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The impact of real-time sensor technology on quality of life for adults with type 1 diabetes: A Dutch national survey

Per Winterdijk^a, Henk-Jan Aanstoot^a, Giesje Nefs^{a,b,c,*}

^a Diabeter, Center for Type 1 Diabetes Care and Research, Blaak 6, 3011 TA Rotterdam, the Netherlands

^b Radboud University Medical Center, Department of Medical Psychology, Huispost 926, PO Box 9101, 6500 HB Nijmegen, the Netherlands

^c Tilburg University, Center of Research on Psychological Disorders and Somatic Diseases (CoRPS), Department of Medical and Clinical Psychology, PO Box 90153, 5000

LE Tilburg, the Netherlands

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ABSTRACT

Aims: To examine the impact of real-time continuous glucose monitoring (RT-CGM) on quality of life in Dutch adults with type 1 diabetes, inside/outside automated insulin delivery (AID) systems. *Methods:* In this cross-sectional retrospective observational study, RT-CGM users completed an online survey

including (adapted) validated questionnaires, study-specific items and open-ended questions. *Results*: Of 893 participating adults, 69% used the RT-CGM as part of AID. The overall sample reported improvements in quality of life related to RT-CGM use (irrespective of initial indication), particularly with respect to physical health, emotional wellbeing and energy. Merits for sleep, intimacy and cognitive diabetes load lagged somewhat behind, mostly when RT-CGM was not integrated in AID. Users of AID had significantly larger improvements in overall quality of life, fatigue and diabetes-specific distress than users of sensor-augmented pump

or Open Loop treatment. In regression analyses, user evaluations were associated with perceptions of benefit and burden. In qualitative content analysis, benefits (e.g. life 'normalization', increased perceptions of control) outweighed burdens (e.g. technology frustrations, confrontation with diabetes).

Conclusions: RT-CGM positively impacted the quality of life of adults with type 1 diabetes. This justifies a (re-) consideration of broader access. Increased support to maximize device benefits and minimize burdens is also warranted.

1. Introduction

Since the broader dissemination of real-time continuous glucose monitoring (RT-CGM) technology in type 1 diabetes (T1D) care over a decade ago, devices have made important advances in accuracy, ease of use and convenience. For example, glucose readings are available every five minutes, devices have become smaller and less invasive, alarms are more customizable, and factory-calibration significantly reduces the need for additional fingerpricks [1]. The glycemic benefits of RT-CGM over intermittently scanned sensors (isCGM) have been previously described in randomized controlled trials, finding higher Time-In-Range (TIR; 60% vs. 52% and 76% vs. 67%) and lower Time-Below-Range (TBR; 0.5% vs. 0.8% and 5% vs. 7%) [2,3]. A *meta*-analysis based on three trials covering 150 participants concluded that RT-CGM had a similar impact on HbA_{1c} and TIR when combined with either open loop

pump therapy or MDI [4].

The recent next step of integrating sensor technology in automated insulin delivery (AID) systems has brought glycemic outcomes even closer to international clinical targets [5–7]. Randomized trials have found the most recent systems to increase TIR up to 70–85% and to reduce or stabilize TBR, while metrics remained largely unchanged for those randomized to MDI plus fingerpricks, MDI plus isCGM, or SAP [8–10]. Real-world studies have confirmed benefits of advanced AID irrespective of previous treatment strategy and baseline HbA_{1c} [11–13].

Qualitative studies and retrospective surveys suggest that sensor technology may also positively affect quality of life (QoL), particularly in terms of increased feelings of safety, confidence in self-management and flexibility in daily life as well as reduced distress and dependency [14,15]. Person-reported outcomes (PROs) in randomized controlled trials have been less consistent, although heterogeneity in study

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^{*} Corresponding author at: Radboud university medical center, Department of Medical Psychology, Huispost 926, PO Box 9101, 6500 HB Nijmegen, The Netherlands.

E-mail addresses: p.winterdijk@diabeter.nl (P. Winterdijk), h.j.aanstoot@diabeter.nl (H.-J. Aanstoot), Giesje.Nefs@radboudumc.nl (G. Nefs).

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characteristics and devices hampers direct comparisons. Positive changes were most pronounced for diabetes-specific (rather than generic) QoL elements and for recent devices [2,8,15,16]. Sensor technology may also have negative effects, including wear-related issues, technology frustrations, work load, life intrusions, distrust or overreliance, and unrealistic expectations [14,15]. Most existing studies have focused on a limited number of PRO domains at the same time, have taken either a qualitative or a quantitative (rather than a mixedmethod) approach, and have not examined whether outcomes differ when RT-CGM is used within as compared to outside an AID system. Furthermore, findings are often scattered across populations, complicating conclusions about the merits of RT-CGM in national settings.

In The Netherlands, RT-CGM reimbursement is limited to four categories (HbA_{1c} > 64 mmol/mol (8%) over extended periods, repeated severe hypoglycemic events and/or impaired awareness of hypoglycemia, pregnancy, and pregnancy wish) [17], creating a societal debate. In light of broader RT-CGM reimbursement, it is important to obtain a representative, detailed overview of the experiences – both positive and negative – of Dutch adults with T1D currently using RT-CGM sensor technology. Therefore, the present study examines the impact of RT-CGM use (inside/outside AID) on QoL in this group.

2. Subjects, materials and methods

2.1. Procedure

This cross-sectional observational study focused on Dutch adults (18 + years) with T1D currently using RT-CGM in regular care (eligible n \approx 8,000–10,000). isCGM sensors were included when integrated in an open source Artificial Pancreas System (APS). Care and advocacy organizations (listed in the Acknowledgements) distributed a link to the information folder, consent form and anonymous Castor survey through their communication channels. Ethical review was waived (CMO-2022–13617); the Declaration of Helsinki was followed.

Table 1 displays survey content.

To describe the sample, we included study-specific questions (categorical, with an option to elaborate on the answer 'Other') measuring age, gender, diabetes duration, recent HbA_{1c} , and TIR and TBR in the previous two weeks. We also measured general affinity with technology using two items from the Technology Readiness Index (TRI) [18,19]. To describe RT-CGM use and prescription, we included study-specific questions (categorical, with an option to elaborate on the answer 'Other') measuring RT-CGM brand, combination with insulin administration modality, duration of use of (any) RT-CGM, frequency of RT-CGM use, indication for RT-CGM, and the decision process around prescription.

Quality of life was measured using (a) (adapted versions of) validated questionnaires, (b) study-specific questions, and (c) open-ended questions. To assess how certain life domains were changed by RT-CGM use, we used a 7-point Likert scale ranging from 'greatly improved' to 'greatly worsened' for the items of the DAWN2 Impact of Diabetes Profile (DIDP-7; perceived impact of diabetes on quality of life [20]), Abbreviated fatigue questionnaire (VVV; fatigue [21]) and Problem Areas in Diabetes questionnaire (PAID-5; diabetes distress [22]). We added study-specific items related to general QoL, exercise, intimacy, energy and sleep. Participants were also asked to indicate their appraisals (5-point Likert scales, ranging from strongly disagree to strongly agree) of RT-CGM using the Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations questionnaire (INSPIRE; impact of technology on QoL [23]), the Convenience and Intrusiveness subscales of the Glucose Monitoring Experiences Questionnaire (GME-Q; satisfaction with glucose monitoring [24]) and the Glucose Monitoring Satisfaction Survey (GMSS-T1D; satisfaction with glucose monitoring [25]). General measures of satisfaction included the Net Promotor Score [26] (based on the question "How likely would you recommend RT-CGM to a friend or colleague?"; calculated by subtracting the percentage of

Table	T	

Overview	of	survey	content.
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CONSTRUCT	MEASURE	ITEMS	SCALE	SCORING
Descriptives	Sensor type, duration and frequency of use, indication,	5+3	Categorical; open-ended	% per category
	decision process System (pump, link)	1 + 2	Categorical; open-ended	% per category
	Diabetes duration	1	Categorical	% per category
	Glucometrics (TIR, TBR, HbA _{1c})	3 + 1	Categorical	% per category
	Age, gender	2+1	Categorical; open-ended	% per category
	TRI OPT4, INN5 [18,19] adapted	2	7 = strongly agree; 1 = strongly disagree	Item score (1–7)
Quality of life	Benefits/burdens	2	Open-ended	
	DIDP-7 [20] adapted	7	1 = greatly improved; 7 = greatly worsened	Item score and mean of completed items (1–7)
	Additional domains: General, exercise, intimacy, energy, sleep	5	1 = greatly improved; 7 = greatly worsened	Item score (1–7)
	VVV [21] adapted	4	1 = greatly improved; 7 = greatly worsened	Item score and mean of completed items (1–7)
	PAID-5 [22] adapted	5	1 = greatly improved; 7 = greatly worsened	Item score and mean of completed items (1–7)
	INSPIRE adults (post) [23]	22	0 = strongly disagree; 4 = strongly agree	Mean of completed items \times 25 (0–100)
	GME-Q	13	1 = strongly	Mean of
	convenience, intrusiveness		disagree; $5 =$ strongly agree	completed items (1–5)
	[24] GMSS-T1D [25]	15	1 = strongly disagree; 5 = strongly agree	Total and subscale scores: Mean of completed items (1–5)
	Sensor satisfaction	1	VAS scale (not satisfied at all; very satisfied)	Item score (1–10)
	Net Promoter Score [26]	1	0 = not likely at all; 10 = very likely	% promoters minus % critics (-100 +100)
	Next year sensor outlook	1	Stop; hesitation in general; hesitation specific sensor; switch; continue	% per category
	Other sensor experiences	1	Open-ended	

DIDP: DAWN2 Impact of Diabetes Profile; GME-Q: Glucose Monitoring Experiences Questionnaire; GMSS: Glucose Monitoring Satisfaction Survey; INSPIRE: Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations questionnaire; PAID: Problem Areas in Diabetes questionnaire; TBR: Time-Below-Range; TIR: Time-In-Range; TRI: Technology Readiness Index; VVV: Verkorte VermoeidheidsVragenlijst ('Abbreviated fatigue questionnaire'); +x: dependent question, i.e. question asked to subsample only, based on answer to previous question. Number of missing values tolerated: DIPD-7 = 3, VVV = 1, PAID-5 = 1, INSPIRE = 21, GME-Q subscales = 2, GMSS subscales = 1.

people giving a rating of \leq 6 from the percentage of people giving a rating of 9 or 10), and study-specific questions asking how satisfied people were to be able to use RT-CGM as part of their diabetes management (Visual Analogue Scale; VAS) and how they viewed the upcoming year with RT-CGM (categorical variable). As input for the qualitative analysis, we asked participants three open-ended questions: "What do you like about the RT-CGM sensor?", "What don't you like about the RT-CGM sensor?".

2.2. Statistical analysis

Quantitative analysis were run using IBM SPSSv25. Descriptive statistics were used to provide information on background sample characteristics, RT-CGM use and prescription, and PROs for the total group (total scores, subscale scores, item scores). Independent-samples t-tests or chi-square tests were used to compare PROs between groups: (a) men versus women, (b) participants having started RT-CGM outside versus within national reimbursement rules, (c) AID versus Sensor-Augmented Pump (SAP) and stand-alone RT-CGM (Open Loop). The general measures of satisfaction were analyzed using descriptive statistics. To determine correlates of positive RT-CGM experience (INSPIRE) and of satisfaction with using RT-CGM as part of diabetes management (dichotomized VAS), we used multiple linear and logistic regression analyses, respectively. P < 0.05 indicated statistical significance.

Answers to the open-ended questions were analyzed using qualitative content analysis in Microsoft Word. Coding steps included coding of different responses (open coding), grouping codes into categories (axial coding) and grouping categories into a hierarchical structure (selective coding). We followed a deductive-inductive approach, i.e. categories were developed using themes from previous research as well as new concepts emerging from the data. The developed coding schemes related to RT-CGM advantages and disadvantages (and their trade-off), as well as the outlook on RT-CGM in diabetes care.

3. Results

3.1. Sample characteristics

Of 1,163 people consenting, n = 21 were not eligible (n = 17 used (unadjusted) isCGM, n = 3 were parents, n = 1 was double) and n = 65 discontinued before submitting any further information. Of the remaining 1,077 eligible participants, n = 184 only completed descriptives and were excluded. In total, n = 893 people shared at least some experiences with RT-CGM of whom n = 777 completed the full survey. Table 2 provides background sample characteristics, Table 3 describes RT-CGM use and prescription. For 92%, the person with diabetes and health care provider(s) had agreed to start RT-CGM. Perceived clinical restrictions included hesitations about indication and –no longer applicable- limited hospital budgets. Non-reimbursed alternatives were out-of-pocket payment, materials from others, open source or experimental solutions, and hospital switches.

3.2. Person-reported outcomes

Table 4 and Supplementary Table 1 report person-related outcomes related to RT-CGM use. Compared to life pre-sensor, the overall sample reported a small-medium (DIDP-7 composite score) or medium-large (individual DIDP-based item; INSPIRE item 16) improvement in general QoL. Mean scores on the adapted DIDP-7 and four additional items indicated small-medium improvements on specific life dimensions. The most positively affected domains were physical health, emotional wellbeing and energy; minimal to small improvements were found for

Table	2

Sample characteristics (n = 893).

iable		% (n) or mean \pm SD
Age	18-25 years	17 (155)
	26-30 years	15 (138)
	31-40 years	26 (231)
	41-50 years	19 (169)
	51-60 years	16 (140)
	61–70 years	5 (49)
	70 + years	1 (11)
Gender	Man	24 (218)
	Woman	75 (669)
	Non-binary	1 (6)
Diabetes duration	<6 months	0.2 (2)
	6-12 months	0.3 (3)
	1-5 years	9 (84)
	6–10 years	12 (110)
	11–15 years	14 (122)
	16-20 years	15 (135)
	21-25 years	12 (110)
	25 + years	37 (327)
HbA _{1c} in previous three months, % (mmol/ mol) ^a	<6.5 (48)	22 (197)
	6.5-6.9	25 (223)
	(48–52)	
	7.0–7.4	20 (179)
	(53–57)	
	7.5–7.9	9 (77)
	(58–63)	
	8.0-8.4	5 (45)
	(64–68)	
	8.5-8.9	2 (22)
	(69–74)	
	9.0–9.4	1 (10)
	(75–79)	
	9.5–9.9	0.6 (5)
	(80–85)	
	10 (86) or	0.3 (3)
	higher	
	I don't know	2 (18)
	No	13 (114)
	measurement	
Time-in-range in previous two weeks	<50%	3 (28)
	50–59%	4 (39)
	60–69%	9 (84)
	70–79%	26 (233)
	80-89%	38 (338)
	90–100%	15 (138)
	I don't know	4 (33)
Time-below-range in previous two weeks	<1%	27 (239)
	1-2%	38 (341)
	3–4%	21 (185)
	5% or higher I don't know	8 (68) 7 (60)
TRI OPT4 'You prefer to use the most		$\textbf{6.1} \pm \textbf{1.4}$
advanced technology available'		
TRI INN5 'You keep up with the latest technological developments in your daily life'		5.7 ± 1.4

Note: Values may not add to 100% due to rounding. ^a Based on laboratory value for n=625, based on sensor Glucose Management Indicator for n=154. TRI: Technology Readiness Index.

one's financial situation, intimacy and relationships. The number of people selecting the response options 'worsened' or 'greatly worsened' was low across domains (range 0.5% for relationships to 3% for financial situation and sleep). Fatigue (VVV) and diabetes-specific distress (PAID-5) showed small to medium improvements.

Overall appraisal of RT-CGM was positive (INSPIRE mean 78). Highest INSPIRE mean item scores were for 'helped me when I was pregnant', 'improved my overall QoL', 'helped me stay in my target range more often' and 'made managing diabetes easier when I was at work or school'. The number of people indicating they (strongly)

Table 3

Description of RT-CGM use and prescription (n = 893).

Description of RT-Com use and pre	3cription (n = 055).	
Variable		% (n)
Sensor brand	Dexcom G5	0.7 (6)
School brand	Dexcom G6	37
	Dexcolii Go	(334)
	Eversense	0.4 (4)
	FreeStyle Libre 3	3 (29)
	Medtronic Guardian Connect 3	26
	Meditolile Guardian Connect 5	(233)
	Medtronic Guardian Connect 4	31
	Meditoliic Guardian Connect 4	(279)
	'Tweaked' FreeStyle Libre 2	(279) 0.9 (8)
Link with inculin nump	-	0.9 (8) 8 (67)
Link with insulin pump	No, insulin pen	
	No, separate pump	10 (93)
	Yes, commercial sensor-	13
	augmented pump	(114)
	Yes, commercial hybrid closed	58
	loop system	(521)
	Yes, open source Artificial	10 (92)
	Pancreas System ^a	
	Yes, experimental system (e.g.	0.7 (6)
	Inreda)	
Duration of use of (any) RT-	<1 month	4 (33)
CGM		
	2–12 months	24
		(213)
	1–2 years	27
		(245)
	3–5 years	27
		(244)
	6-10 years	13
		(113)
	10 + years	5 (45)
Intensity of RT-CGM use	Sometimes (<50% of the time)	0.1 (1)
	Regularly (50–75% of the time)	0.7 (6)
	Often (76–90% of the time)	2 (22)
	Almost always (over 90% of the	97
	time)	(864)
Indications		
Within national	High HbA _{1c}	22
reimbursement rules		(198)
	Hypoglycemia	40
		(359)
	Pregnancy (wish)	17
	0	(154)
	Start before turning 18 years	1 (7)
Outside national	Unspecified	14
reimbursement rules	*	(128)
	Glucose fluctuations	2 (20)
	Work	1 (6)
	Psychological	1 (6)
	Sports	1 (6)
	Pilot or experimental use	1 (5)
	Co-morbidities	0.4 (4)
Decision making process		
Consensus	HCP agreed (almost)	31
	immediately	(281)
	HCP agreed after some	11 (97)
	discussion	11 ()/)
	HCP agreed after extensive	5 (49)
	discussion	- ()
	PWD agreed (almost)	39
	immediately	(344)
	PWD agreed after some	4 (33)
	discussion	. (30)
	PWD agreed after extensive	1 (6)
	discussion	- (5)
	Joint process ^b	1 (11)
Delayed consensus	After HCP saw benefits of out-	1 (5)
Dentyea consensus	of-pocket RT-CGM	1 (3)
No consensus	No prescription	3 (23)
110 CONSCIISUS	No discussion	3 (23)
	HCP (cautiously) positive, yet	3 (29) 1 (6)
	no prescription	1 (0)
Unclear	no prescription	1 (0)
Unclear		1 (9)

Note: Values may not add to 100% due to rounding. $^{\rm a}$ Also known as Do-It-Yourself Closed Loop System; $^{\rm b}$ often facilitated by intermittently scanned

glucose monitoring devices falling short or the need for a new insulin pump. PWD: person living with diabetes; RT-CGM: real-time continuous glucose monitoring sensor.

Table 4

Person-reported outcomes for RT-CGM users (total and subscale scores), for the total group and stratified according to treatment modality.

	n	Total group Mean ± SD	SAP or Open Loop ^d Mean ± SD	AID Mean ± SD	<i>p</i> -value
DIDP-7 adapted composite score ^a	859	2.5 ± 0.8	2.6 ± 0.8	2.4 ± 0.8	<0.001
VVV adapted composite score ^a	837	$\textbf{2.6} \pm \textbf{1.1}$	2.9 ± 1.2	2.5 ± 1.0	<0.001
PAID-5 adapted composite score ^a	727	$\textbf{2.6} \pm \textbf{1.1}$	2.8 ± 1.1	2.6 ± 1.1	0.01
INSPIRE scaled score	843	$\begin{array}{c} \textbf{78.4} \pm \\ \textbf{15.3} \end{array}$	75.8 ± 16.2	79.5 <u>+</u> 14.8	0.001
GME-Q ^c					
Convenience	801	$\textbf{3.9}\pm\textbf{0.7}$	$\textbf{4.0} \pm \textbf{0.7}$	$\textbf{3.9}\pm\textbf{0.6}$	0.24
Intrusiveness	798	1.9 ± 0.6	2.0 ± 0.6	1.9 <u>+</u> 0.6	0.006
GMSS ^c					
Composite score	785	$\textbf{4.1}\pm\textbf{0.6}$	$\textbf{4.1} \pm \textbf{0.6}$	$\textbf{4.2}\pm\textbf{0.5}$	0.26
Openness	779	$\textbf{4.0} \pm \textbf{0.7}$	$\textbf{4.0} \pm \textbf{0.7}$	$\textbf{4.1} \pm \textbf{0.7}$	0.15
Emotional burden	779	1.8 ± 0.7	1.9 ± 0.8	1.7 ± 0.7	0.01
Behavioral burden	779	1.8 ± 0.6	1.7 ± 0.6	1.8 ± 0.7	0.21
Trust	783	$\textbf{4.1}\pm\textbf{0.8}$	$\textbf{4.1} \pm \textbf{0.8}$	$\textbf{4.1}\pm\textbf{0.8}$	0.71

^a1 = greatly improved, 7 = greatly worsened; ^b0 = very negative appraisal, 100 = very positive appraisal; ^c1 = lowest endorsement, 5 = highest endorsement; ^d RT-CGM paired with insulin pen or stand-alone insulin pump. Bold: statistically significant at p < 0.05. AID: Automated Insulin Delivery system (i.e. commercial, open-source, experimental); DIDP: DAWN2 Impact of Diabetes Profile; GME-Q: Glucose Monitoring Experiences Questionnaire; GMSS: Glucose Monitoring Satisfaction Survey; INSPIRE: Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations questionnaire; PAID: Problem Areas in Diabetes questionnaire; SAP: Sensor-Augmented Pump; VVV: Verkorte VermoeidheidsVragenlijst ('Abbreviated fatigue questionnaire').

disagreed with statements of improvement were highest for 'made it easier to eat when I wanted to' (11%), 'helped me sleep better' (11%) and 'improved my HbA1c to target level" (9%). While for most domains well over half of participants (strongly) agreed with statements of improvement, for helping diabetes management in sex life this lagged with 45%. On average, people agreed with RT-CGM convenience (GME-Q mean subscale score 3.9), trustworthiness (GMSS mean Trust score 4.1) and freedom (GMSS mean Openness score 4.0); they disagreed with its intrusiveness (GME-Q mean subscale score 1.9) and emotional/ behavioral burden (GMSS mean subscale scores 1.8 and 1.8, respectively). As to individual GME-Q and GMSS items, the largest benefits focused on feeling less restricted by diabetes and feeling more satisfied with diabetes management. The most pronounced burdens included constantly looking at glucose levels, sleep disruptions, excessive thinking about diabetes, RT-CGM not being as accurate as desired, and skin irritations or bruises.

We found no significant differences in the eleven person-reported outcomes of Table 4 when stratifying by gender (data not shown). The only exceptions were diabetes-distress (mean \pm SD PAID-5: 2.8 \pm 1.1 for men, 2.6 \pm 1.1, p = 0.03, Cohen's d = 0.18) and Openness (GMSS: 3.9 \pm 0.7 for men, 4.1 \pm 0.7 for women, p = 0.006, Cohen's d = -0.23). Based on these findings we did not explore the role of gender in more detail. We also did not find significant differences in the eleven person-reported outcomes of Table 4 when comparing people who started with RT-CGM outside (n = 175) versus within (n = 718) national reimbursement rules (data not shown).

When comparing the person-reported outcomes in Table 4 according to treatment modality, users of AID systems reported a significantly larger improvement in overall QoL (Cohen's d = 0.25), fatigue (d =0.32) and diabetes-specific distress (d = 0.20) than those using SAP or Open Loop. They also had a significantly more positive appraisal of RT-CGM use (d = -0.24) and experienced a lower level of intrusiveness (d =0.22) and emotional burden (d = 0.21). Scores on convenience, openness, behavioral burden and trust did not differ significantly. When repeating this comparison for the main themes that lagged behind in improvement for the total sample, people using AID reported more optimal sleep (DIDP sleep item 2.1 \pm 1.4 vs. 2.7 \pm 1.5, p < 0.001, Cohen's d=0.42; GMEQ item 6 - sleep disruptions 2.2 \pm 1.1 vs. 2.6 \pm 1.2, p < 0.001, d = 0.27) and less cognitive load (GMEQ item 14 - intensity of glucose checking 2.4 ± 1.1 vs. 2.9 ± 1.1 , p < 0.001, d = 0.38; GMSS item 2 – excessive thinking about diabetes 2.2 ± 1.0 vs. 2.5 ± 1.1 , p < 0.001, d = 0.27) than those using SAP or Open Loop. Similarly, significantly less people using AID (strongly) disagreed with statements of improvement regarding sleep (INSPIRE item 14; 9% vs. 15%, p =0.01) and HbA_{1c} reduction (INSPIRE item 8; 7% vs. 15%, p < 0.001) than those using SAP or Open Loop. Intimacy did not differ significantly between both groups (DIDP); neither did the number of people (strongly) disagreeing with the statement that RT-CGM brought them more freedom of eating (INSPIRE item 9).

3.3. Satisfaction

Satisfaction with being able to use RT-CGM in diabetes management was high (VAS mean \pm SD: 9.4 \pm 1.1; median, interquartile range: 10, 9–10; 88% >8). The Net Promotor Score was excellent (+87; n = 684 9–10, n = 9 0–6). In the upcoming year, 81% (n = 630) wanted to continue with their current sensor, 17% (n = 128) wanted to switch to a different RT-CGM, 2% (n = 12) hesitated about continuing with their current sensor, 0.4% (n = 3) hesitated about continuing RT-CGM in general, and 0.1% (n = 1) wanted to quit RT-CGM altogether.

3.4. Regression analyses

Positive experiences (INSPIRE) and high satisfaction (VAS \geq 9) were significantly positively associated with GME-Q Convenience, GMSS Openness and Trust, and negatively associated with GMSS Emotional burden (Table 5). Additional negative correlates for INSPIRE were age 51–70 + years (vs. 26–50 years), TIR < 70% (vs. \geq 70%) and TBR \geq 5% (vs. < 5%). For satisfaction, this included GMSS Behavioral burden.

3.5. Qualitative evaluation

With a few exceptions ('it sucks', 'too complicated', 'forced' AID precondition), reactions were skewed in favor of the positive. Prerequisite was a 'good quality system', working as it should. Partly, evaluations were model-specific in terms of design, features and technical limitations (e.g. displays; pump connection; remote control or app; calibrations; retrospective data; sharing). Benefits and burdens could span the same domain, e.g. nocturnal alerts costing sleep. In the benefit-burden trade-off, many described a 'love-hate relationship' where merits surpassed any inconvenience. 'I have walked around with blisters and torn pieces of skin in order to be able to wear the RT-CGM, and it was well worth it' [Woman, 51–60 years, open source APS].

3.5.1. Becoming more like a person without diabetes

3.5.1.1. More stable glucose levels. Often as part of AID, RT-CGM helped people achieve unprecedented TIR and HbA_{1c}. Glucose excursions (particularly at night) were significantly reduced in terms of frequency, variability, amplitude, duration, symptomatology and severity. *Without RT-CGM, achieving near-normal TIR is not possible; imagine having to keep*

Table 5

Correlates of positive experiences with RT-CGM (total INSPIRE scaled score) and satisfaction with being able to use RT-CGM in diabetes management (dichotomized VAS scale).

	Positive experiences (total INSPIRE scaled score) n = 779		High satisfaction (item score $\ge 9^{c}$) n = 776	
	Beta	P-value	OR (95% CI)	P-value
Age				
18–25 years (vs. 26–50 _ years)	-0.05	0.09	0.75 (0.42–1.36)	0.34
51–70 + years (vs. 26–50 years)	-0.09	0.001	0.67 (0.41–1.11)	0.12
Gender				
Women (vs. men)	-0.01	0.61	1.14 (0.70–1.83)	0.60
Non-binary (vs. men)	0.02	0.37	-	1.00
AID (vs. SAP or Open Loop ^a)	0.03	0.34	0.64 (0.38–1.07)	0.09
GME-Q				
Convenience	0.12	<0.001	2.14 (1.36–3.35)	<0.001
Intrusiveness	-0.01	0.77	0.79 (0.50–1.24)	0.30
GMSS				
Openness	0.38	<0.001	1.77 (1.18–2.64)	0.005
Emotional burden	-0.13	0.002	0.59 (0.38–0.92)	0.02
Behavioral burden	-0.05	0.22	0.64 (0.41–0.99)	0.04
Trust	0.12	<0.001	1.59 (1.15–2.19)	0.005
Time-In-Range, <70% (vs. \geq 70%) ^b	-0.07	0.02	0.77 (0.42–1.42)	0.41
Time-Below-Range, \geq 5% (vs. < 5%) ^b	-0.09	<0.001	0.97 (0.44–2.13)	0.95
HbA _{1c} ^b				
53–68 mmol/mol, 7–8.4% (vs. < 53 mmol/mol)	-0.06	0.06	0.63 (0.38–1.06)	0.08
≥69 mmol/mol, ≥8.5% (vs. < 53 mmol/mol)	-0.05	0.07	1.21 (0.39–3.75)	0.74

Bold: statistically significant at p < 0.05. ^a RT-CGM paired with insulin pen or stand-alone insulin pump; ^{bs}Unknown' was included as category; ^c 80% (n = 617). AID: Automated Insulin Delivery system (i.e. commercial, open-source, experimental); CI: Confidence Interval; GME-Q: Glucose Monitoring Experiences Questionnaire; GMSS: Glucose Monitoring Satisfaction Survey; OR: Odds Ratio; SAP: Sensor-Augmented Pump; VAS: Visual Analogue Scale.

to the speed limit while driving without having a speed indicator.' [Man, 41–50 years, commercial AID]. There was less need for emergency services and, for women, RT-CGM aided in healthy pregnancy. Coping with multi-morbidity also became easier, including slowing down existing complications, handling conditions with a glycemic effect, recovering from medical procedures, and distinguishing diabetes from other symptoms. Unmet expectations regarding glycemic benefits mostly related to glucose fluctuations and hypoglycemia.

3.5.1.2. Getting (part of) your life back. By using RT-CGM, people commonly felt less like a 'patient', regaining independence, spontaneity, and freedom: 'For the first time in 30 years I can go out without a bag, with only a phone and some glucose tablets in my pockets' (Woman, 41–50 years, commercial AID). It gave some the confidence to 'start living again' and engage in activities long-abandoned or endured with great anxiety such as driving, exercising, eating certain foods, being alone (with small children), outside activities and pregnancy. It became easier to 'keep up with the rest', e.g. work productivity, sick days, student life. For some, it was the only way to navigate work with irregularity or responsibility, to work fulltime, or to work altogether. It also obviated compensatory

behaviors, e.g. keeping glucose higher at work. Being able to sleep throughout (most of) the night meant 'starting the day with a 1–0 lead'. People felt 'better than ever before': less depressed, more resilient and fitter. 'I still feel tired, but it more closely resembles 'normal' fatigue' [Woman, 26–30 years, commercial AID]. RT-CGM could also facilitate (recovery from) physical exercise, by providing timely access to glucose (trends) or -for AID- by allowing people to enjoy and focus on activity instead.

3.5.2. Changing perceived personal control over diabetes

3.5.2.1. Increased glucose actionability. Generally, people could take early action, improved hypo- and hyperglycemia awareness, and benefited from AID. Glucose readings were more accessible (e.g. smartwatches, CarPlay). Real-time continuous data and trends facilitated decision making, activity anticipation (e.g. driving) and situational adaptation (e.g. illness). 'When comparing diabetes management with and without RT-CGM, having no sensor compares best to trying to drive a car while blindfolded and only getting a snapshot of the road every couple of miles.' [Woman, 18–25 years, Open Loop with pump]. RT-CGM also illustrated the glycemic effects of foods, exercise and stress, informed insulin adjustments, and enriched hospital consultations.

3.5.2.2. Increased sense of safety. People described peace of mind, relying on alerts and alarms and sharing data with others. AID corrected human omissions or input errors. 'Without RT-CGM, I feel like a tightrope walker without a safety net' [Man, 41–50 years, open source APS]. RT-CGM instilled a sense of 'not having to do it alone' and 'sharing diabetes burden'. This significantly reduced worries (e.g. unnoticed and nocturnal hypoglycemia; complications). 'In my case RT-CGM did not necessarily lead to improvements in TIR or HbA_{1c}, because those were optimal already. But only because I was checking my glucose constantly, leaving little room in my life for relaxation' [Woman, 18–25 years, commercial AID]. It also resulted in better sleep, less family member worries, less hypo-related binges and increased bodily trust.

3.5.3. Changing diabetes burden

3.5.3.1. RT-CGM as a 'lifesaver'. For many, RT-CGM was a relieve: from 'unlivable' to '(very well) livable' and from 'adrift' to 'in control'; some spoke of 'life before' and 'life after'. 'For me, it's the invention of the century. I was so depressed because of all the restrictions I seriously considered ending my life.' [Woman, 41–50 years, Open Loop with pen]. It brought back value and improved perspective, i.e. more hope of growing old without or despite complications. 'My father died from diabetes at a young age. Due to the RT-CGM, I believe I WILL be able to see my children grow up!' (Woman, 31–40 years, commercial AID).

3.5.3.2. Changed diabetes work-load. Particularly with AID, RT-CGM freed up time, energy and head space for other activities. 'It makes diabetes somewhat less like a 24/7 job' [Woman, 18-25 years, commercial AID], 'It saves me 80% of the thinking' [Woman, 51–60 years, open source APS], 'It means having to do much less yourself for much better glucose levels' [Man, 61-70 years, commercial AID]. Compared with fingerpricks and isCGM, ease of use was greater. 'I can check my glucose at night and during driving without the inconvenience of scanning. Even if I'm wearing my coat, it's convenient that I don't have to scan anymore but can immediately see [my glucose]' [Woman, 18-25 years, Open Loop with pump]. In contrast, some people felt lived by RT-CGM, becoming stuck in perfectionism and micromanagement. 'The sheer surplus of insight and information sometimes leads to overstimulation [...] Therefore, on some days, I decide not to wear a sensor.' [Woman, 18-25 years, commercial AID]. By uncovering all excursions, it provoked a sense of personal failure. Other people described diabetes care had become technology management (Supplementary Table 2). Supplementary Table 3 details AID-related experiences.

3.5.3.3. (*Dis*)comfort. No longer having to 'pincushion' one's fingers was a relief. Some had skin reactions to adhesives (itch, irritation, rash, blisters), entry point inflammation, wounds and scar tissue from forced overuse or removals. Sensor insertion (slightly removal) was 'clumsy', 'error-prone' and at times 'painful' and 'stressful'. Given its bulkiness, RT-CGM could be uncomfortable during sleep. Few expressed health concerns related to other sensor materials.

3.5.3.4. Confrontation with diabetes. RT-CGM could help to 'engage rather than ignore' diabetes, finally rewarding efforts. However, continuous glucose availability meant not being able to 'switch off' or 'escape' diabetes, instilling dejection and self-judgement. 'Sometimes I just want to put my head in the sand and eat a bag of M&Ms without further thought, but the RT-CGM confronts me with it.' [Woman, 41-50 years, commercial AID]. While phone monitoring offered discreteness, having a (nother) device attached to one's body was a nuisance (e.g. summer; dress). Alerts and alarms were too frequent (persistent glucose excursions, updates, calibrations, connectivity), pointless, 'fake' (compression lows), intrusive (social or work activities, at night, while driving), and insistent (volume; continuing after action). 'During a silent event, e.g. theater, cinema, I always have an unsettled, stressed feeling that an alarm will go off." [Woman, 61–70 years, Open Loop with pump]. Some people wished to have had RT-CGM earlier, reflecting on a life with complications, burn-out and extensive (emergency) health care use.

3.5.3.5. Having become dependent on RT-CGM. RT-CGM was deemed 'essential for a successful life with diabetes'; going back to the 'old ways' unimaginable or 'a nightmare'. 'I am dreading the moment of having to return to isCGM after the pregnancy. [...] If I have to go back, this would mean having to spend 3–4 h per day again on [glucose] management, many worries, many hypo's, broken nights and feeling depressed. [...] And by that time I have to care not only for myself, but also for a child.' [Woman, 31–40 years, commercial AID]. There was a returning 're-negotiation' and 'battle' with health providers and insurers about getting or keeping RT-CGM. This instilled stress and insecurity. 'I still live in fear, the fear of losing my RT-CGM sensor! This anxiety is hanging above my head like the Sword of Damocles [...] [Woman, 41–50 years, SAP]. Some felt limited by always carrying their phone.

3.5.4. Future outlook on diabetes care

Participants stressed the need for bridging health inequalities and for further technological advancements (Supplementary Table 4). They believed reimbursement should not depend on pre-determined criteria and 'bureaucratic red tape' but be broadly accessible, '#cgm4all'. This would save insurance companies money in the long-run, given reduced complications. Decision making should lie with people with diabetes and their health providers, not 'third-parties'. At the same time, RT-CGM was no panacea, it was an 'aid, not the replacer of the diabetes aspect' [*Man, 31–40 years, Open Loop with pen]*; specialized psychological counseling was appreciated.

4. Discussion

In quantitative analysis, Dutch adults with T1D retrospectively reported QoL improvements related to RT-CGM use (irrespective of initial indication), particularly with respect to physical health, emotional wellbeing and energy. No life domains deteriorated. Merits for sleep, intimacy and cognitive diabetes load lagged somewhat behind, mostly outside AID. User evaluations were mostly determined by perceived benefits and burdens. In qualitative analysis, device merits tended to surpass inconveniences (e.g. malfunctions, dislodgments, skin reactions).

Importantly adding to literature [14,27] is that AID users reported larger improvements in overall QoL, fatigue and diabetes-specific distress than those using RT-CGM in SAP or Open Loop. They also reported more optimal sleep. While AID may not relieve sleep discomfort [14,28], it may reduce awakenings with average nighttime TIR up to 85–90% [8,10] and decreased worries about hypoglycemia [28]. RT-CGM -irrespective of AID- only slightly improved intimacy; technology is known to interfere with sexual activity (e.g. hindrance, dislodgements, attractiveness) [29,30]. Most people described RT-CGM (often AID) as having profoundly reduced diabetes burden. In a small study, mean AID app use was 16 min per day [31]. Compared with those using SAP, adults using open source APS spent 3.5 h more in target per day [10]. Many of our participants were dreading to return to self-care with isCGM, requiring at least 25 active scans (and related decisions) for HbA_{1c} 53 mmol/mol (7%), with other glucometrics still lagging behind [32,33].

If RT-CGM is making experiences more similar to life without diabetes, can prescription be withheld based on clinical criteria? Access criteria may amplify health inequalities [34,35]. Furthermore, compared with isCGM plus MDI/pump, a first generation AID system was modeled to be cost-effective over the lifespan for adults with T1D, mostly by reduced acute/long-term complications [36]. Models including the most recent systems, daily time-above-range and nonsevere hypoglycemic events [37] can further optimize estimates. To maximize RT-CGM benefits (in AID) in regular diabetes care, it is required to address the identified burdens. Design improvement focuses on hardware (e.g. reducing size, increasing durability) and software customization [38]. Technological advancements may directly improve PROs [39]. Explicit attention to expectations and hassles is also needed, upfront and during longer-term use [40,41]. Clinician efforts may be supplemented by peer support, behavioral intervention programs and psychological counseling [42-44].

Study strengths are the large sample, quantitative-qualitative approach and inclusion of common questionnaires. Limitations include the cross-sectional, retrospective design and the lack of measurement of potentially relevant sociodemographic factors such as ethnicity and socioeconomic status. In addition, there was an overrepresentation of people with frequent sensor use. As time spent in AID algorithm is positively associated with TIR [45], we might have missed a subgroup less positive about RT-CGM use. Also, as the study was advertised by national diabetes advocacy organizations and pro-tech care organizations, people with significant adjustment difficulties related to their diabetes or those from a less technology-oriented niche might be underrepresented. Furthermore, our key focus was on experiences of current users, which may be biased towards the positive. Future research may zoom in on the views of those who have discontinued RT-CGM. Data from the pre-AID era suggest an RT-CGM discontinuation rate of 28-41% [46,47], whereas discontinuation of the most recent AID systems is 5–10% [48–50]. The overrepresentation of women is at odds with similar CGM use reported across gender previously, although more girls than boys used an insulin pump [51]. Gender differences in technology use deserve further examination, even though there did not appear to be clear gender differences with respect to PROs in the present study. Lastly, current Dutch RT-CGM reimbursement rules introduced the primary sample bias [17].

In conclusion, RT-CGM use (particularly in AID) is related to improvements across a broad range of QoL domains. In making the benefitburden trade-off, most people tend to a positive evaluation. Combined with data from trials and real-life studies, our findings encourage policy makers to revisit the discussion on broader RT-CGM access. With further technological advancements underway, increased support for people to maximize RT-CGM benefits and minimize burdens is warranted.

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Declaration of interest

Diabeter is an independent clinic, which was acquired by Medtronic. The research presented here was independently performed and there is no conflict of interest.

PW: None related to this study.

HJA: Member of the Diabeter (international) board, Member of Dexcom's Dutch advisory board; Reimbursements in Diabeter flow to the institution and not the individual.

GN: None related to this study. Received a research discount from Dexcom on the purchase of sensors for a different research project (appr. EUR 5,000). Is independently involved in the mixed-method PRO evaluation of an AID system, as part of a larger producer-initiated study (Inreda Diabetic B.V.), for which she receives no renumeration other than (co–)authorship.

CRediT authorship contribution statement

Per Winterdijk: Conceptualization, Formal analysis, Investigation, Methodology, Writing - original draft and review & editing. **Henk-Jan Aanstoot:** Conceptualization, Formal analysis, Investigation, Methodology, Writing - original draft and review & editing. **Giesje Nefs:** Conceptualization, Formal analysis, Investigation, Methodology, Writing - original draft and review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Henk-Jan Aanstoot reports a relationship with Dexcom that includes: board membership. Giesje Nefs reports a relationship with Dexcom that includes: funding grants. Giesje Nefs reports a relationship with Inreda Diabetic B.V. that includes: non-financial support. Diabeter is an independent clinic, which was acquired by Medtronic. The research presented here was independently performed and there is no conflict of interest.

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Appendix A. Supplementary material

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