during exercise. Because if it was still making my blood sugar have
 better control, it would stop me from getting low during exercise and then spiking

afterwards. I think it would be very useful if you do a lot of sport (Adolescent, Focus
 group).

3 Experiencing hypoglycemia during intense or vigorous exercise is a common barrier to

4 exercise. The ability to be able to consistently train without a worry of experiencing

5 hypoglycemia was a perceived benefit:

6 If we're just talking about something that's say similar to an insulin pump on a CGM,

7 from a personal perspective, I would be absolutely fine with that if it means that I can

8 run without becoming hypoglycaemic after only a few miles and it means that I could

9 smash it through and run any distance that I want to run (Adult, Focus group).

Partners of the adult participants with T1D also shared the belief that the freedom to exercisewhen they wanted and as hard as they wanted would be a great benefit to their quality of life:

Just being able to say we're going to take a walk and we go take a walk. That wouldbe great (Partner, Focus group).

Similarly, children had a notion that automated insulin delivery systems would allow them toimprove sport performance:

It's keeping your numbers up during the match, so you don't have to like at half-time,
test and that. You can keep on routines and focus more on the actual game (Child,
Interview).

19 *Relief from worry*

The belief that automated insulin delivery systems would provide some relief from constant
worry about the possibilities of going hypoglycaemic and/or hyperglycaemic before, during,
and after exercise was discussed:

- Yeah,... I coach a junior football team so it would be nice not to have to panic while I
 am doing that and I am going to run low and have to run back and grab some more
 sweets (Adult, Focus group).
- The hardest time would probably be when I am doing exercise, because sometimes when I am doing exercise, I'm quite prone to go very low. And so, that would tell me if I am going up or going down, and I could just look and think I'm going to do this or do that and it would just really help (Child, Focus group).

1 Because, personally, sometimes when I do exercise, I go down, and sometimes I go 2 up... And I don't know how to prepare for it because if I eat food beforehand, and then I end up going up, I'll go really high. Or if ... I do exercise, I'll go really low. It 3 would definitely help with that (Adolescent, Interview) 4 Parents and children also highlighted the potential benefit of automated insulin delivery 5 6 systems especially during and after exercise for glycaemic control: 7 It's also the 'after exercise' effect that you can never be quite sure what's going to 8 happen and how long it is going to last for. It [would] be useful for that if you could go and do the exercise and not have to have all the extra thinking afterwards (Parent, 9 10 Focus group) 11 Since you're exercising, your blood sugar goes low. It could probably manage it and give you glucose at the same time (Child, Focus group) 12 We go to every game and everybody else is dropping their kids off and we're sitting 13 there just making sure that this – some of the coaches are volunteers so the last thing 14 you want to do is inconvenience them by "Okay, so if this ever happens, like this red 15 box right here; if she has this out, she could be low". And then to her recreational -16 the recreational district it is like, I don't know if I feel comfortable trusting – you 17 know the coaches are great, but it is like, I don't know if they feel comfortable 18 (Parent, Focus group). 19 20 The decrease in the constant worry concerning blood sugar levels were reported to aid frustration that currently can be a deterrent from exercise. 21 22 It can be really frustrating to have to eat immediately and so I think if it helped you in exercise that would be good and actually, I think it would potentially encourage more 23 24 people to exercise as well if it took away that risk of hypos and highs (Adult, Focus 25 group). 26 Partners also discussed the positive impact that this decrease in worry would have in their 27 partner's enjoyment of exercise. I do like the fact that while she's exercising, (...) the machine would be monitoring 28 and telling her before she got to that point, "Wait a minute, you just need to back off a 29 30 minute," take a few seconds or a few minutes, and maybe have something to eat if it's going down too quickly. So I think that would help her, she'd be able to do the 31

exercise and feel a lot more confident that at the end of it her blood sugar is still going
 to be okay (Partner, Focus group).

3 Relief from guesswork

Another potential benefit was the hope that automated insulin delivery systems would be able
to accurately measure blood sugar levels while exercising and adjust accordingly, decreasing
the need to "guess" the correct dose of insulin:

It does seem like it would take the human error aspect out of it... So it could
potentially – what I see as a benefit of this being for me is when I go out and ride for
three or four hours then I come home, I don't have to mess around with these
calculations. Potentially this could help and say okay well I don't need as much
insulin or my blood sugar is going down and then it would react accordingly (Adult,
Focus group).

Again, I can imagine that anything that reduces sort of the guess work of needing to know where her blood sugar is going to go, and eat appropriately or take the appropriate amount of insulin. She'd have to eat so much sugar to compensate for her blood sugar dropping during a workout that it wasn't worth it. And if the artificial pancreas [automated insulin delivery systems] could help avoid some of that guess work, I think it'd be great (Partner, Focus group).

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20 Potential Barriers

21 *Doubts about accuracy*

Although many participants anticipated a benefit of the system would be to automatically
adjust dosing based on exercise, confusion remained about what the system could offer in
these terms..

Sometimes during sports I wouldn't trust it... Or if I had a low I probably wouldn't
trust it. For sports, sometimes I'll get huge spikes, and it's from adrenaline not from
something else, so I'm afraid it might correct for that, and then just drop me down in
the middle of my hockey game or something and I'd get really sick (Adult, Focus
group).

For those who already had experienced using automated insulin delivery systems in clinical
trials, this was shown as one of the results of having used the system.

I deliberately didn't do any major walking or cycling on the weekends while I was on
 the system because I just didn't want to risk having a bad hypo in the night (Adult,
 Focus group).

These concerns were also shown as a worry regarding how automated insulin delivery
systems would adjust if they decided not to exercise.

No, I think it would actually be more restrictive in some ways. Because right now, I
would have to know, before I would have lunch, for instance, and then I decide 'Oh, I
want to walk after lunch.' Well, I can do something to finagle that, but if I said to it
'About to exercise, and I'm going to have lunch.' And then I decide not to exercise,
then what? (Adult, Focus group).

In addition, the terms of 'moderate' versus 'light' or 'vigorous' exercise inserted into thesystem feared it could potentially cause a problem.

13 [Respondent 4]: What is moderate exercise and what is light exercise?

[Respondent 5]: And how would you know what you are going to do? Like you could
give yourself insulin for moderate exercise and it turns out you do light exercise
(Adult, Focus group).

Well, and I know that [Name] just said, how are we going to define exercise too
because sometimes you will walk seven miles in a day and you don't necessarily think
of it as being exercise; you are just at work and you're busy, so how are we going to
quantify that? Does that only mean we're going to the gym or does that mean being
on your feet at work? I think it is kind of a slippery slope as it is with craving food. I
don't know – or just cleaning your house. You don't always know when you're
'exercising' (Adult, Focus group).

24 Physical appearance and comfort

When discussed specific situations where participants would want to disconnect the
automated insulin delivery systems, some participants, mainly teens and children, argued that
they would disconnect it to prevent someone seeing them wearing it during exercise or sport
events.

I probably wouldn't want to wear it when I exercise and do sports, but I don't really have a choice in that. That's the main time of movement where I wouldn't want to wear it (Child, Focus group). 1 Most participants stated that physical appearance was not a big issue for them. However,

2 some argued that they would not wear automated insulin delivery systems if the nature of the

3 exercise or sport prohibited comfortable usage, for example:

4 5 When I'm doing sports, it would be cool if I'd be able to remove it. Like with my insulin pump, I could unclip it (Adolescent, Focus group).

6 **Discussion**

7 One of the most prominent themes for the participants was the desire to feel they have the freedom to exercise. The common concern regarding the negative impact and constant worry 8 while exercising was consistent with previous research.^{9,10} However, these results present 9 participants' hope of lessening this negative impact on their exercise routine through using 10 11 automated insulin delivery systems. As inaccuracies of current treatment for exercise has been a strong deterrent from exercising for those with $T1D^{1,2,9}$, these findings demonstrate 12 13 that as systems become more accurate, people with T1D may exercise more regularly. The sense of freedom was also reported in being able to exercise without restrictions, e.g., not 14 pausing to eat or drink to prevent hypoglycaemia. This research shows that through the use of 15 automated insulin delivery systems, more people with T1D may be more confident to 16 exercise and as a result, feel the benefits of a regular exercise routine. 17

18 The perceived impact of what using automated insulin delivery systems would be like 19 was commonly reported as decreased worry with regards to exercising safely. Automated 20 insulin delivery systems have shown to provide a more accurate level of blood sugar 21 regulation and decrease instances of hypoglycaemia.^{11,12} The participants expressed that with 22 a constant regulation and ability to automatically adjust blood sugar accordingly to exercise 23 level, automated insulin delivery systems may decrease worry and fear.

24 The discussions of potential benefits and drawbacks of using automated insulin delivery systems for exercise have shown it was perceived to be beneficial to not only the 25 consistency of exercise, but reduce worry of hypo and hyperglycaemic incidents, if 26 automated insulin delivery systems worked accurately. However, these positives relied on the 27 ability for the person using automated insulin delivery systems to trust the device, and as 28 potential uncertainties were evident, this trust might not be arrived at easily. Limitations of 29 this study were the differences in demographic data collected that limited the ability to 30 compare across groups based on demographic and behavioural aspects.^{7,8} 31

- 1 Findings from this study have provided novel first-hand insight into the potential
- 2 benefits and barriers to automated insulin delivery systems during exercise. Further research
- 3 is encouraged into providing accurate algorithms and increase confidence for those using
- 4 automated insulin delivery systems and in turn, their exercise colleagues and loved ones.

5 Conclusion

- 6 First-hand insight was shown of the potential benefits and drawbacks of using automated
- 7 insulin delivery systems for exercise. Although the insights have been mostly positive and
- 8 ones of hope, worries still remain. Trust in the system must play a fundamental role in
- 9 onboarding and training associated with automated insulin delivery systems. Automated
- 10 insulin delivery systems can potentially lead to an increase in exercise levels for people with
- 11 diabetes and, subsequently, improved health status if managed effectively.
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