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DIABETIC Medicine

REVIEW ARTICLE

Impact of glycaemic technologies on quality of life and related outcomes in adults with type 1 diabetes: A narrative review

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Abstract

Aims: To explore the association between the use of glycaemic technologies and person-reported outcomes (PROs) in adults with type 1 diabetes (T1D).

Methods: We included T1D and technology publications reporting on PROs since 2014. Only randomised controlled trials and cohort studies that used validated PRO measures (PROMs) were considered.

Results: T1D studies reported on a broad range of validated PROMs, mainly as secondary outcome measures. Most studies examined continuous glucose monitoring (CGM), intermittently scanned CGM (isCGM), and the role of continuous subcutaneous insulin infusion (CSII), including sensor-augmented CSII and closed loop systems. Generally, studies demonstrated a positive impact of technology on hypoglycaemia-specific and diabetes-specific PROs, including reduced fear of hypoglycaemia and diabetes distress, and greater satisfaction with diabetes treatment. In contrast, generic PROMs (including measures of health/functional status, emotional well-being, depressive symptoms, and sleep quality) were less likely to demonstrate improvements associated with the use of glycaemic technologies. Several studies showed contradictory findings, which may relate to

study design, population and length of follow-up. Differences in PRO findings were apparent between randomised controlled trials and cohort studies, which may be due to different populations studied and/or disparity between trial and real-world conditions.

Conclusions: PROs are usually assessed as secondary outcomes in glycaemic technology studies. Hypoglycaemia-specific and diabetes-specific, but not generic, PROs show the benefits of glycaemic technologies, and deserve a more central role in future studies as well as routine clinical care.

KEYWORDS

continuous glucose monitoring (CGM), insulin pump, intermittently scanned continuous glucose monitoring (isCGM), person-reported outcome measure (PROM), person-reported outcomes (PROs), quality of life (QoL), type 1 diabetes

1 | INTRODUCTION

Type 1 diabetes (T1D) is a chronic condition with a significant self-management and health burden, requiring frequent insulin administration and glucose monitoring.[1] Given the overwhelming evidence that maintaining recommended glycaemic targets reduces long-term complications,[2] numerous studies focus on reducing glycated haemoglobin (HbA_{1c}). Recently, this focus has shifted to additional glycaemic markers such as time in range, glycaemic variability and hypoglycaemic exposure, given the advances and increasing accessibility of diabetes technologies, and their additional prognostic value.[3]

While attention to glycaemia is unquestionably key for preventing acute and long-term complications, it does not take into account the person's experiences, priorities and preferences, which are equally important.[4] A particular challenge in T1D management is the relative lack of adverse symptoms associated with hyperglycaemia, such that quality of life (QoL) can be negatively impacted more in the short-term by the burden of intensified therapy than by above-target glucose levels.[5] For at least two decades, it has been recognised that successful and sustainable approaches to managing T1D must include strategies that recognise and reduce the burden of self-management.[6]

Person-reported outcome measures (PROMs) are standardised, validated questionnaires completed directly by the individual living with the condition, enabling them to share their perceptions and experiences of the condition and/or its treatment. This is crucial for person-centred clinical care.[7] PROMs can be used to assess the impact of a management strategy on satisfaction with treatment, and involvement in clinical care, as well as emotional well-being, health status, and QoL. It is now appreciated that "adding life to years" is as important to many people as "adding years to life". Therefore, strategies to improve QoL are moving from the periphery to the centre of clinical diabetes care with PROMs used increasingly for benchmarking and in clinical quality registries.[8]

What's new?

- While Patient Related Outcomes Measures (PROMs) are important, this review demonstrates they are mainly studied as secondary outcomes in individuals with type 1 diabetes using technology to aid diabetes management.
- Generally, studies show a positive impact of technology on diabetes-specific PROMs, with limited effects, if any, on generic PROMs.
- PROMs deserve a more central role in type 1 diabetes technology studies, as well as clinical management of these individuals.

Most clinical T1D studies focus on glycaemic markers, with PROMs relegated to secondary outcomes, if included at all. Therefore, if the glycaemic effects of a particular intervention are modest or non-significant, the study is often labelled as negative even if a clear improvement in PROs is demonstrated. A distinguishing feature of the UK DAFNE trial was that it recognised the burden of T1D self-management and included QoL as a co-primary end point alongside HbA_{1c}.[9] Consequently, benefits for QoL were afforded equal priority to improvements in HbA_{1c}. This is a salient lesson for technology studies that have shown only modest improvements in glycaemic markers (usually HbA_{1c}), which has meant that these devices may not have been funded or subsidised by health authorities, despite demonstrating favourable effects on PROMs. Conversely, inappropriate selection of PROMs and/or misinterpretation of findings can mean that relevant benefits are not

demonstrated even when clinical experience would suggest the contrary.[10]

The aim of this narrative review is to examine the impact of diabetes technologies on person-reported outcomes (assessed with validated PROMs) among adults with T1D, regardless of glycaemic outcomes.

2 | SEARCH STRATEGY

We searched PubMed for T1D and terms synonymous with PROMs and technology. Terms for PROMs included commonly used measures such as the Diabetes Distress Scale (DDS), Diabetes Treatment Satisfaction Questionnaire (DTSQ), EuroQoL-5 Dimensions (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Hypoglycaemia Fear Survey (HFS), Problem Areas in Diabetes (PAID), Short Form 36 items (SF-36) and Patient Health Questionnaire (PHQ), as well as quality of life (QoL) as an umbrella term used to describe one or more PROMs. Technology terms included insulin pumps, continuous glucose monitoring (CGM), flash glucose monitoring, intermittently scanned CGM and hybrid closed loop, artificial pancreas or automated insulin delivery systems. Our search strategy may have missed PROMs that are rarely used or if these measures were not apparent in the title/abstract.

As technology use in T1D has rapidly expanded in the past 6–8 years, we limited our search to articles published in English since 2014. We checked reference lists of relevant articles for additional studies and included older articles in the review if relevant. We focused on randomised controlled trials and longitudinal cohort studies, excluding cross-sectional studies. It is beyond the scope of this review to fully synthesise qualitative studies, though relevant publications are cited.

Each author performed a search for their technology section, and the last author performed an independent search to ensure all relevant studies were included.

3 | PERSON-REPORTED OUTCOME MEASURES (PROMS)

Determining the suitability of PROMS involves assessing how well the subjective latent constructs can be reported as reliable and valid measures.[11] The statistical methods for validating PROMs have been defined in the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) initiative.[12] Table 1 summarises key constructs used in the psychometric validation of PROMs. The development and validation of PROMs requires multidisciplinary collaboration. Patient and public involvement (PPI) is important for determining the constructs to be assessed, item generation, and for debriefing PROMs (e.g., understandability, comprehensiveness, redundancy and ease of completion).

TABLE 1 Definition of key constructs used when validating person-reported outcome measures (PROMS)

Construct	Definition
Reliability	The degree to which the measure is free from measurement error
Internal consistency	The degree to which items in the measure are inter-related
Test–retest/ Reproducibility	The ability to provide consistent scores over time in a stable population, i.e. when no change in scores would be expected
Validity	The degree to which the measure assesses what it sets out to measure
Content	The extent to which the measure includes the most relevant and important aspects of the construct(s) it sets out to measure
Structural	The degree to which the relationships among items reflect the theoretical framework, i.e. how well each individual item maps to expected constructs to form scales/subscales
Construct	The degree to which scores relate to other measures in a manner that is consistent with a priori hypotheses concerning the concepts measured
Convergent	The degree to which the measure is related to similar measures
Divergent	Demonstration that the measure is unrelated to other measures that it is not expected to have a relationship with
Known groups	The degree to which scores differentiate between groups in the population expected to differ on that construct
Criterion	The degree to which the measure is an adequate reflection of a 'gold standard' measure
Responsiveness/ Sensitivity to change	The extent to which a PROM can detect changes in the construct being measured over time

4 | THE IMPACT OF DIABETES TECHNOLOGIES ON PROs BY TECHNOLOGY TYPE

Key studies examining the impact of diabetes technologies using PROMs are summarised in Tables 2, 3 and discussed in the following sections.

TABLE 2 Person-reported outcome measure (PROM) findings by technology comparison/type and study: Continuous subcutaneous insulin infusion, sensor-augmented pump and closed loop studies

Technology[a]	Study name (Citation)	Study duration & design[b] (*N*)	Inclusion criteria[c]	PROMs[d]	Findings
CSII vs. MDI	HypoCOMPaSS[13,14]	6-month multi-centre RCT plus 18-month observation (24 m total) ($N = 96$ at 6 m; $N = 76$ at 24 m)	IAH ± recurrent SH	DTSQ, HFS-II, ITSQ, Gold, Clarke, HypoA-Q	At 6 months: between-group differences (t-tests) in CSII group diabetes treatment satisfaction (DTSQ) and satisfaction with insulin delivery device (ITSQ Delivery Device subscale) was higher than in the MDI group (both $p < 0.001$). There were no between-group differences for fear of hypoglycaemia (HFS-II), IAH (Gold, Clarke, HypoA-Q), perceived frequency of hypo-hyperglycaemia (DTSQ items 2/3). At 24 months (observation during which individuals continued with their preferred technology): improvements maintained; no significant differences between groups for any of the PROMs.
	REPOSE[15]	24-month cluster RCT with data analysed at 6, 12 and 24 m ($N = 317$; $N = 245$ at 6 m; $N = 237$ at 12 m and 24 m)	N/A	SF-12, DSQOL, WHOQOL-BREF, HFS, HADS, EQ-5D, DTSQ	At 6 months: no statistically significant difference between CSII and MDI groups. At 12 months: CSII group reported greater treatment satisfaction (DTSQ) ($p < 0.001$) and greater improvements in diabetes-specific QoL (DSQOLS) in subdomains: daily hassle or functions ($p = 0.019$), diet restriction ($p = 0.010$). At 24 months: CSII group reported greater treatment satisfaction (DTSQ) ($p < 0.001$); greater improvement in diabetes-specific QoL (DSQOLS) total ($p = 0.006$) and in subdomains: leisure time restrictions and flexibility ($p = 0.016$), daily hassle or functions ($p = 0.006$), diet restriction ($p = 0.004$); and reduced FoH (HFS worry scale only) ($p = 0.010$). No between-group differences at any timepoints in generic health status (SF-12 MCS or PCS scores, EQ-5D) and quality of life (WHOQOL-BREF) or depression and anxiety symptoms (HADS).
CSII only (Cohort study)	Oldham et al[16]	Baseline (start CSII) and 12 m FU ($N = 47$)	N/A	PAID	At 3–6 months follow up: significant reduction in diabetes distress ($p = 0.0002$) At 6–12 months follow up: significant reduction in diabetes distress ($p < 0.00001$), but difference between two FU points was not significant ($p = 0.07$).

TABLE 2 (Continued)

Technology[a]	Study name (Citation)	Study duration & design[b] (*N*)	Inclusion criteria[c]	PROMs[d]	Findings
SAP+PLGS vs. CSII/SMBG	SMILE[17]	6-month open-label, multi-centre and multi-country RCT ($N = 153$)	HbA_{1c} 5.8–10% (40–86 mmol/mol), IAH or SH past year CSII	DTSQ(s+c), HFS, Gold, Clarke	At 6 months: SAP group showed increased treatment satisfaction (DTSQc only) (2.3 vs. 1.6; $p < 0.0001$) compared to CSII/SMBG group. SAP group also reported reduced fear of hypoglycaemia (HFS: Total −17.6 vs. −7.2; $p = 0.0010$, Worry subscale −13.5 vs. −5.9; −4.1 vs. −1.3 $p = 0.0004$; Behaviour subscale $p = 0.043$). No between-group differences in IAH (Gold and Clarke).
HCL vs. current therapy (CSII or MDI)	Australian HCL trial[18]	6-month RCT ($N = 120$)	HbA_{1c} ≤10.5% (≤91 mmol/mol) 50% MDI/CSII at baseline	DTSQ, PAID, DIDP, PSQI, PRMQ, W-BQ28 subscale: diabetes-specific positive wellbeing	At 6 months: HCL group had greater diabetes-specific positive well-being (W-BQ28 subscale: $p = 0.0048$) and diabetes-specific quality of life (DIDP) ($p = 0.023$) compared to CSII/MDI group. No between-group differences for diabetes treatment satisfaction (DTSQ), diabetes distress (PAID), sleep quality (PSQI) or memory (PRMQ).
HCL vs SAP	Diabeloop[19]	12-week multi-centre, open-label crossover RCT with 8-week washout ($N = 63$)	HbA_{1c} ≤10% (86 mmol/mol) CSII IAH & SH excluded	DTSQ	At 12 weeks: No between-group difference in treatment satisfaction (DTSQ).
	Kropff et al[20]	2-month, multi-centre, crossover RCT evening/night HCL (2x8 weeks) with 4-week washout ($n = 32$)	HbA_{1c} 7.5–10% (58–86 mmol/mol) SH excluded	HFS-II, DTSQ(s+c)	At 2 months: No between-group differences for treatment satisfaction (DTSQ Total or DTSQ Perceived Frequency of Hyperglycaemia or Hypoglycaemia items) or fear of hypoglycaemia (HFS-II Total, and Worry and Behaviour subscales).
	Bisio et al[21]	Single-arm 2x4-week SAP and HCL ($N = 15$)	HbA_{1c} <10%, no SH history Age: ≥65 years	HFS-II, DDS, CES-D, PSQI	At 4 weeks: HCL use associated with reduced diabetes distress (DDS: $p = 0.046$). No between-group differences for fear of hypoglycaemia (HFS-II), depressive symptoms (CES-D), or sleep quality (PSQI).

(Continues)

TABLE 2 (Continued)

Technology[a]	Study name (Citation)	Study duration & design[b] (*N*)	Inclusion criteria[c]	PROMs[d]	Findings
HCL only (Cohort studies)	Real-world HCL Pinsker et al[22]	Observational study. T1: at least 3 weeks after start using HCL. T2: 4 weeks after T1; $N = 1435$. ≥14 years; 95% ≥18 years	N/A	WHO-5, DIDS	At 4 weeks: reduction in impact of diabetes on person's life (DIDS: $p < 0.01$), improvement in device-related satisfaction (DIDS: $p < 0.001$), but a reduction in general emotional well-being (WHO-5) ($p < 0.001$).
	Real-world HCL Beato-Vibora et al[23] Polonsky et al[24]	3-month multi-centre prospective study ($N = 58$; 34 adults, 22 children). At baseline, using MDI ± CGM, CSII+SMBG or SAP-PLGS 3-month prospective, single-arm study using Omnipod 5 automated insulin delivery system ($N = 115$ adults)	N/A	HFS, DDS, DQoL, DTS(Q), PSQI, Gold, Clarke DDS, HCS, DTSQ, IDDS, WHO-5, PSQI	At 3 months: reduced fear of hypoglycaemia (HFS Total $p = 0.005$; Worry subscale $p = 0.016$; Behaviour subscale $p = 0.024$) and diabetes distress (DDS scores: $p = 0.002$); improved diabetes-specific quality of life (DQoL: $p < 0.001$), diabetes treatment satisfaction (DTS(Q): $p = 0.037$), sleep quality (PSQI: from 49% to 40% 'poor sleepers'; $p = 0.004$) and awareness of hypoglycaemia (Clarke $p = 0.023$; Gold score not reported separately). At 3 months: reduced diabetes distress (DDS: $p < 0.0001$), and improvements in confidence in managing hypoglycaemia (HCS: $p = 0.0002$), satisfaction with insulin device (IDDS: $p = 0.0007$), and satisfaction with diabetes treatment (DTSQ: $p < 0.0001$); but no changes observed in general emotional well-being (WHO-5: $p = 0.7912$) or perceived sleep quality (PSQI: $p = 0.4217$).

[a]Technology: rtCGM, real-time continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; DBLG1, diabeloop generation 1; HCL, hybrid closed loop; isCGM, intermittently scanned CGM, MDI, multiple daily injections; PLGS, predictive low glucose suspend; SAP, sensor-augmented pump therapy; SMBG, self-monitoring of blood glucose.

[b]RCT, randomised controlled trial. In RCTs, comparisons are made between study arms at follow-up, while in single-arm studies, comparisons are made between baseline and study end.

[c]Specific inclusion criteria beyond 'adult with type 1 diabetes': IAH, impaired awareness of hypoglycaemia; SH, severe hypoglycaemia.

[d]PROMs: BGMSRQ, Blood Glucose Monitoring System Rating Questionnaire; CES-D, Centre for Epidemiological Studies Depression Scale; CIDS(−s), Confidence in Diabetes Self-Care (sensor subscale); DDS, Diabetes Distress Scale; DIDS, Diabetes Impact and Devices Satisfaction; DIDP, Dawn2 Impact of Diabetes Profile; DQOL, Diabetes Quality Of Life; DSQOL, Diabetes-Specific Quality of Life; DTQ, Diabetes Technology Questionnaire; DTSQ(s+c), Diabetes Treatment Satisfaction Questionnaire (status and change versions); EQ-5D, EuroQoL five dimensions; GME-Q, Glucose Monitoring Experience Questionnaire; GMSS, Glucose Monitoring Satisfaction Scale; HADS, Hospital Anxiety and Depression Scale; HCS, Hypoglycaemic Confidence Scale; HFS, Hypoglycaemia Fear Survey; HypoA-Q, Hypoglycaemia Awareness Questionnaire; IDDS: Insulin Device Satisfaction Survey; ITSQ, Insulin Treatment Satisfaction Questionnaire; PAID (-Peds), Problem Areas in Diabetes (Pediatric version); PRMQ, Prospective and Retrospective Memory Questionnaire; PSQI, Perceived Sleep Quality Index; SF-12, 12-item short-form health survey (MCS, Mental health Component Summary; PCS, Physical health Component Summary); W-BQ28, 28-item Well-Being Questionnaire; WHO-5: Well-Being Index Scale; WHOQOL-BREF, World Health Organization Quality Of Life—BREF.

TABLE 3 Person-reported outcome measure (PROM) findings by technology comparison, type and study: Continuous glucose monitoring studies

Technology[a]	Study name (Citation)	Study duration & design[b] (N)	Inclusion criteria[c]	PROMs[d]	Findings
CGM vs. SMBG	HypoCOMPaSS[13,14]	6-month multi-centre RCT plus 18-month observation (24 m total) (N = 96 at 6 m; *N* = 76 at 24 m)	IAH ± recurrent SH	DTSQ, HFS-II, GME-Q, Gold, Clarke, HypoA-Q	At 6 months and at 24 months (observation during which individuals continued with their preferred technology): no between-group differences for any PROMs.
	DIAMOND[25]	24-week prospective multicentre RCT (*N* = 155)	HbA_{1c} 7.5–10.0% MDI	WHO-5, EQ-5D-5L, DDS, HFS-II (Worry subscale), HCS, CGM Satisfaction Survey (for CGM group only)	At 24 weeks: increase in confidence in managing hypoglycaemia (HCS) ($p = 0.03$; d = 0.40) in the CGM group compared to the SMBG group; and a modest reduction in diabetes distress (DDS) in the CGM group and increase in the SMBG group ($p = 0.03$; d = 0.44). No between-group differences detected in general emotional well-being (WHO-5), general health status (EQ-5D-5L) or fear of hypoglycaemia (HFS-II 'Worry'). At 24 weeks: CGM satisfaction (measured at study-end only) was moderately associated with all PROMs except EQ-5D-5L.
	GOLD[26]	26-week multi-centre cross-over RCT: 2 x 6 m periods plus 4 m washout (*N* = 161)	HbA_{1c} ≥ 7.5% (≥58 mmol/mol) MDI	WHO-5, DTSQ (status and change) HFS, PAID, HCQ	At 26 weeks: increase in treatment satisfaction (DTSQ), emotional well-being (WHO-5) and confidence in managing hypoglycaemia (HCQ) while using CGM compared to SMBG (DTSQ 30.21 vs. 26.62, $p < 0.001$; WHO-5 66.1 vs. 62.7, $p = 0.02$; HCQ 3.40 vs. 3.27, $p < 0.001$). No between-group difference for fear of hypoglycaemia (HFS). For diabetes distress (PAID) descriptive statistics reported only (with no significance testing).
	GOLD-3[27]	69-week RCT; extension of GOLD		HCQ	At 69 weeks: greater confidence in managing hypoglycaemia in CGM compared to the SMBG group (HCQ: 3.40 [95% CI 3.32–3.47] vs. 3.27 [95% CI 3.18–3.35]).
	HypoDE[28]	6-month multi-centre open-label RCT (*N* = 149)	History IAH or SH past year MDI	T1-DDS, HFS, EQ-5D, GMSS, Clarke	At 6 months: rtCGM group more satisfied with method of monitoring (GMSS) compared to the SMBG group. In both groups, fear of hypoglycaemia (HFS) and diabetes distress (T1-DDS) reduced significantly from baseline, with between-group differences at 6 months apparent only for GMSS subscales: 'openness' ($p = 0.003$) and 'behavioural burden' ($p = 0.046$); and T1-DDS subscale: 'hypoglycaemia distress' ($p = 0.010$). No between-group difference for EQ-5D. IAH (Clarke) improved by ~40% but no between-group difference.

(Continues)

TABLE 3 (Continued)

Technology[a]	Study name (Citation)	Study duration & design[b] (N)	Inclusion criteria[c]	PROMs[d]	Findings
	IN CONTROL[29]	16-week crossover, open-label RCT with 12-week washout ($N = 52$)	History IAH	Gold, Clarke, PAID-5, HFS, CIDS, EQ-5D, WHO-5	At 16 weeks: fear of hypoglycaemia (HFS Worry subscale) was lower after CGM compared to SMBG (32.5 vs. 38.9, mean difference 6.4 95% CI1.4–11.4; $p = 0.014$). No between-group difference for IAH (Gold, Clarke) or any other PROMs. No change in IAH (Gold, Clarke) from baseline.
	Laffel et al[30]	26-week multi-centre open-label RCT $N = 153$, $n = 52$ (34%) (≥19 years)	HbA_{1c} 7.5%–<11%	PAID-Peds, GMSS, HCS, PSQI	At 26 weeks: rtCGM group reported greater satisfaction with glucose monitoring (GMSS) than SMBG group (difference 0.27 [95% CI 0.06–0.54], $p = 0.003$). No between-group differences for diabetes distress (PAID-Ped), confidence in managing hypoglycaemia (HCS) or sleep quality (PSQI).
	Pratley et al[31]	26-week multi-centre RCT ($N = 203$)	HbA_{1c} <10% Age ≥ 60 years	HFS-II Worry, T1-DDS, Clarke, PROMIS Global Health Short form (Emotion and Cognition)	At 26 weeks: no between-group differences observed for any PROMs.
	CONCEPTT[32]	At least 12-month multi-centre / multi-country open-label RCT. Pregnant ($N = 215$) or planning pregnancy ($N = 110$)	Pregnant or planning pregnancy. Age 18–40 years	BGMSRQ, HFS-II PAID, SF-12	At end of RCT (min 12 m): No between-group differences observed for any PROMs. In the pregnancy group: Significant group-by-time interaction effects favouring the CGM group observed for satisfaction with glucose monitoring (BGMSRQ Total: $p = 0.043$) and reduced hypoglycaemia avoidance behaviours (HFS-II Behaviour subscale: $p = 0.035$). In the pregnancy planning group: Significant group-by-time interaction effects favouring the CGM group observed for satisfaction with glucose monitoring (BGMSRQ Total: $p = 0.43$; BGMSRQ Impact and Obstruction subscales: both $p = 0.003$) and reduced fear of hypoglycaemia and hypoglycaemia avoidance behaviours (HFS-II Worry and Behaviour subscales: $p = 0.03$ and $p = 0.039$ respectively).
CGM only (Cohort study)	Nefs et al[33] Jimenez-Sahagun et al[34]	6-month single centre observational study ($N = 60$) 3-month observational study ($N = 114$)	HbA_{1c} >8% (>64 mmol/mol) Adults meeting national criteria for isCGM use & committed to completing three educational isCGM sessions	PAID, HFS Worry, CIDS, CIDS-s, HADS, Clarke DTSQ, DQOL, DDS	At 6 months: $n = 56$ continued with rtCGM, of whom $n = 37$ completed PROMS, which showed reduced diabetes distress (PAID) ($p = 0.002$, d = −0.6), fear of hypoglycaemia (HFS Worry) ($p = 0.02$, d = −0.4), increased sensor-specific self-efficacy (CIDS-s) ($p = 0.03$, d = 0.5). No change from baseline in IAH, CIDS, HADS. At 3 months; significant improvements in diabetes treatment satisfaction (DTSQ: $p < 0.001$), and diabetes-specific quality of life (DQOL: $p = 0.017$); but no reduction in diabetes distress (DDS: $p = 0.157$). The change in DTSQ was evident regardless of HbA_{1c}. However, the improvement in DQOL score was driven by those with a starting HbA_{1c} ≤8.0% ($p = 0.019$), while those with HbA_{1c} >8.0% demonstrating no benefit ($p = 0.728$).

TABLE 3 (Continued)

Technology[a]	Study name (Citation)	Study duration & design[b] (N)	Inclusion criteria[c]	PROMs[d]	Findings
rtCGM vs. isCGM	Reddy et al[35]	8-week parallel group RCT ($N = 40$)	History IAH or SH in past year	HFS-II, PAID, Gold	At 8 weeks: rtCGM group reported reduction in fear of hypoglycaemia (HFS-II Total and Worry subscale) compared with isCGM (both $p = 0.02$). No within- or between-group differences for diabetes distress (PAID) or HFS-II Behaviour subscale. IAH (Gold) improved by 60% but no between-group difference.
	CORRIDA[36]	4-week RCT ($N = 60$)	No history IAH or SH	WHOQOL-BREF, Gold	At 4 weeks: no changes from baseline or no between-group differences for generic quality of life or IAH (Gold).
isCGM vs. SMBG	IMPACT[37]	6-month, multi-centre RCT ($N = 241$)	$HbA_{1c} < 7.5\%$ (<58 mmol/mol), no IAH	DDS, DQOL, DTSQ, HFS-II	At 6 months: isCGM group showed improved treatment satisfaction (DTSQ) compared with SMBG, and in perceived frequency of hyperglycaemia (DTSQ item 2) (both $p < 0.0001$). No between-group differences for diabetes distress (DDS), diabetes-specific quality of life (DQoL) or fear of hypoglycaemia (HFS-II).
isCGM only (Cohort studies)	FLARE-NL4[38]	6- and 12-month nationwide, single-arm observational ($N = 1365$, including 1.054 (77%) with T1D)	N/A	SF-12, EQ-5D-3L, EQ-VAS	At 6 and 12 months: improved general health status (EQ-5D-3L and EQ-VAS) and mental health status (SF-12 MCS) compared with baseline. No change in physical health status (SF-12 PCS).
	Al-Hayek et al[39]	3-month prospective cohort study ($N = 95$)	Age: 18–40 years	DDS, PSQI	At 3 months: reduced diabetes distress (DDS: 3.8 vs. 2.5; $p < 0.001$) and improved sleep quality (PSQI: 8.7 vs. 3.9; $p < 0.001$).
	Deshmukh et al[40]	National audit At follow up 98% T1DM, ($N = 3182$)	N/A	Gold, DDS2	At follow-up: improved awareness of hypoglycaemia (Gold: 2.7 to 2.4, $p < 0.0001$) and reduced diabetes distress (DDS2: item 1, 2.9 to 2.2; item 2, 3.0 to 2.2; $p < 0.0001$).

[a]Technology: rtCGM, real-time continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; DBLG1, diabeloop generation 1; HCL, hybrid closed loop; isCGM, intermittently scanned CGM, MDI, multiple daily injections; PLGS, predictive low glucose suspend; SAP, sensor-augmented pump therapy; SMBG, self-monitoring of blood glucose.

[b]RCT, randomised controlled trial. In RCTs, comparisons are made between study arms at follow-up, while in single-arm studies, comparisons are made between baseline and study end.

[c]Specific inclusion criteria beyond 'adult with type 1 diabetes': IAH, impaired awareness of hypoglycaemia; SH, severe hypoglycaemia.

[d]PROMs: BGMSRQ, Blood Glucose Monitoring System Rating Questionnaire; CES-D, Centre for Epidemiological Studies Depression Scale; CIDS(−s), Confidence in Diabetes Self-Care (sensor subscale); DDS, Diabetes Distress Scale; DIDS, Diabetes Impact and Devices Satisfaction; DIDP, Dawn2 Impact of Diabetes Profile; DQOL, Diabetes Quality Of Life; DSQOL, Diabetes-Specific Quality of Life; DTQ, Diabetes Technology Questionnaire; DTSQ(s+c), Diabetes Treatment Satisfaction Questionnaire (status and change versions); EQ-5D, EuroQoL five dimensions; GME-Q, Glucose Monitoring Experience Questionnaire; GMSS, Glucose Monitoring Satisfaction Scale; HADS, Hospital Anxiety and Depression Scale; HCS, Hypoglycaemic Confidence Scale; HFS, Hypoglycaemia Fear Survey; HypoA-Q, Hypoglycaemia Awareness Questionnaire; ITSQ, Insulin Treatment Satisfaction Questionnaire; PAID (-Peds), Problem Areas in Diabetes (Pediatric version); PRMQ, Prospective and Retrospective Memory Questionnaire; PSQI, Perceived Sleep Quality Index; SF-12, 12 item short form health survey (MCS, Mental health Component Summary; PCS, Physical health Component Summary); W-BQ28, 28-item Well-Being Questionnaire; WHO-5: Well-Being Index Scale; WHOQOL-BREF, World Health Organization Quality Of Life—BREF.

4.1 | Insulin pumps (CSII)

A systematic review published in 2007 reported equivocal evidence for continuous subcutaneous insulin therapy (CSII), also known as insulin pumps, on QoL and other PROs.[5] It is likely that differences in results are due to heterogeneity in study design, sample size and selection, as well as variation in PROMs (very few of the studies actually assessed QoL). Indeed, many studies examining the benefits of CSII use generic measures, which may not be sensitive to subtle differences between insulin delivery devices.[13]

However, more recent studies show that people with T1D using CSII report greater treatment satisfaction and diabetes-specific QoL than those using multiple daily injection (MDI), with low discontinuation rates for CSII. An important example is the REPOSE cluster randomised controlled trial (RCT), which compared CSII with MDI in the presence of equivalent structured education.[15] REPOSE had a large sample ($N = 317$) and longer follow-up period (2 years) than most previous studies and benefitted from a high PROM completion rate (90%). Both groups experienced improvements in psychosocial outcomes, but there were some notable differences between arms. At 24 months, those allocated to CSII reported greater diabetes-specific QoL in three domains (i.e., leisure, dietary freedom and daily hassles), as well as greater diabetes treatment satisfaction and less worry about hypoglycaemia compared to the MDI group. Some differences were also evident earlier at 12 but not 6 months. Of note, no differences were detected in generic health status or depression/anxiety assessments at any of the time points (Table 2).

Similarly, the HypoCOMPaSS RCT compared CSII to MDI in 96 adults with long-standing T1D and impaired awareness of hypoglycaemia (IAH) and provided equivalent psycho-education and attention to both groups.[13] At 6 months, between-group analyses showed comparable reductions in severe hypoglycaemia, fear of hypoglycaemia, and insulin doses, with equivalent HbA_{1c}. However, diabetes treatment satisfaction and satisfaction with insulin "delivery device" was higher with CSII than MDI at 6 months.[14,41] These differences were no longer apparent at 24 months, following an 18-month observational phase during which individuals used their preferred insulin delivery system.

While this review focuses on RCTs, it is worth mentioning that observational and qualitative studies also report improved QoL and related outcomes with CSII, demonstrating enhanced lifestyle flexibility and improved diabetes self-management among CSII users.[42,43] A small cohort study involving 47 individuals with T1D starting on CSII showed reduced diabetes distress at 3–6 months compared with baseline, which was also evident at 6–12 months follow-up.[16]

4.2 | Continuous glucose monitoring (CGM)

Several trials have assessed the impact of CGM on PROs. The DIAMOND RCT compared CGM with self-monitoring of blood glucose (SMBG) in adults with T1D using multiple daily injections (MDI) and demonstrated a greater increase in confidence in managing hypoglycaemia in the CGM arm and moderate improvement in diabetes distress compared with the SMBG group over 24 weeks. No between-group differences were observed in general emotional well-being, health status, or fear of hypoglycaemia.[25] Additionally, participants in the CGM arm scored high on CGM satisfaction, primarily related to "benefits" and "loss of hassles".[44] Importantly, CGM satisfaction was not related to glycaemic changes and it is worth noting that because the measure was CGM-specific, there was no comparison with baseline, previous monitoring, or the SMBG group.

The GOLD study, a crossover RCT of CGM versus SMBG in those on MDI, demonstrated improved general emotional well-being and confidence in managing hypoglycaemia in the CGM group at 6 months, but no between-group differences for fear of hypoglycaemia.[26,27] A RCT assessed CGM versus SMBG in 153 adolescents and young adults with diabetes (only a third were older than 19 years).[30] At 26 weeks, the CGM group reported greater glucose monitoring satisfaction, but there were no between-group differences for diabetes distress, hypoglycaemia confidence, sleep quality or IAH. A RCT of CGM in 203 older adults (>60 years) found no differences at 26 weeks in any PROMs.[31]

The CONCEPTT RCT compared CGM with SMBG in women (18–40 years) with T1D who were pregnant or planning pregnancy.[32] While there were no between-group differences in any PROMs at the study end, there were group-by-time interactions favouring CGM for satisfaction with glucose monitoring and fear of hypoglycaemia both during pregnancy and pregnancy planning.

A single-arm observational study of 60 adults with T1D (36 of whom completed PROs) showed that CGM use is associated with reduced diabetes distress and fear of hypoglycaemia together with increased sensor-specific self-efficacy 6 months after starting CGM.[33]

People with T1D are often excluded from RCTs if they have a history of problematic hypoglycaemia. The HypoDE study is the largest RCT to date ($N = 149$) assessing the impact of CGM in adults with a history of IAH or severe hypoglycaemia.[28] CGM use in adults using MDI led

to a 72% reduction in subsequent hypoglycaemic events. Although there was a trend towards superior improvements in each score with CGM versus SMBG at 6 months, between-group differences were detected only for satisfaction with the monitoring method and diabetes distress. Similarly, in the HypoCOMPaSS study (which also assessed the impact of CGM versus SMBG among 96 adults with problematic hypoglycaemia), treatment satisfaction improved and fear of hypoglycaemia reduced across the whole cohort at 6-month follow-up, and was maintained at 24 months.[14] However, there were no between-group differences in these outcomes, suggesting that equivalent clinical attention and psycho-education is as important as the technology. In a 16-week crossover trial (with a 12-week washout period), of 52 individuals with T1D and IAH, fear of hypoglycaemia was lower in the CGM than in the SMBG group. However, no between-group differences were detected in IAH, diabetes self-care, diabetes distress, general emotional well-being or health status.[29]

In summary, it appears CGM may have an important role in improving PROs, which may be mediated by the prevention or pro-active management of hypoglycaemia, but this needs further investigation in future studies.

4.3 | Intermittently scanned CGM

Intermittently scanned CGM (isCGM or Flash glucose monitoring) has the advantage of long sensor life and factory calibration, thus eliminating the need for capillary glucose monitoring, except in cases of extreme glucose levels. Unlike CGM, the first iteration of isCGM did not have low/high glucose alarms but the latest version (FreeStyle Libre 2) has optional glucose alarms.

The IMPACT RCT, investigating isCGM in 241 adults with T1D and baseline HbA_{1c} <7.5%, found less hypoglycaemia in the isCGM group compared to the SMBG group after 6-month follow-up.[37] Diabetes treatment satisfaction was greater, and perceived frequency of hyperglycaemia was lower, in the isCGM compared with the SMBG group. Although the difference in diabetes-specific QoL did not reach statistical significance in the full analysis, there was a trend favouring isCGM, but no between-group differences for diabetes distress or fear of hypoglycaemia.

An observational study, involving 1365 individuals with diabetes (1054 with T1D), showed improved general and mental health status at 6 and 12 months (but not physical health status) compared with baseline.[38] Given most had T1D (77%), it may be reasonably assumed that these benefits apply to this subgroup.

In a 3-month prospective cohort study (95 adults with T1D) isCGM use was associated with reduced diabetes distress and improved sleep quality.[39] Another 3-month single-arm study of 114 individuals with T1D showed improved treatment satisfaction and diabetes-specific quality of life but no reduction in diabetes distress with the use of isCGM.[34] A UK national audit collected diabetes distress data at baseline and follow-up (median 7.5 months) in 2532 individuals with diabetes (97% with T1D) starting isCGM. It showed reduced diabetes distress and improved awareness of hypoglycaemia. However, follow-up data were unavailable for two-thirds of the 8320 participants originally approached.[40]

The CORRIDA RCT compared isCGM with real-time CGM in 60 individuals with T1D and showed no between-group differences in IAH or general QoL at 4 weeks.[36] Another study involving 40 individuals with T1D and IAH showed CGM is superior to isCGM for reducing fear of hypoglycaemia but without effect on diabetes distress.[35] IAH improved by 60% irrespective of device allocation.

4.4 | Sensor-augmented pumps (SAP) and hybrid closed loop (HCL)

Sensor-augmented pumps (SAP) combine CGM with CSII. The first iterations could only suspend insulin delivery if glucose was too low (threshold suspend) or predicted to be too low (predictive suspend). The latest versions, so-called hybrid closed loops (HCL; also known as "artificial pancreas"), can also deliver insulin as either changes to basal rates or small boluses to prevent high glucose excursions.

A network meta-analysis and narrative synthesis of 52 T1D studies compared the effects of various technologies on HbA_{1c}, hypoglycaemia and PROs.[45] The work concluded that, although risk of bias was moderate-to-high and certainty of evidence was low, SAP therapy may be superior to other diabetes technologies for improving PROs. However, incremental advances in SAP, from suspend on low to predictive suspend and HCL, were not compared. Importantly, CGM was consistently associated with improved PROs irrespective of how insulin was delivered.

SMILE was an open-label RCT comparing SAP with predictive low glucose suspend (PLGS) to CSII/SMBG (control) in adults with long-standing T1D at high risk of hypoglycaemia and who used CSII prior to enrolment.[17] SAP-PLGS improved diabetes treatment satisfaction and reduced fear of hypoglycaemia compared to CSII/SMBG, but there were no between-group differences for IAH.

A RCT of the "Diabeloop" HCL system compared to SAP, in 63 adults with T1D, found no between-group differences at 12 weeks in diabetes treatment satisfaction.[19] A 6-month RCT comparing HCL with standard care (without CGM) in 120 adults with T1D found improved diabetes-specific positive well-being and diabetes-specific QoL at 6 months but no between-group differences in diabetes treatment satisfaction, diabetes distress, subjective sleep quality or cognition.[18]

Beyond RCTs, observational studies on HCL reported improved sleep and general well-being and reduced diabetes burden.[46] A real-world evaluation of the Medtronic 670G in 92 youth (including $n = 27$ aged 18+) found no changes in fear of hypoglycaemia or diabetes distress across time, with 30% of youth discontinuing HCL in the first 6 months. The authors report this may be related to challenges with calibration and the high workload required to maintain the system in automated mode.[47] These data contrast with a 3-month observational, single-arm study (34 adults and 22 children), showing HCL use is associated with improved diabetes-specific QoL, diabetes treatment satisfaction, subjective sleep quality, and awareness of hypoglycaemia, and reduced diabetes distress and fear of hypoglycaemia.[23] These differences may reflect different study designs, populations, expectations and reimbursement criteria.

A crossover RCT of 32 individuals with T1D compared HCL and SAP over a 2-month period (with 4-week washout). No between-group differences were detected in fear of hypoglycaemia or treatment satisfaction.[20] A small, single-arm 4-week pilot of SAP in 15 older adults with diabetes (mean age 69 ± 3 years), followed by 4 weeks of automated insulin delivery (Control IQ), showed the latter is associated with reduced diabetes distress. There were no changes in fear of hypoglycaemia, depressive symptoms or subjective sleep quality.[21]

Real-world follow-up of 967 users of the Tandem Control-IQ HCL reported improved satisfaction with device use over time and reduced diabetes impact.[48] Another real-world study invited 9085 Tandem control IQ HCL users to complete several PROMs at two timepoints: the first at least 3 weeks after starting the pump and the second 4 weeks later. A total of 1435 users completed study questionnaires at both timepoints, showing improved device-related satisfaction and emotional well-being at the second timepoint.[22] A recent single-arm study using the Omnipod 5 automated delivery system in 115 adults with T1D has shown improvement in diabetes-specific PROMs at 3 months of device use, including reduced diabetes distress, improved confidence in managing hypoglycaemia and satisfaction with diabetes treatment.[24]

In summary, although evidence regarding the effect of HCL on PROs is limited by small, short-duration studies and few RCTs, evidence is accumulating to suggest that this approach has considerable benefits for some PROs.

4.5 | Open-source automated insulin delivery systems

Open-source automated insulin delivery systems are designed and built by people with diabetes for their own personal use, based on open-source algorithms, developed by the #WeAreNotWaiting movement.[49] These "user-led" or "Do-It-Yourself (DIY)" systems are also referred to as "OpenAPS", "DIYAPS" or "Looping". They are built with ease of use, automation, communication and the user interface in mind. At present, there is a relative paucity of evidence for such systems using validated PROMs. A large, multi-country quantitative survey (employing study-specific items) of 722 adults using OpenAPS showed self-reported benefits of putting diabetes on "auto-pilot" (81% of users) and for subjective sleep quality (72% of users).[50] A large qualitative (ethnographic) study identified a range of QoL benefits by extracting user experiences from Twitter posts.[51] Further qualitative thematic analysis reported in the same paper illustrated the quantitative findings showing that improved QoL was due largely to reducing the burden of diabetes self-management, improving sleep, reducing diabetes distress and burnout, and increasing autonomy/personal control. It should be noted that the current evidence base has been led largely by the OpenAPS community, and is characterised by cohort studies and surveys (as opposed to RCTs). Robust, independent evidence is needed and may, in part, be provided by the upcoming ABCD nationwide DIYAPS audit launched in 2020 (http://abcd.care/diyaps).

5 | THE IMPACT OF DIABETES TECHNOLOGIES ON QUALITY OF LIFE AND RELATED OUTCOMES BY TYPE OF PROs

Table 4 summarises study outcomes by psychological construct and the PROMs used for assessment. The PROMs identified in this review assessed several psychological constructs, including:

- Hypoglycaemia-specific: fear and confidence in managing hypoglycaemia;
- Diabetes-specific: QoL, well-being and distress, satisfaction with treatment;
- Generic: health or functional status, emotional well-being, depressive symptoms, subjective sleep quality.

5.1 | Hypoglycaemia-specific PROMs

Fear of hypoglycaemia was most commonly assessed in RCTs. Three of eight RCTs showed reduced fear of hypoglycaemia and/or improved confidence in managing hypoglycaemia with CGM. Of the two RCTs comparing real-time CGM (rtCGM) with isCGM, one reported a between-group difference in fear of hypoglycaemia, favouring rtCGM, suggesting that low glucose alarms are beneficial. Two RCTs comparing MDI with CSII

TABLE 4 Summary of study findings by psychological construct and person-reported outcome measure (PROM)

Construct and PROM	Study name: duration & design (ref)	SMBG	rtCGM	isCGM	MDI	CSII	SAP	HCL
Confidence in diabetes self-care								
Confidence in Diabetes Self-care (CIDS)	6-month Cohort (Nefs et al, 2020)[33]		+[a]					
Confidence in Diabetes Self-care sensor-specific (CIDS-s)	6-month Cohort (Nefs et al, 2020)[33]		+[a]					
Diabetes distress								
Diabetes Distress Scale (DDS)	DIAMOND: 24-week RCT (Polonsky et al, 2017)[25]	−	+					
	26-week RCT (Pratley et al, 2020)[31]	−	−					
	4-week Pilot crossover (Bisio et al, 2021)[21]						−	+
	3-month Cohort (Polonsky et al, 2022)[24]							+
	3-month Cohort (Jimenez-Sahagun et al, 2022)[34]			+				
	3-month Cohort (Beato-Vibara et al, 2020)[23]							+
	3-month Cohort (Hayek et al, 2020)[39]			+				
Diabetes Distress Scale, 2-item short-form (DDS2)	Audit (Deshmukh et al, 2020)[40]			+				
Diabetes Distress Scale for Type 1 diabetes (T1-DDS)	HypoDE: 6-month RCT (Heineman et al, 2018)[28]	−	+					
	IMPACT: 6-month RCT (Bolinder et al, 2016)[37]	−		−				
Problem Areas In Diabetes (PAID) scale	Australian HCL: 6-month RCT (McAuley et al, 2020)[18]				−	−		−
	CONCEPTT (Pregnancy and Pregnancy planning): 12-week RCT (Feig et al, 2017)[32]	−	−					
	GOLD: 26-week Crossover RCT (Lind et al, 2017)[26]	−	−					
	IN CONTROL: 16-week RCT (van Beers et al, 2016)[29]	−	−					
	8-week RCT (Reddy et al, 2017)[35]		−	−				
	26-week RCT (Laffel et al, 2020)[30]	−	−					
	6-month Cohort (Nefs et al, 2020)[33]		+					
	12-month Cohort (Oldham et al, 2020)[16]					+		
Diabetes-specific positive well-being								
4-item subscale of the W-BQ28	Australian HCL: 6-month RCT (McAuley et al, 2020)[18]				−	−		+
Diabetes-specific quality of life								
DAWN Impact of Diabetes Profile	Australian HCL: 6-month RCT (McAuley et al, 2020)[18]				−	−		+

(Continues)

TABLE 4 (Continued)

Construct and PROM	Study name: duration & design (ref)	SMBG	rtCGM	isCGM	MDI	CSII	SAP	HCL
Diabetes Quality of Life (DQoL) questionnaire	IMPACT: 6-month RCT (Bolinder et al, 2016)[37]	−		−				
	3-month cohort (Jimenez-Sahagun et al, 2022)[34]			+				
	3-month Cohort (Polonsky et al, 2022)[24]							+
	3-month Cohort (Beato-Vibara et al, 2020)[23]							+
Diabetes-Specific Quality Of Life Scale (DSQOLS)	REPOSE: 12/24-month RCT (Heller et al, 2017)[15]				−	+		
Fear of hypoglycaemia / Confidence in managing hypoglycaemia								
Hypoglycaemic Confidence Scale (HCS)	DIAMOND: 24-week RCT (Polonsky et al, 2017)[25]	−	+					
	GOLD: 26-week Crossover RCT (Lind et al, 2017)[26]	−	+					
	GOLD-3: 69-week Crossover RCT (Olafsdottir et al, 2018)[27]	−	+					
	3-month Cohort (Polonsky et al, 2022)[24]							+
	26-week RCT (Laffel et al, 2020)[30]	−	−					
Hypoglycaemia Fear Survey (HFS / HFS-II)	CONCEPTT (Pregnancy and Pregnancy planning): 12-month RCT (Feig et al, 2017)[32]	−	−					
	HypoCOMPaSS: 6-month RCT (Little et al, 2014)[41 *]	−	−		−	−		
	HypoDE: 6-month RCT (Heineman et al, 2018)[28 *]	−	−					
	IMPACT: 6-month RCT (Bolinder et al, 2016)[37]	−		−				
	IN CONTROL: 16-week RCT (van Beers et al, 2016)[29]	−	+[b]					
	REPOSE: 6/12-month RCT (Heller et al, 2017)[13]				−	−		
	REPOSE: 24-month RCT (Heller et al, 2017)[13]				−	+		
	SMILE: 6-month RCT (Bosi et al, 2019)[17]					−	+[c]	
	Crossover RCT (Kropff et al, 2016)[20]						−	−
	8-week RCT (Reddy et al, 2017)[35]		+[d]	−				
	26-week RCT (Pratley et al, 2020)[31]	−	−					
	4-week Pilot crossover (Bisio et al, 2021)[21]						−	−
	3-month Cohort (Beato-Vibara et al, 2020)[23]							+[c]
Hypoglycaemia Fear Survey (HFS / HFS-II), Behaviour subscale only	CONCEPTT (Pregnancy): 12-month RCT (Feig et al, 2017)[32]	−	+					
	CONCEPTT (Pregnancy planning): 12-month RCT (Feig et al, 2017)[32]	−	+					

TABLE 4 (Continued)

Construct and PROM	Study name: duration & design (ref)	SMBG	rtCGM	isCGM	MDI	CSII	SAP	HCL
Hypoglycaemia Fear Survey (HFS / HFS-II), Worry subscale only	CONCEPTT (Pregnancy): 12-month RCT (Feig et al, 2017)[32]	–	–					
	CONCEPTT (Pregnancy planning): 12-month RCT (Feig et al, 2017)[32]	–	+					
	DIAMOND: 24-week RCT (Polonsky et al, 2017)[25]	–	–					
	6-month Cohort (Nefs et al, 2020)[33]		+					
General emotional well-being, depressive symptoms, anxiety symptoms								
Centre for Epidemiological Studies Depression Scale (CES-D)	Pilot crossover (Bisio et al, 2021)[21]						–	–
Hospital Anxiety and Depression Scale (HADS)	REPOSE: 6/12/24-month RCT (Heller et al, 2017)[12]				–	–		
	6-month Cohort (Nefs et al, 2020)[32]		–					
WHO-5 Well-being Index	DIAMOND: 24-week RCT (Polonsky et al, 2017)[25]	–	–					
	GOLD: 26-week Crossover RCT (Lind et al, 2017)[26]	–	+					
	3-month Cohort (Polonsky et al, 2022)[24]							–
	IN CONTROL: 16-week RCT (van Beers et al, 2016)[29]	–	–					
	4-week Cohort (Pinkser et al, 2021)[22]							+
Generic health status								
EuroQol-5D (EQ-5D)	DIAMOND: 24-week RCT (Polonsky et al, 2017)[25]	–	–					
	FLARE-NL4: 6/12-month cohort (Fokkert et al, 2019)[37]			+				
	REPOSE: 6/12/24-month RCT (Heller et al, 2017)[13]				–	–		
Short-Form Health Survey, 12 items (SF-12)	CONCEPTT (Pregnancy and Pregnancy planning): 12-month RCT (Feig et al, 2017)[32]	–	–					
Short-Form Health Survey, 12 items (SF-12): Mental Component Summary	FLARE-NL4: 6/12-month cohort (Fokkert et al, 2019)[38]			+				
	REPOSE: 6/12/24-month RCT (Heller et al, 2017)[15]				–	–		
Short-Form Health Survey, 12 items (SF-12): Physical Component Summary	FLARE-NL4: 6/12-month cohort (Fokkert et al, 2019)[38]			–				
	REPOSE: 6/12/24-month RCT (Heller et al, 2017)[15]				–	–		
Generic quality of life								
WHOQOL-BREF	CORRIDA: 4-week RCT (Haskova et al, 2020)[36]		–	–				
	REPOSE: 6/12/24-month RCT (Heller et al, 2017)[15]				–	–		
Impaired awareness of hypoglycaemia								
Clarke score	HypoCOMPaSS: 6-month RCT (Little et al, 2014)[41]	–	–		–	–		

(Continues)

TABLE 4 (Continued)

Construct and PROM	Study name: duration & design (ref)	SMBG	rtCGM	isCGM	MDI	CSII	SAP	HCL
	HypoDE: 6-month RCT (Heineman et al, 2018)[28 *]	–	–					
	IN CONTROL: 16-week RCT (van Beers et al, 2016)[29]	–	–					
	SMILE: 6-month RCT (Bosi et al, 2019)[17]					–	–	
	26-week RCT (Pratley et al, 2020)[31]	–	–					
	3-month Cohort (Beato-Vibara et al, 2020)[23]							+
	6-month Cohort (Nefs et al, 2020)[33]		–					
Gold score	Audit (Deshmukh et al, 2020)[40]			+				
	CORRIDA: 4-week RCT (Haskova et al, 2020)[36]		–	–				
	HypoCOMPaSS: 6-month RCT (Little et al, 2014)[41]	–	–		–	–		
	IN CONTROL: 16-week RCT (van Beers et al, 2016)[29]	–	–					
	SMILE: 6-month RCT (Bosi et al, 2019)[17]					–	–	
	8-week RCT (Reddy et al, 2017)[35 *]		–	–				
HypoA-Q	HypoCOMPaSS: 6-month RCT (Little et al, 2014)[41]	–	–		–	–		
Memory								
Prospective and Retrospective Memory Questionnaire (PRMQ)	Australian HCL: 6-month RCT (McAuley et al, 2020)[18]				–	–		–
Satisfaction with diabetes treatment / glucose monitoring								
Blood Glucose Monitoring Satisfaction Rating Questionnaire (BGMSRQ)	CONCEPTT (Pregnancy): 12-week RCT (Feig et al, 2017)[32]	–	+					
	CONCEPTT (Pregnancy planning): 12-week RCT (Feig et al, 2017)[32]	–	+					
Diabetes Treatment Satisfaction Questionnaire (DTSQ) (DTSQ-s = status version; DTSQ-c = change version)	Australian HCL: 6-month RCT (McAuley et al, 2020)[18]				–	–		–
	Diabeloop: Crossover RCT (Benhamou et al, 2019)[19]						–	–
	GOLD: 26-week Crossover RCT (Lind et al, 2017)[26]	–	+					
	HypoCOMPaSS: 6-month RCT (Little et al, 2014)[41]	–	–		–	+		
	HypoCOMPaSS: 24-month (preference) (Little et al, 2018)[13]	–	–		–	–		
	IMPACT: 6-month RCT (Bolinder et al, 2016)[29]	–		+				
	REPOSE: 6-month RCT (Heller et al, 2017)[15]				–	–		
	REPOSE: 12/24-month RCT (Heller et al, 2017)[15]				–	+		
	SMILE: 6-month RCT (Bosi et al, 2019)[17]					–	+	
	Crossover RCT (Kropff et al, 2016)[20]						–	–
	3-month cohort (Jimenez-Sahagun et al, 2022)[34]			+				
	3-month Cohort (Polonsky et al, 2022)[24]							+
	3-month Cohort (Beato-Vibara et al, 2020)[23]							+

TABLE 4 (Continued)

Construct and PROM	Study name: duration & design (ref)	SMBG	rtCGM	isCGM	MDI	CSII	SAP	HCL
Glucose Monitoring Experiences Questionnaire (GME-Q)	HypoCOMPaSS: 6-month RCT (Speight et al, 2019)[14]	−	+					
	HypoCOMPaSS: 24-month (preference) (Speight et al, 2019)[14]	−	−					
Glucose Monitoring Satisfaction Scale (GMSS)	HypoDE: 6-month RCT (Heineman et al, 2018)[28]	−	+					
	26-week RCT (Laffel et al, 2020)[30]	−	+					
Insulin Treatment Satisfaction Questionnaire (ITSQ)	HypoCOMPaSS: 6-month RCT (Speight et al, 2019)[14]				−	+		
	HypoCOMPaSS: 24-month (preference) (Speight et al, 2019)[14]				−	−		
Sleep quality								
Pittsburgh Sleep Quality Inventory (PSQI)	Australian HCL: 6-month RCT (McAuley et al, 2020)[18]				−	−		−
	26-week RCT (Laffel et al, 2020)[30]	−	−					
	3-month Cohort (Polonsky et al, 2022)[24]							−
	4-week Pilot crossover (Bisio et al, 2021)[21]						−	−
	3-month Cohort (Beato-Vibara et al, 2020)[23]							+
	3-month Cohort (Al-Hayek et al, 2020)[39]			+				

Technology: CSII, continuous subcutaneous insulin infusion; HCL, hybrid closed loop; isCGM, intermittently scanned CGM; MDI, multiple daily injections; rtCGM, real-time continuous glucose monitoring; SAP, sensor-augmented pump therapy (±PLGS, predictive low glucose suspend); SMBG, self-monitoring of blood glucose. (−) indicates no effect on the outcome measured, (+) indicates an improvement in the outcome measured.

[a]Improvement in CIDS-s only.

[b]Reduction only for HFS Worry subscale.

[c]Reduction HFS Total, Worry and Behaviour subscales.

[d]Reduction only for HFS Total score and Worry subscale.

*Within-group reduction.

(REPOSE and HypoCOMPaSS) reported no between-group differences in fear of hypoglycaemia at 6 or 12 months. Both trials included equivalent psycho-education, attention and clinical support suggesting that equivalent benefits can be achieved regardless of technology use.

Three RCTs assessed the impact of more advanced, automated insulin delivery technologies, two of which reported positive impacts on fear of hypoglycaemia compared to MDI/CSII.

None of the trials showed a difference in IAH between rt/isCGM and SMBG, suggesting that awareness of hypoglycaemia is not necessarily improved with CGM.

5.2 | Diabetes-specific PROMs

Two of nine RCTs reported reduced diabetes distress among those allocated to CGM compared to SMBG. Two studies reported reduced diabetes distress and one improved confidence with glucose sensor use. One cohort study showed CSII was associated with reduced diabetes distress.

CGM use resulted in greater satisfaction with diabetes treatment in general and specifically with the monitoring device, compared to SMBG. One crossover SAP/HCL trial found no between-group differences for diabetes treatment satisfaction. Overall, CSII appeared to lead to greater treatment satisfaction compared to MDI.

Three RCTs assessed the impact of more advanced, automated insulin delivery technologies, two of which reported positive impacts on diabetes-specific-well-being and QoL compared to MDI/CSII, but not for diabetes distress. Two cohort studies observed improvements after 3 months of HCL use for several diabetes-specific PROMs.

5.3 | Generic PROMs

Eight generic PROMs were assessed in 10 studies. General emotional well-being improved in one RCT (between-group difference favouring CGM over SMBG) and one cohort study of HCL. One cohort study of isCGM showed improved general and mental health (but not physical health). No benefits were shown for general anxiety or depressive symptoms or generic QoL.

Improved subjective sleep quality was reported for both isCGM and HCL in two cohort studies but none of the RCTs measured it.

6 | DISCUSSION

This review demonstrates that diabetes technologies are often associated with considerable benefits for QoL and related outcomes, particularly in reducing the negative impact of diabetes and hypoglycaemia, while there appear to be fewer benefits for generic PROs. While technology can benefit people with diabetes, there can also be subjective burdens and barriers to uptake (Figure 1), which can only be assessed using PROMs. PROMs offer a systematic, valid and reliable approach to understanding a person's experiences (e.g., satisfaction, confidence, well-being, impact on QoL) regarding the management of their diabetes. It is important that PROMs analyse constructs that are affected by, and sensitive to, the condition and/or the technology.

6.1 | Implication of study design in technology studies

The studies described here are mostly, though not exclusively, RCTs. While RCTs have high internal validity, other study designs are stronger on external validity (Figure 2). Moreover, some RCT protocols are demanding, which may disrupt a person's routine, sleep or QoL. This may be a reason why some cohort studies show greater benefits than RCTs for (generic) PROs. Therefore, RCT evidence needs to be complemented by real-world cohort studies to fully understand the impact of technology on the PROs. A key challenge for all study designs is how quickly diabetes technologies are evolving—by the time findings are published, the technology has advanced and the findings may lack relevance. There is a need to apply

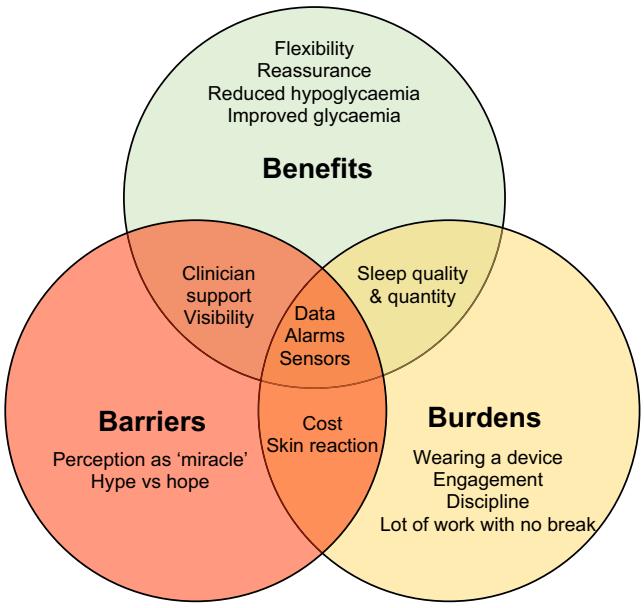

FIGURE 1 Summary of the potential benefits, burdens and barriers associated with using diabetes technologies from the perspective of the person with type 1 diabetes.

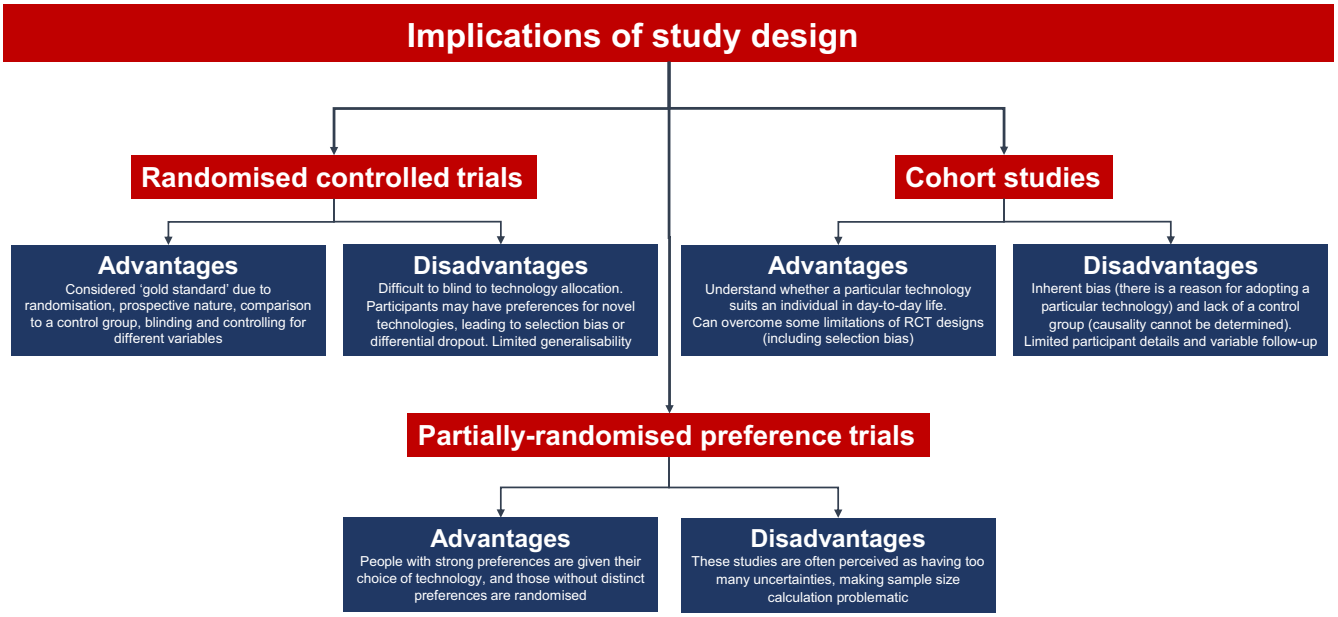

FIGURE 2 Implications of study design when assessing PROMs. RCT: randomised controlled trial, FU: follow-up.

adaptive trial designs that can keep up with this fast-paced area.[52]

As for all studies, participant selection is crucial. Historically, adults with problematic hypoglycaemia, pregnant women and older adults have been excluded from technology RCTs. It is only recently that such groups have been included, yet arguably these people could benefit the most. Other groups with limited representation include people with higher HbA_{1c}, people from minority ethnic groups, people with lower socioeconomic status, and those who do not speak English. Moreover, RCT participants are frequently well-educated, motivated and often have low levels of depressive symptoms or impaired diabetes-specific of generic well-being. While cohort studies may be less restrictive, they can only include those who have routine access to technologies. Thus, technology studies can exclude large proportions of individuals with diabetes who may benefit from glycaemic technologies.

Very few studies include details of the extent to which participants have used the technology as intended (e.g., wearing sensors at least 80% of the time). Consequently, many studies offer relatively limited insights into the real-world experiences of people using these technologies. This is where qualitative studies are particularly beneficial,[53,54] as they provide evidence of how the technology works in real life, for whom and how well.

Another important consideration is the issue of education and attention. When people adopt a new diabetes technology, they are often seen by specialist teams and receive intensive education/support, resulting in overall improved clinical care, which may improve PROs.[55] Both the REPOSE and HypoCOMPaSS trials were designed to ensure that participants received equivalent education, attention and support regardless of allocation to intervention or control group. In both RCTs, there were few differences (between CSII and MDI, or CGM and SMBG) in biomedical or psychological outcomes, with the notable exception of treatment satisfaction being greater among those allocated to pump.

Finally, interpretation of PROM findings needs to consider the statistical analysis. RCTs typically report between-group differences at follow-up, rather than within-group differences over time. Comparative effectiveness trials are becoming more common, such that improvements in both groups (despite lack of between-group difference) could be viewed positively.

6.2 | Implication of PROM selection in technology studies

This review has highlighted the numerous PROMs that exist and may be suitable for the evaluation of glycaemic technologies. The psychological construct that the PROM is assessing needs to be considered in the context of the technology. Questions need to be asked whether, and in study time frame, the technology used could lead to significant changes in the PRO of interest. For example, where fear of hypoglycaemia is low at baseline, it is unlikely that a significant difference will be observed, whereas confidence in managing hypoglycaemia likely has room for improvement.

It is crucial that PROs are valued by all stakeholders and selected judiciously. RCTs largely relegate PROs to

secondary outcomes and perhaps it is time to move these to a more central role and enable studies to be designed and powered appropriately for PROMs. It is also important that PROMs are not too lengthy or burdensome to complete.[56] Online assessments are efficient and can improve completion rates, eliminate data entry errors, fast-track data analysis, and are, overall, a cost-effective approach.[57] Ecological momentary assessments offer a convenient method for study participants to provide real-time completion of PROMs to demonstrate day-to-day impacts.[58]

Psychological constructs examined less frequently in the technology RCTs included confidence in managing hypoglycaemia, diabetes-specific positive well-being and generic PROs, such as emotional well-being, sleep, memory, and QoL. These are all of interest because qualitative research suggests improvements in most of these constructs following technology,[59,60] and therefore these constructs may require greater attention in future quantitative research. Although there were relatively fewer studies assessing generic constructs, the findings suggest no significant differences between groups, while hypoglycaemia confidence and diabetes-specific positive well-being both showed benefits in RCTs. Taken together, these findings suggest that generic PROMs may be less responsive to glycaemic technologies than diabetes-specific or hypoglycaemia-specific measures, as previously discussed.[5]

6.3 | Implementing PROMs in clinical diabetes care

PROMs are undoubtedly valuable tools to inform decision making, improve symptom monitoring and strengthen communication.[61–63] Their clinical use has the potential to increase the holistic care of people with T1D, e.g., through screening and identifying problems, understanding perceptions and experiences, and monitoring outcomes over time,[61] as well as through care co-ordination, including transition from primary to speciality care or from paediatric to adult services. Several studies demonstrate that most adults with T1D are willing to complete PROMs at annual reviews.[64,65] Routine use of clinic consultation tools (incorporating PROMs) enables agenda setting, monitoring of the impact of management strategies in real-world settings, and truly person-centred care.[66,67]

However, PROMs are only a tool for identifying experiences and perceived problems, requiring follow-up with appropriate action taken by the health care professionals to improve either biomedical or psychological outcomes of people.[68] It is important that health care professionals receive adequate training and resources to enable effective implementation. This includes ensuring people with diabetes understand how to complete the assessments and that their feedback will be valued.[69] Some health care professionals may be concerned about "response bias", whereby individuals respond in a certain way if they perceive this affects recommendation or management (e.g., for their suitability to drive, whether they are 'deserving' access to a certain technology). The main counter to this phenomenon is for health care professionals to ensure that their relationship with the person with T1D is built on trust and open communication. There are also challenges in identifying how to collect and incorporate sufficient PROM data into clinical records for easy access and monitoring over time.[68]

7 | CONCLUSIONS

This review has demonstrated that PROs are usually assessed as secondary outcomes in glycaemic technology studies. While there are many nuances among these findings, hypoglycaemia-specific and diabetes-specific PROMs appear to show greater benefits of glycaemic technologies than generic PROMs. These findings show the importance of understanding and appreciating (in both research and clinical care) the impact that glycaemic technologies may have on the experiences of the person with T1D. Where benefits for PROs exist, health care professionals and policymakers need to value these as much as the glycaemic benefits, to realise the full potential of technologies for maintaining or improving both health and QoL.

AUTHOR CONTRIBUTIONS

RAA, PC, EGW and JS conceived and developed the plan for the review. JS and CH critically reviewed the results section, led the discussion section, refined Table 2, provided Tables 1 and 4, as well as Figure 1; PC and HF led the CSII section; EGW and TC led the CGM section; WYC provided an overview of PROMs; RM critically reviewed the work and helped write the abstract and conclusions; GTT and AH led the section on PROMs and clinical practice; RAA led the introduction, abstract and isCGM sections; RAA and JS coordinated and critically reviewed the overall manuscript. All authors read and approved the final paper.

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CONFLICT OF INTEREST

JS has served on advisory boards for Insulet, Janssen, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; received unrestricted educational grants and in-kind support from Abbott Diabetes Care, AstraZeneca, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; received sponsorship to attend educational meetings from Medtronic, Roche Diabetes Care, and Sanofi Diabetes, and consultancy income or speaker fees from Abbott Diabetes Care, AstraZeneca, Medtronic, Novo Nordisk, Roche Diabetes Care, and Sanofi Diabetes. In all cases, her research group (The Australian Centre for Behavioural Research in Diabetes [ACBRD]) has been the beneficiary of these funds. PC has received personal fees from Medtronic, Abbott, Dexcom, Insulet, Glooko, Novo Nordisk, Sanofi and Eli Lilly. EGW has received personal fees from Abbott, Dexcom, Eli Lilly, Insulet, Medtronic, Novo Nordisk and Sanofi Aventis. TC has received speaker fees/honoraria and educational grants from Sanofi, Abbott Diabetes Care and NovoNordisk. RAA Institutional Research Grants; Abbott, Bayer, Eli Lilly and NovoNordisk. Honoraria/education support/Consultant; Abbott, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Menarini Pharmaceuticals Merck Sharp & Dohme and NovoNordisk. All other authors reported to conflict of interest in relation to this review.

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