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ORIGINAL ARTICLE

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Continuous glucose monitoring in noninsulin-treated type 2 diabetes: A critical review of reported trials with an updated systematic review and meta-analysis of randomised controlled trials

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Abstract

Aims: We aimed to review the observational and randomised clinical trial evidence and provide pragmatic recommendations for using continuous glucose monitoring (CGM) in individuals living with noninsulin-treated type 2 diabetes (T2DM).

Materials and Methods: We first undertook a narrative review of observational studies that enrolled noninsulin-users or mixed populations of noninsulin and insulin-users with T2DM as well as randomised controlled trials (RCTs) that enrolled mixed populations with T2DM. We then performed a systematic review of the RCTs that specifically enrolled noninsulin-treated populations with T2DM and compared CGM to BGM/usual care. A meta-analysis of glycaemic outcomes was conducted with predefined subgroups based on CGM type.

Results: RCTs in mixed populations and observational studies demonstrated a largely consistent benefit of CGM on glycaemic and nonglycaemic outcomes with cost effectiveness and reduced healthcare resource utilisation. The meta-analysis of RCTs in noninsulin users included 8 studies encompassing 541 participants, among whom 297 (55%) were assigned to the CGM group. CGM was associated with significantly reduced HbA1c (weighted mean difference [WMD] −0.37%; 95% CI −0.49, −0.24; $p < 0.00001$; $I^2 = 0\%$), increased % time in range (WMD 8.84; 95% CI 4.62, 13.06; $p < 0.0001$; $I^2 = 0\%$) and lower % time above range (WMD −8.14; 95% CI −12.66, −3.63; $p = 0.0004$; $I^2 = 0\%$). There were no significant subgroup differences.

Conclusions: CGM use in noninsulin-treated individuals living with T2DM was associated with improved glycaemic outcomes and patient experience, reduced health care resource utilisation, and acceptable cost-effectiveness. These findings provide

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additional evidence to support CGM use among people living with T2DM who are not using insulin therapy.

KEYWORDS
continuous glucose monitoring, meta-analysis, noninsulin treated, type 2 diabetes

1 | INTRODUCTION AND BACKGROUND

Blood glucose monitoring (BGM) to optimise glucose control is part of standard self-care for individuals living with type 1 diabetes and offers meaningful benefits to those living with type 2 diabetes (T2DM). The traditional method of finger pricking for capillary glucose is less convenient and limited in its ability to provide temporal insight. Continuous glucose monitoring (CGM) devices provide continuous measurements of subcutaneous interstitial glucose, providing a broad picture of glycaemia, including overall trends, patterns, and fluctuations.[1–3] For T2DM, the initial trials that evaluated CGM predominantly enrolled people using insulin therapy. This evidence underlies current recommendations in most national and international clinical practice guidelines and consensus documents that have recommended the use of CGM in individuals living with T2D who are on insulin therapy. With the advent of newer studies of CGM in noninsulin-treated individuals and increasing uptake, the utility of CGM is progressively being endorsed in this population.[4–6]

Given the need for an evidence-based review of CGM in people living with T2DM who are not using insulin, an expert forum was convened in April 2025 to critically examine the evidence on the role of CGM in noninsulin-treated T2DM settings. The expert panel comprised a family physician and seven endocrinologists with clinical and/or research experience with CGM. The authors used a narrative synthesis approach to review relevant observational studies and randomised controlled trials (RCTs) in mixed populations with insulin- and noninsulin-treated individuals living with T2DM. For the RCTs in noninsulin-treated populations living with T2DM, a systematic review and meta-analysis was concomitantly performed to study the impact of CGM on glycaemic outcomes. Our search strategy for both our narrative review and systematic review included the PubMed, Embase and Cochrane Library databases with search terms including 'CGM' or 'flash glucose monitoring' in addition to 'T2DM'. We included in our analyses studies that enrolled either non-insulin using individuals only or mixed populations of insulin and non-insulin users with T2DM.

This document aims to provide a pragmatic perspective of the current literature on CGM in the setting of noninsulin-treated T2DM to offer practical evidence-based recommendations and to highlight the considerations in personalising CGM among adults living with T2DM who are not using insulin.

CGM devices can either consist of a superficial (or transcutaneous) sensor, most commonly, or an implantable sensor. There are four types of superficial CGM systems—intermittently scanned CGM (isCGM), real-time CGM (rtCGM), professional (also known as retrospective) CGM, and over-the-counter CGM (a type of rtCGM).[4,5] Table 1 summarises the CGM devices available by prescription for use in diabetes management. In brief, isCGM systems require users to actively scan a sensor while rtCGM systems receive transmitted sensor data at regular intervals so that users' glucose profiles can be tracked in real time. Professional CGM devices store data so that later retrieval can inform on glucose trends and patterns and guide behavioural and medication modifications.

We review herein the observational studies and the RCTs evaluating rtCGM, isCGM, and professional CGM that have been performed in individuals either living with T2DM and being treated with noninsulin therapies with or without insulin (mixed populations) or individuals treated with noninsulin therapies only.

2 | OBSERVATIONAL STUDIES OF CGM AND GLYCAEMIC OUTCOMES

Numerous observational studies have analysed the impact of CGM implementation on various glycaemic outcomes. Although all observational studies have limitations due to inherent biases related to measured and unmeasured confounders, they can inform our understanding of the potential impact of CGM implementation on glycaemia. It should be noted that in most of these reports, the cohorts described had an elevated level of HbA1c in the period prior to CGM initiation.

2.1 | Intermittently scanned continuous glucose monitoring

2.1.1 | Mixed population studies with isCGM

Details on observational studies with isCGM in mixed populations of insulin and noninsulin-treated T2DM are summarised in Table 2. Miller et al. performed a retrospective observational analysis of change in HbA1c after initiating a FreeStyle Libre™ (FSL) system in individuals living with T2DM who were treated with basal insulin or noninsulin therapies using data from claims databases in the United States.[7] Among the noninsulin therapy users, they observed HbA1c reductions of 0.9% ($n = 497$; $p < 0.0001$) and 0.7% ($n = 120$; $p < 0.0001$) at 6 and 12 months, respectively, with a mean baseline

TABLE 1 Summary of CGM systems for use in diabetes.

	Intermittently scanned continuous glucose monitors		Real-time continuous glucose monitors						Professional continuous glucose monitors		
System	**Abbott FreeStyle Libre**	**Abbott FreeStyle Libre 2**	**Dexcom G6**	**Dexcom G7**	**Abbott FreeStyle Libre 3**	**Medtronic Guardian Sensor 3**	**Medtronic Guardian Sensor 4**	**Senseonics Eversense CGM systems**	**Dexcom G6 Pro**	**Abbott FreeStyle Libre Pro**	**Medtronic iPro 2**
Components	Disposable sensor/ transmitter *Note: Requires scan every 8 h for continuous data. Measures blood sugars every minute but displays at user request.*		Disposable sensor, reusable data transmitter (up to 3 months) that attaches to the sensor	Disposable sensor/ transmitter		Medtronic Guardian Sensor 3 and Guardian Link 3	Medtronic Guardian Sensor 4 and Guardian Link 4	Surgically implantable, under-the-skin sensor, removable and rechargeable transmitter	Disposable sensor/ transmitter, receiver owned and kept at health care facility, optional compatibility with individual's smartphone (blinded or unblinded)	Disposable sensor/ transmitter, receiver owned and kept at the health care facility (blinded)	Disposable sensor (Enlite), reusable transmitter attaches to sensor, iPro2 recorder dock for data uploads (blinded)
Receiver	Yes		Yes			No			Yes		
Accuracy (MARD, %)	9.4	9.3	9	8.2% arm; 9.1% abdomen	7.9	8.7	10.6	8.5	9	12.3	11% (Enlite)
Smart device integration	iOS, Android		iOS, Android, Apple Watch		iOS, Android	iOS, Android	iOS and Android, Apple Watch	iOS, Android, Apple Watch			
Sensor lifetime (days)	14		10	10 plus 12-h grace period	14	7		180	10	14	6
Warm up time (h)	1		2	0.5	1	2		24			
Finger-stick calibrations	No		No			Yes Day 1: 2 h after placement with 2nd calibration required within 6 h of first calibration	No	Yes Twice daily through day 21 then primarily once daily for the remaining 159 days of sensor wear	No		3–4 per day

(Continues)

TABLE 1 (Continued)

System	Intermittently scanned continuous glucose monitors		Real-time continuous glucose monitors						Professional continuous glucose monitors		
	Abbott FreeStyle Libre	Abbott FreeStyle Libre 2	Dexcom G6	Dexcom G7	Abbott FreeStyle Libre 3	Medtronic Guardian Sensor 3	Medtronic Guardian Sensor 4	Senseonics Eversense CGM systems	Dexcom G6 Pro	Abbott FreeStyle Libre Pro	Medtronic iPro 2
						Days 2–7: every 12 h					
Alarms for high/low readings	No	Yes	Yes								
Recommended placement	Back of upper arm		Abdomen, upper buttock (age 2–17 years)	Back of upper arm (age ≥2 years), upper buttock (age 2–6 years)	Back of upper arm	Abdomen or back of upper arm	Abdomen or back of upper arm; upper buttock aged (7–17 years)	Back of upper arm	Abdomen, upper buttock (aged 2–17 years)	Back of upper arm	Abdomen
Potential interfering substances	Ascorbic acid, salicylic acid		Hydroxyurea, acetaminophen		Ascorbic acid, salicylic acid	Acetaminophen		Tetracycline class; mannitol	Hydroxyurea	Ascorbic acid, salicylic acid	Acetaminophen
FDA-approved minimum age (years)	18	4	2		4	14	7	18	2	18	18
Data sharing compatibility	Up to 20 people using LibreLinkUp app		Up to 10 people using Dexcom Follow app		Up to 20 people using LibreLinkUp app	Up to 5 people using CareLink app		Up to 5 people using Eversense NOW app	Using Clarity app	Using LibreView	Using CareLink app
Water resistance	0.91 m for 30 min		2.5 m for 24 h		0.91 m for 30 min	2.5 m for 30 min		0.98 m for 30 min	2.4 m for 24 h	0.91 m for 30 min	2.4 m for 30 min

TABLE 2 Observational studies with isCGM, rtCGM and professional CGM.

Publication	Study design	Population	*N*	No insulin, *n* (% of T2DM)	Intervention	Primary outcome(s)	Time frame	Mean baseline HbA1c	Glycaemic outcomes
Observational studies with isCGM									
Mixed populations									
Al Hayek 2023[10]	Retrospective single cohort, single centre, Saudi Arabia	T2DM Not on intensive insulin	93	36 (38.7%)	FSL	Average glucose, TIR, GMI, HbA1c	2 years	8.3% NI: 8.2%	HbA1c 7.9%, $p < 0.001$ NI subgroup HbA1c 7.8%, $p < 0.001$
Conti 2024[9]	Retrospective, single cohort, 2 hospitals, Italy	T2DM Basal insulin ± noninsulin therapy	132	27 (20.4%)	FSL2	HbA1c, TIR	3 and 6 months	8.1%	At 3 months, HbA1c change: −0.4%, $p = 0.003$ HbA1c 7.51%; $p = 0.003$ At 6 months, HbA1c change: −0.6%, $p < 0.0001$ HbA1c 7.54%; $p < 0.001$ NI subgroup At 3 months, HbA1c 7.37%; $p = 0.003$ At 6 months, HbA1c 7.13%; $p = 0.3$
Ko 2025[14]	Prospective single cohort, single centre, South Korea	T2DM treated with insulin or noninsulin therapies Prediabetes	234 (T2DM 161; Prediabetes 73)	146 (90.7%)	FSL x 2 weeks + personalised structured education	HbA1c	8 weeks	T2DM: 6.9%	HbA1c at 8 weeks: 6.5%; $p < 0.001$
Miller 2020[7]	Retrospective, data linking from different databases, single cohort, USA	T2DM Long-acting insulin Noninsulin therapy	6 months: 774 12 months: 207	6 months: 497 (64%) 12 months: 120 (58%)	FSL	HbA1c	6 and 12 months	NI: 8.5%–8.6%	NI: At 6 months, HbA1c change: −0.9%; $p < 0.0001$ At 12 months, HbA1c change: −0.7%; $p < 0.0001$
Miller 2024[11]	Retrospective, health record claims database, single cohort, USA	T2DM GLP-1RA	1454	432 (30%)	FSL and FSL2	HbA1c	6 months (within 2–10 m)	9.8%	HbA1c change: −1.5%; $p < 0.001$ NI subgroup HbA1c change: −1.7%; $p < 0.001$
Ratzki-Leewing 2025[13] FRONTIER Study	Retrospective, longitudinal, administrative health database, Canada	T2DM BI with GLP-1RA BI without GLP-1RA GLP-1RA without insulin Oral antihyperglycaemic agent only	20 253	2688 (13.2%)	FSL	HbA1c and healthcare resource utilisation		8.1–8.7	HbA1c reduction: 0.3%–0.8%; all $p < 0.0001$ NI subgroup HbA1c reduction: 0.3%–0.6%; all $p < 0.0001$

(Continues)

TABLE 2 (Continued)

Publication	Study design	Population	*N*	No insulin, *n* (% of T2DM)	Intervention	Primary outcome(s)	Time frame	Mean baseline HbA1c	Glycaemic outcomes
Observational studies with isCGM									
Mixed populations									
Wright 2021[8]	Retrospective, single cohort, USA	T2DM BI or noninsulin therapy	1034	728 (70.4%)	FSL, FSL2	HbA1c	6 months	10.1%	HbA1c change: −1.5%; $p < 0.001$ NI subgroup HbA1c change: −1.6%; $p < 0.001$
Wright 2024[12]	Retrospective, health record claims database, matched cohorts, USA	T2DM GLP-1RA ± background insulin	GLP-1RA + FSL: 478 GLP-1RA: 2390	1145 (47.9%) [GLP-1 arm] 229 (47.9%) [GLP_1 + FSL arm]	FSL within ±30 days of initiating GLP-1RA vs. matched control with GLP-1 without FSL	HbA1c	6 months	10.2%	GLP-1RA + FSL HbA1c change: −2.45%; $p < 0.001$ GLP-1RA HbA1c change: −2.02; $p < 0.001$ Difference: −0.37; $p < 0.001$ NI subgroup only in unmatched cohort Difference: −0.68; $p < 0.001$
Noninsulin-treated populations									
Dehghani Zahedani 2021[16]	Prospective, unblinded, single cohort, multicentre, USA	Noninsulin-treated T2DM Prediabetes Healthy	665	192 (100%)	FSL + Sugar AI app x 10 days	TIR	10 days		In T2DM cohort, improved TIR by 22.7% in those with low baseline TIR
Polonsky 2023[15]	Prospective single arm, interventional, USA	T2DM No insulin	35	35 (100%)	FSL + personalised DSMES based on FSL readings over 5 weeks	CGM metrics	3 months	7.7% (GMI)	TIR change: +20.1%; $p = 0.01$ TAR change: −20.5%; $p = 0.01$
Observational studies with rtCGM									
Mixed populations									
Grace 2022[17]	Prospective, single-arm, USA	T2DM treated with basal insulin only or noninsulin therapy	38	16 (42%)	rtCGM (Dexcom G6)	HbA1c, average glucose, CV, TIR, TBR, TAR	6 months	10.1%	HbA1c change: −3.0%; $p < 0.001$ Average glucose change: −1.3 mmol/L; $p < 0.001$ TIR: +15.2%; $p < 0.001$ TBR: targets achieved by all CV: No change

TABLE 2 (Continued)

Publication	Study design	Population	*N*	No insulin, *n* (% of T2DM)	Intervention	Primary outcome(s)	Time frame	Mean baseline HbA1c	Glycaemic outcomes
Observational studies with rtCGM									
Mixed populations									
Shields 2024[18]	Prospective, retrospectively matched controls, multicentre, primary care setting, USA	T2DM treated with basal insulin ± noninsulin therapies or noninsulin therapies without basal insulin	182	67 (74%) [rtCGM arm] 50 (55%) [control arm]	rtCGM (Dexcom G6)	HbA1c, CGM metrics	3 and 6 months		HbA1c change: −1.3%; $p = 0.01$ Participants with HbA1c <7.0%: 22% vs. 9% (rtCGM vs. control) TIR: +27%
Noninsulin-treated populations									
Cox 2016[21]	Pilot, single-arm, USA	Recent T2DM diagnosis (mean 2.6 years)	4	4 (100%)	GEM + rtCGM (Dexcom 4 Platinum)		3 months	7.8%	HbA1c change: −1.1%
Layne 2024[19]	Retrospective analysis of uploaded data from Dexcom app users	T2DM and not using insulin	3840	3840 (100%)	rtCGM (Dexcom G6 and G7)	Change in CGM metrics	1 year		TIR change: +17.3%; $p < 0.001$ GMI change: −0.5%; $p < 0.001$ TITR change: +16.4%; $p < 0.001$
Reed 2024[20]	Single arm two-phase cross-over: 10 days blinded, 90 days unblinded, USA	T2DM with high cardiovascular risk and not using insulin	47	47 (100%)	rtCGM (Dexcom G6)	Change in CGM metrics	90 days	8.4%	HbA1c change: −1.5%; $p < 0.001$ TIR change: +25%; $p < 0.001$
Observational studies with professional CGM									
Mixed populations									
Anjana 2017[22]	Retrospective, multicentre, India	T1DM and T2DM (insulin or noninsulin therapy) with matched control patients (18% of T2DM on CGM)	2339 T2DM	421 (18.0%) [CGM arm] 1093 (46.7%) [control arm]	FSLP	HbA1c	Median 116–125 days	9.2%	HbA1c declined more in CGM group (0.2% difference); benefit independent of insulin use
Jain 2021[27] GLITTER study	Retrospective, single centre, single arm, India	T2DM Insulin and/or noninsulin therapy	105	70 (66.7%)	14-day FSLP + interim intervention technique includes 3-visits within 14 days; visit 2 includes diet	CGM metrics	14 days		Average glucose: 10.6–7.6 mmol/L TIR: 42% to 80% TBR 21% to 2% in subset with recurrent hypoglycemia at baseline

(Continues)

TABLE 2 (Continued)

Observational studies with professional CGM									
Mixed populations									
Publication	**Study design**	**Population**	***N***	**No insulin, *n* (% of T2DM)**	**Intervention**	**Primary outcome(s)**	**Time frame**	**Mean baseline HbA1c**	**Glycaemic outcomes**
					and pharmacotherapy modifications				
Kim 2014[25]	Retrospective, single centre, matched cohort, Korea	T2DM Insulin and/or noninsulin therapy	65 CGM 301 outpatient controls	45 (69.2%) [CGM arm] 223 (74.1%) [control arm]	3-day Medtronic CGMS Gold	HbA1c	6 months	7.9%	Significant HbA1c reductions with CGM vs. control at 3 months (7.4% vs. 7.9; $p = 0.001$) and 6 months (7.3% vs. 7.7%; $p = 0.01$) More treatment changes in the control arm
Kesavadev 2017[62]	Retrospective, single centre, India	T2DM Insulin or noninsulin therapy	296 CGM 296 controls	26 (8.8%) [CGM arm] 21 (7.1%) [control arm]	6–7 days Medtronic iPro2 + counselling with 6-month follow-up	HbA1c	6 months	7.5% to 7.7%	HbA1c improvement with CGM (7.5% to 7.0%; $p < 0.0001$) but not in control arm (7.7% to 7.4%; $p = 0.059$). No significant HbA1c change in underpowered noninsulin treated subgroups. BGM: increased in CGM group
Rivera-Ávila 2021[25]	Quasi-experimental, 3 months, Mexico	T2DM Insulin or noninsulin therapy	152 CGM 150 controls	110 (27.6%) [CGM arm] 73 (51.3%) [control arm]	1-week Medtronic iPro2 at baseline and 3 months + education + diet plan by dietician	HbA1c	3 months	9.3% to 9.8%	Adjusted HbA1c diffference ofr CGM vs. control: −0.48% ($p = 0.0023$) TIR increased (+7.25%, $p = 0.011$) TAR decreased (−6.01%, $p = 0.045$)
Sierra 2018[25]	Claims-based, USA	T2DM Oral or injectable antihyperglycaemic agents	5677 T2DM 5677 controls		FSLP per CPT codes				HbA1c sub-cohort: decreased by 0.44% ($p < 0.001$) 1 year after CGM compared to matched controls
Simonson 2021[25]	Quality improvement initiative, USA	T2DM Any regimen	68	81% on basal insulin and 57% on mealtime insulin	14-day FSLP + follow-up with physician, nurse or educator in 3–6 months; subset wore a second FSLP		6 months	8.8%	HbA1c: 8.8% to 8.2% ($p = 0.006$) attributed to lifestyle changes and medication adjustments TIR and TAR improved in subset that wore a second CGM

Abbreviations: AI, artificial intelligence; BI, basal insulin; CGM, continuous glucose monitoring; CPT, current procedural terminology; DSMES, diabetes self-management education and support; FSL, FreeStyle Libre™; FSL2, FreeStyle Libre 2; FSLP; FreeStyle LibrePro; GEM, glycaemic excursion minimisation; GLP-1RA, glucagon-like peptide-1 receptor agonist; GMI, glucose monitoring indicator; HbA1c, glycated haemoglobin; isCGM, intermittently scanned CGM; NI, not on insulin; rtCGM, real-time continuous glucose monitoring; T2DM, type 2 diabetes; TIR, time in range.

HbA1c of 8.5%–8.6%.[7] In a larger retrospective, observational study of adults living with T2DM who were receiving noninsulin therapies ($n = 728$) or basal insulin ($n = 306$), Wright et al. reported a significant HbA1c reduction from 10.1 ± 1.7 to 8.6 ± 1.8% (difference −1.5 ± 2.2%, $p < 0.001$) 6 months after initiation of FSL. The noninsulin therapy group had a mean HbA1c reduction of 1.6% ($p < 0.001$).[8] A smaller retrospective observational study from Italy by Conti et al. included 132 adults living with T2DM (of whom 21.3% were noninsulin users) and demonstrated significant reductions in HbA1c of 0.6 ± 1.3% ($p < 0.0001$).[9] Al Hayek et al. performed a retrospective review of 93 individuals living with T2DM in Saudi Arabia, 36 (39%) of whom were not on insulin, and reported an HbA1c reduction from 8.3% to 7.9% ($p < 0.001$) over 1 year. Among the noninsulin users, average glucose, time in range (TIR), time above range (TAR) and coefficient of variation (CV) also changed favourably.[10]

Two large health claims database studies have recently investigated the impact of isCGM exclusively in those using glucagon-like peptide-1 receptor agonists (GLP-1RAs). In a cohort of 1454 GLP-1RA users (30% non-insulin using), Miller et al. observed a 1.5 ± 1.9% ($p < 0.001$) HbA1c reduction after acquisition of FSL, which was similar to the 1.7 ± 1.9% reduction seen among just the noninsulin users ($n = 432$).[11] Similarly, Wright et al. found greater HbA1c reductions in a GLP-1RA-using cohort that started FSL within a month of starting GLP-1RA ($n = 478$) compared to a matched cohort that did not use FSL ($n = 2390$) (−2.43% vs. −2.06%, difference 0.37%, $p < 0.001$)—with similar findings in the noninsulin group that comprised 47.9% of the entire cohort (−2.46% vs. −1.78%, $p < 0.001$).[12] In one of the larger and longest duration retrospective studies, Ratzki-Leewing and colleagues used the Ontario provincial health database in Canada to identify 20,253 people living with T2DM who had a first claim for FSL.[13] The cohort was divided into basal insulin users, GLP-1RA users (without insulin therapy), and oral therapy users. HbA1c from the last 12 months of the 24-month follow-up period declined significantly in each cohort. Among the 2206 oral therapy users, HbA1c declined by 0.6% for those ≤65 years of age and by 0.3% for those >65 years of age ($p < 0.0001$).

A few prospective observational single cohort interventional studies have investigated the effects of short-term isCGM use in conjunction with other feedback. In a single centre in South Korea, Ko and colleagues followed 234 individuals (146 noninsulin and 15 insulin users living with T2DM, 73 living with prediabetes) who received personalised structured education on diet and physical activity during 2 weeks of wearing FSL. Among those in the T2DM group, HbA1c was significantly lower (6.9% ± 1.2% to 6.5% ± 0.8%) at 8 weeks compared to baseline and persisted after a mean follow-up of 6.4 months.[14]

2.1.2 | Noninsulin-treated population studies with isCGM

There are few observational reports of isCGM in only noninsulin-treated cohorts. Polonsky and colleagues conducted a single-arm pilot study of 35 non-insulin-using adults as part of a 'discovery learning'-based diabetes self-management education (DSME) programme[15] and found that 3 months after the introduction of isCGM, TIR increased significantly from 55% to 74% ($p = 0.01$) with a parallel decrease in TAR from 44% to 25% ($p = 0.01$).

In another study of isCGM combined with a mobile app that links an individual's glucose tracing to meal composition, heart rate and physical activity, Dehghani Zahedani et al. found that 10 days of isCGM use was associated with improvements in TIR, even among those living with prediabetes.[16]

2.2 | Real-time continuous glucose monitoring

2.2.1 | Mixed population studies with rtCGM

Details on observational studies with rtCGM in mixed populations of insulin and noninsulin treated T2DM are also summarised in Table 2. A single arm study by Grace et al. utilised the Dexcom G6™ (G6) for 6 months in 38 participants (among whom 42% were on insulin therapy) and observed an HbA1c reduction of 3.0% from a mean baseline of 10.1%.[17] In a prospective study where data from 91 individuals on G6 in a primary care setting were compared to those from 91 participants who acted as retrospective controls, Shields et al. documented HbA1c decreases of 1.3% and 0.8% ($p < 0.01$) for the G6 and control groups, respectively.[18]

2.2.2 | Noninsulin-treated population studies with rtCGM

Layne and colleagues[19] followed a large cohort of 3840 noninsulin-treated individuals using Dexcom G6 or G7™ for 12 months and showed sustained decreases in glucose management indicator (GMI) by 0.5% with concomitant increases in TIR and time in the tight range by 17.3% and 16.4%, respectively. In a study of 47 non-insulin users, Reed et al. found that 3 months of G6 use was associated with significant decreases in mean HbA1c (8.4%–6.9%; $p < 0.001$) and improvements in TIR (57.8%–82.8%; $p < 0.001$).[20] In a small single arm pilot study of 4 participants, Cox and colleagues used the Dexcom 4 Platinum™ in conjunction with their glycaemic excursion minimisation (GEM) protocol and showed an HbA1c reduction of 0.9%.[21]

2.3 | Professional CGM

Several observational studies have explored the utility of professional CGM in mixed populations of insulin- and noninsulin-treated people living with T2DM (Table 2). In a multicentre study from India, Anjana and colleagues reported on a cohort of 2339 individuals and found that those who had used FreeStyle LibrePro (FSLP) showed a slightly greater decline in HbA1c of 0.2%, independent of insulin use.[22]

Using US healthcare claims and lab datasets, Sierra et al. uncovered a significant reduction in HbA1c (0.44%) when comparing values 1 year before and 1 year after professional CGM (Medtronic iPro2 or Dexcom G4) initiation among individuals living with T2DM being treated with oral or injectable antihyperglycaemic agents.[23] In a small cohort in Korea ($n = 65$), Kim et al. observed significantly greater HbA1c reductions over 6 months in the professional CGM (Medtronic CGMS Gold) group compared to the matched controls (7.4% ± 1.2% vs. 7.9% ± 1.6%, $p = 0.010$).[24] Declines in mean HbA1c (8.8% to 8.2%; $p = 0.006$) following professional CGM (FSLP) use were similarly observed in a quality improvement project in a primary care setting in the United States.[25] In both studies, CGM was deemed instrumental in making therapy changes, regardless of insulin use. Finally, Rivera-Ávila et al. found that a 7-day professional CGM (Medtronic iPro2) in a primary care diabetes programme led to greater improvements in HbA1c (−0.48%, $p = 0.023$) compared to controls, regardless of insulin use.[26]

The GLITTER study by Jain et al. evaluated a structured 'interim intervention technique' using a 14-day professional CGM (FSLP) period and 3 clinic visits for feedback and adjustments.[27] Among 105 adults living with T2DM (67% on noninsulin therapies), average daily glucose dropped from 10.6 to 7.6 mmol/L, TIR increased from 42% to 80%, TBR decreased from 5.7% to 1.5% and TAR decreased from 52% to 18%. A subgroup with recurrent hypoglycaemia who were likely treated with sulphonylureas showed a dramatic reduction in time below range (TBR), from 21% to 2%.

3 | RANDOMISED CONTROLLED TRIALS

3.1 | Review of RCTs in mixed populations of noninsulin- and insulin-treated T2D

3.1.1 | Mixed population studies with isCGM

A few RCTs have studied the impact of isCGM in individuals with insulin- or noninsulin-treated T2DM with conflicting results (Table 3). Choe and colleagues incorporated a robust education component in their trial that enrolled individuals living with T2DM (72.5% noninsulin-treated) and reported a significant 0.5% reduction in HbA1c after 12 weeks with isCGM.[28] The GLiMPSE trial assigned participants to either a non-continuous CGM protocol (6 weeks continuous isCGM followed by monthly isCGM) or BGM 4 times each day.[29] The LIBERATES trial by Ajjan et al. had a mixed sample of participants, all of whom were using either insulin (49.6%) or sulphonylurea (50.4%), with or without other antihyperglycaemic agents.[30] Interestingly, trial participants had to be included within 5 days of a recent myocardial infarction. While TIR at days 76–90 and HbA1c at days 91 did not differ between the isCGM and BGM groups, there was a lower TBR (−80.5 min/day) in the isCGM group. This TBR difference was similarly evident in each of the sulphonylurea-using and insulin-using subgroups. Finally, the IGNITE study compared isCGM (FSL2) to BGM in a mixed population of individuals with T2DM (86% noninsulin- treated) enrolled in a medically supervised ketogenic diet programme.[31] Glycaemic outcomes such as TIR, TAR, and HbA1c improved significantly in both groups after 3 and 6 months, with no statistically significant differences between the isCGM and BGM groups. The authors concluded that the diet intervention likely overpowered any potential impact of the glucose monitoring strategy.[31]

3.1.2 | Mixed population studies with rtCGM

There are four RCTs of rtCGM in individuals with either insulin or noninsulin-treated T2DM (Table 3). Bergenstal and colleagues evaluated the DexCom SevenPlus™ rtCGM versus a structured, four times daily BGM approach. Their design was a multi-arm parallel trial of participants living with T2DM using metformin alone or with either a sulphonylurea, an incretin-based agent, or insulin.[32] At the end of 16 weeks, both groups had significant HbA1c reductions (rtCGM −1.12% and BGM −0.82%, $p = 0.11$). rtCGM users had fewer CGM-derived hypoglycaemia events compared to BGM users, driven by the insulin and sulphonylurea groups.

Erhardt et al. studied individuals who were not using prandial insulin, and found that periodic rtCGM (DexCom SEVEN™) over 12 weeks led to a 0.5% greater HbA1c decrease versus BGM four times daily ($p = 0.006$).[33] Yoo et al. randomised insulin- and noninsulin-treated individuals to either periodic rtCGM (Medtronic Guardian™, 3 days a month) or BGM for 3 months and found that the CGM group showed a greater HbA1c reduction ($p = 0.004$).[34] In a 3-month RCT with basal insulin- or noninsulin-treated individuals, Soriano et al. demonstrated a significant improvement in HbA1c for users of FSL3 (−0.9%, $p < 0.001$) as opposed to BGM (−0.5%, $p = 0.065$), in addition to improved T2DM engagement scores.[35]

3.1.3 | Mixed population studies with professional CGM

Evidence from RCTs supports the clinical utility of professional CGM in individuals living with T2DM who are being treated with insulin or noninsulin therapies (Table 3).

The GP-OSMOTIC investigators assigned people living with T2DM to either blinded isCGM (FSLP) for up to 14 days or usual care. While the difference in HbA1c at 12 months was not statistically significant, interim analyses at 6 months showed a reduction of 0.5% favouring CGM, with CGM users spending more time in their target range at 12 months.[36] Among individuals living with T2DM who participated in a study in France, Cosson et al. demonstrated greater reductions in HbA1c (−0.63%) at 3 months in the professional CGM (GlucoDay) group (for 48 h) versus the control group (−0.28%).[37] In a high-risk population living with both T2DM and DKD,[38] HbA1c improved with both professional CGM (Medtronic iPro) and BGM, and CGM users spent less time in hyperglycaemia, with no increase in hypoglycaemia, supporting its use in high-risk T2DM populations.[38]

TABLE 3 Randomised controlled trials with isCGM, rtCGM and professional CGM.

Publication Trial Name	Population	*N*	No insulin, *n* (% of T2DM)	Intervention	Primary endpoint	Time frame	Mean baseline HbA1c	Outcomes
isCGM RCTs (Mixed populations)								
Ajjan. 2023[30] LIBERATES England	T2DM with recent MI and using insulin and/or a sulphonylurea	141	33 (48%) [isCGM arm] 38 (53%) [control arm]	isCGM (FSLP) vs. BGM (usual care)	TIR	3 months	8.8% (median)	TIR: Non-significant difference HbA1c (secondary endpoint): Non-significant difference TBR (<3.9 mmol/L): lower in isCGM group; −80.5 min/day (95% CI −118, −43) at days 76–90 TAR: No significant difference
Chandran 2024[29] GLiMPSE Singapore	T2DM with an HbA1c ≥ 7.5% to ≤10.0% and using oral antihyperglycaemic agents with/without basal insulin	176	61 (68%) [isCGM arm] 62 (72) [control arm]	isCGM for 6 weeks then one isCGM per month till week 24 vs. 4 BGM/day; both groups received education at weeks 0, 2, 8 and 16	HbA1c	24 weeks	8.1%	HbA1c: Non-significant difference TIR (secondary endpoint): Non-significant difference TBR (<3.9 mmol/L), TBR (<3.0 mmol/L), number of nocturnal hypoglycaemic episodes (<3.0 mmol/L), mean glucose and CV: No significant differences
Choe 2022[28] PDF Study South Korea	T2DM with an HbA1c ≥7.0% to ≤10.0 and on stable antihyperglycaemic therapy for ≥3 months	126	33 (57%) [isCGM arm] 26 (42%) [control arm]	isCGM + structured education vs. conventional diabetes care (BGM guided to twice daily measurement and logging)	HbA1c	12 weeks	7.9%	HbA1c: favoured the isCGM + structured education group; adjusted difference −0.50%; $p < 0.001$ FPG: favoured the isCGM + structured education group; adjusted difference 0.9 mmol/L; $p = 0.017$ No comparative CGM parameters between arms
Willis 2025[31] IGNITE Study USA	T2DM enrolled in MSKDP	163	71 (88%) [isCGM arm] 69 (85%) [control arm]	isCGM (FSL2) vs. BGM (instructed to measure 1–2 times daily)	TIR	6 months (primary analysis at 3 months)	8.1%	isCGM: TIR improved from 61% to 89% ($p < 0.001$) HbA1c improved from 8.1% to 6.5%; $p < 0.001$ BGMBGM:

(Continues)

TABLE 3 (Continued)

Publication Trial Name	Population	*N*	No insulin, *n* (% of T2DM)	Intervention	Primary endpoint	Time frame	Mean baseline HbA1c	Outcomes
								TIR improved from 63% to 85%; $p < 0.001$ HbA1c improved from 8.1% to 6.6% ($p < 0.001$) NS differences between groups
isCGM RCTs (noninsulin treated)								
Aronson 2023[49] IMMEDIATE Canada	T2DM ≥6 months with an HbA1c ≥7.5% and using ≥1 noninsulin antihyperglycaemic therapy	116	116 (100%)	isCGM vs. BGM (with matched structured DSME in both groups)	TIR	16 weeks	8.6%	TIR: favoured the isCGM + DSME group; adjusted mean difference 9.9% (2.4 h; $p < 0.01$) HbA1c (secondary endpoint): favoured the isCGM + DSME group; adjusted mean difference −0.3%; $p = 0.048$ TITR: adjusted mean difference 8.5% (2.0 h); $p < 0.042$ TAR: adjusted mean difference 8.1% (1.9 h); $p = 0.037$ TBR (<3.9 mmol/L), TBR (<3.0 mmol/L), mean glucose, SD and CV: No significant differences
Lau 2024[44] Canada	T2DM with an HbA1c >7.0% and not using insulin	105	105 (100%)	6 weeks of isCGM + telemonitoring vs. enhanced usual care which may include BGM (with educator visits in both groups)	HbA1c	12 weeks	8.0%	HbA1c: favoured the isCGM + telemonitoring group; HbA1c difference adjusted for baseline HbA1c −0.65%; $p = 0.008$ No comparative CGM parameters between arms
Ssemmondo 2025[43] England	T2DM and not using insulin	40	40 (100%)	isCGM vs. usual care (BGM if used pre-trial)	HbA1c	12 weeks	9.6%	HbA1c: Non-significant difference TIR (secondary endpoint): favoured the isCGM group and improved by 18%; $p = 0.028$

TABLE 3 (Continued)

Publication Trial Name	Population	*N*	No insulin, *n* (% of T2DM)	Intervention	Primary endpoint	Time frame	Mean baseline HbA1c	Outcomes
								No significant change in other CGM parameters
Wada 2020[48] Japan	T2DM and not using insulin	100	100 (100%)	12 weeks of isCGM vs. BGM (DSME in both groups)	HbA1c	24 weeks	isCGM: 7.83% BGM: 7.84%	HbA1c: favoured the isCGM group; difference −0.29%; $p = 0.022$ TIR: favoured the isCGM group; adjusted mean difference 2.36 h; $p < 0.01$ BGRI, CONGA 2 h, mean glucose, MAGE, MODD, SD and TAR: favoured isCGM FPG, TBR, CV: No significant change
rtCGM RCTs (mixed populations)								
Bergenstal[32] USA	T2DM with an HbA1c ≥ 7.0% treated with metformin ± sulphonylurea, metformin ± incretin or insulin ± metformin	114	31 (53%) [rtCGM arm] 32 (58%) [control arm]	rtCGM (Dexcom SevenPlus) vs. BGM (≥4 times daily with structured review)	HbA1c	16 weeks	rtCGM: 8.19% BGM: 7.85%	HbA1c: no difference between groups; −1.12% vs. −0.82%; $p = 0.11$ TBR: lower in rtCGM group vs. BGM group
Ehrhardt[33] USA	T2DM with an HbA1c ≥7.0% and ≤ 12% and not on prandial insulin	50	31 (62%) [rtCGM arm] 36 (72%) [control arm]	Periodic rtCGM (Dexcom SEVEN) (4 2-week cycles with 2 weeks on/1 week off) vs. BGM before each meal and at bedtime	HbA1c	52 weeks	rtCGM: 8.4% BGM: 8.2%	HbA1c: favoured the rtCGM group; −1.0% vs. −0.5%; $p = 0.006$
Soriano 2025[35] USA	T2DM on basal insulin or noninsulin therapy	110		rtCGM (FSL3) vs. BGM	HbA1c	3 months	rtCGM: 9.2% BGM: 8.9%	HbA1c: rtCGM improved to 8.3%; $p < 0.01$ No significant change in BGM group
Yoo[34] Korea	T2DM with an HbA1c 8.0%–10%	57	13 (45%) [isCGM arm] 10 (36%) [control arm]	Periodic rtCGM (Medtronic Guardian) (3 days each month) vs. BGM (twice daily, at least 4 times weekly)	HbA1c	12 weeks	rtCGM: 8.7% BGM: 9.1%	HbA1c: favoured the rtCGM group; −1.1% vs. −0.4%; $p = 0.004$
rtCGM RCTs (noninsulin treated)								
Cox 2020[50] USA	T2DM and not using insulin	30	30 (100%)	Periodic rtCGM (Dexcom G5) (four 7-day periods) plus	HbA1c Medication effect score	3 months	8.8%	HbA1c: favoured the rtCGM group; −1.30% vs. −0.19%

(Continues)

TABLE 3 (Continued)

Publication Trial Name	Population	N	No insulin, n (% of T2DM)	Intervention	Primary endpoint	Time frame	Mean baseline HbA1c	Outcomes
				GEM vs. BGM (usual care)				Medication effect score: favoured the rtCGM group; 0.81 vs. −0.02%; $p = 0.009$
Moon 2023[51] Korea	T2DM and on ≥3 noninsulin oral antihyperglycaemic agents	48	48 (100%)	Periodic rtCGM (Medtronic Guardian 3) (one 7-day period) vs. Periodic rtCGM (two 7-day periods, 3 months apart) vs. usual care (may include BGM)	HbA1c	6 months	8.2%	HbA1c change: At 3 months, favoured the rtCGM groups; −0.8%/−0.8% vs. −0.3%; $p < 0.05$ for each rtCGM group comparison to control At 6 months, favoured the rtCGM group; −0.6%/−0.6% vs. 0%; $p = 0.082$ for 1 session rtCGM group, $p = 0.018$ for the 2 session rtCGM group vs. control
Price 2021[47] COMMITTED	T2DM with an HbA1c 7.8%–10.5% and on ≥2 noninsulin antihyperglycaemic therapies	68	68 (100%)	Periodic rtCGM (Dexcom G6) (10-day periods at weeks 0, 4 and 8) vs. BGM (instructed to measure daily)	HbA1c	12 weeks	rtCGM: 8.4% BGM: 8.5%	HbA1c: Non-significant difference
Professional CGM RCTs (mixed populations)								
Cosson 2009[37] France	T1DM and T2DM	25 T2DM	8 (73%) [CGM arm] 8 (57%) [control arm]	48 h CGM GlucoDay system + therapy adjustment at baseline and 3 months vs. BGM (usual care)	HbA1c	3 months	9.13%	HbA1c: reduced in T2D (−0.63% vs. −0.31%)
Furler 2020[36] GP-OSMOTIC Australia	T2DM	299	74 (50%) [CGM arm] 69 (46%) [control arm]	isCGM (FSLP) at baseline, 3, 6, 9 and 12 months vs. BGM (with education)	HbA1c	12 months	8.9%	HbA1c: 0.5% reduction at 6 months ($p = 0.0001$); no difference at 12 months TIR: improved at 12 months
Yeoh 2018[38] Singapore	T2DM with an HbA1c >8.0% for >6 months and DKD ≥ Stage 3 for 3 months single tertiary centre	30	8 (57%) [CGM arm] 9 (56%) [control arm]	Professional CGM (Medtronic iPro) for 6 days vs. BGM (twice daily, 3 days weekly)	HbA1c	12 weeks	9.9%	HbA1c improved at 3 months in both arms but no significant difference between groups ($p = 0.87$) CGM reduced TAR after 6 weeks ($p = 0.033$) but no significant change in TIR

TABLE 3 (Continued)

Publication Trial Name	Population	N	No insulin, n (% of T2DM)	Intervention	Primary endpoint	Time frame	Mean baseline HbA1c	Outcomes
Professional CGM RCTs (noninsulin treated)								
Allen 2008[45] USA	Sedentary T2DM not using insulin	52	52 (100%)	CGM (Medtronic CGMS Gold) + DSME at baseline and follow-up phone call after 4 weeks vs. BGM + DSME	HbA1c	8 weeks	CGM: 8.9% in completers Control: 8.4%	HbA1c: significant improvement in CGM group: −1.16% ($p < 0.05$), nonsignficant −0.32% change in control group ($p < 0.05$ for comparison of differences)

Abbreviations: BGM, blood glucose monitoring; BGRI, blood glucose risk index; CGM, continuous glucose monitoring; CONGA, continuous overlapping net glycaemic action; CV, coefficient of variation; DKD, diabetic kidney disease; DSME, diabetes self-management education; FPG, fasting plasma glucose; GEM, glycaemic excursion minimisation; GLiMPSE, GLucose monitoring programme SingaporE; HbA1c, glycated haemoglobin; IMMEDIATE, IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with noninsulin Antihyperglycaemic ThErapy; isCGM, intermittently scanned CGM; LIBERATES, Improving Glucose Control in Patients With Diabetes Following Myocardial Infarction: Role of a Novel Glycaemic Monitoring Strategy; MAGE, mean amplitude of glycaemic excursions; MI, myocardial infarction; MODD, mean of daily difference; MSKDP, medically supervised ketogenic diet programme; PDF, Patient-Driven lifestyle modification using FreeStyle Libre in patients with T2D; QoL, quality of life; RCTs, randomised controlled trials; rtCGM, real-time continuous glucose monitoring; SBP, systolic blood pressure; SD, standard deviation; T1DM, type 1 diabetes; T2DM, type 2 diabetes; TAR, time above range; TBR, time below range; TIR, time in range; TITR, time in the tight range.

3.2 | Updated systematic review and meta-analysis of glycaemic outcomes in individual RCTs conducted exclusively in non-insulin-treated T2DM

3.2.1 | Background

To the best of our knowledge, there is to date only one systematic review and meta-analysis of RCTs dedicated to the use of CGM in noninsulin-treated individuals living with T2D.[39] Given that several RCTs have been reported since the publication of this meta-analysis, we undertook an updated systematic review and meta-analysis to provide more current insights into the impact of CGM on glycaemic outcomes in populations living with T2DM who are using noninsulin therapies.

3.2.2 | Methods

We followed the guidelines described in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[40] RCTs of CGM versus usual care/BGM and enrolling only noninsulin-treated individuals living with T2DM were considered eligible; the trials were grouped according to the type of CGM used—specifically, isCGM, rtCGM, and professional CGM. The following were excluded: observational studies, those that included insulin-treated individuals living with T2DM, and studies that did not report our endpoints of interest.

In addition to conducting a manual search of prior meta-analyses, we employed the same search strategy utilised by Ferreira and colleagues,[39] searching the PubMed, Embase and Cochrane Library databases between September 1, 2023, and March 5, 2025 (inclusive). R.M.G. performed the initial screening. R.M.G. and R.A. subsequently and independently extracted the following information from the final set of reports—number and characteristics of the participants, type of CGM used and baseline and follow-up data for the endpoints of interest that included HbA1c, % TIR (3.9–10.0 mmol/L), % TBR (<3.9 mmol/L), % TBR (<3.0 mmol/L), % TAR (>10.0 mmol/L), % TAR (>13.9 mmol/L) and CV. The same individuals used the Cochrane Collaboration's risk-of-bias tool to categorise each trial as having a low, unclear, or high risk of bias for each domain and visually inspected funnel plots to assess publication bias.[41] Finally, the Grading of Recommendation, Assessment, Development and Evaluations (GRADE) guidelines were used to assess the overall quality of evidence.[42]

Endpoints were analysed using weighted mean differences (WMDs) with 95% confidence intervals (CIs) to compare treatment effects. The meta-analysis was conducted with an inverse variance random effect model with predefined subgroups based on CGM type. Overall effect results were deemed significant if a p value of <0.05 was achieved. A Cochrane Q-test p value of <0.10 indicated significant heterogeneity while an I^2 >25% to <50% suggested moderate heterogeneity and an $I^2 \geq 50\%$ indicated high heterogeneity. Final value scores were utilised for all outcomes when available and changes from baseline when final values were missing. Missing SDs for final values that could not be calculated were imputed from the mean of the SDs of final value scores across similar treatment arms. Studies with more than one active intervention arm were pooled. Sensitivity analyses included a leave-one-out analysis for each outcome

and imputation of the highest SD in place of imputation of the mean SD in applicable studies. Other planned sensitivity analyses included an examination of outcomes for continuous and periodic CGM by the CGM subgroups of isCGM and rtCGM. All analyses were performed as per the Cochrane Handbook for Systematic Reviews of Interventions[41] and completed using the Review Manager (RevMan) 5.4 software. The review protocol has neither been registered nor published.

3.2.3 | Search results and study characteristics

Our two search approaches yielded 427 additional papers, 2 new trial records[43,44] and a third trial[45] that was identified from a meta-analysis by Seidu et al.[46] A trial reported by Bergenstal and colleagues[32] that was included in the meta-analysis by Ferreira and colleagues[39] was excluded from our meta-analysis since the participant population was a mix of noninsulin- and insulin-treated individuals living with T2DM. The PRISMA flow diagram is shown in Figure S1. Our updated meta-analysis included 541 participants from a total of 8 RCTs,[43–45,47–51] among whom 297 (55%) were assigned to the CGM group.

Table S1 summarises the key features of the included trials. In brief, four used continuous isCGM, three used periodic rtCGM, and one used professional CGM. None of the trials used periodic isCGM or continuous rtCGM. Across treatment arms, diabetes duration ranged from 5.4 to 13.9 years, female participants comprised 31%–80% of the cohorts, age ranged from 50.7 to 59.2 years, baseline HbA1c was from 7.8% to 9.7%, and baseline TIR ranged from 30% to 78.1%.

3.2.4 | Results of individual RCTs included in meta-analysis

The key results from the individual RCTs in our meta-analysis are summarised in Table 3 and briefly described below.

isCGM RCTs

In the IMMEDIATE trial by Aronson et al., noninsulin-treated individuals living with T2DM were randomised to isCGM plus DSME or BGM plus DSME.[49] After 16 weeks, the isCGM group had a significantly greater adjusted mean TIR of about 10% ($p < 0.01$), significantly lower adjusted mean TAR of 8.1% ($p = 0.037$), and a greater reduction in adjusted mean HbA1c by 0.3% ($p = 0.048$) versus the BGM plus DSME group. Lau et al. compared 6 weeks of isCGM with telemonitoring to enhanced usual care and reported an adjusted HbA1c reduction of 0.65% ($p = 0.008$) after 12 weeks.[44] There was no comparison of CGM metrics in this study. In a small RCT involving 40 individuals, Ssemondo et al. did not find a statistically significant difference in HbA1c between isCGM and usual care groups after 12 weeks, but TIR improved by 18% ($p = 0.028$) in a comparison of change from baseline in each group.[43] TAR improved from 69% to 50% in the isCGM group and from 64% to 61% in the usual care group, with no statistically significant difference between groups. A Japanese study by Wada et al. compared isCGM for 12 weeks to BGM.[48] Although there was no HbA1c difference at 12 weeks, there was a statistically significant reduction of HbA1c of 0.29% ($p = 0.022$) at 24 weeks. At 12 weeks, mean glucose and TIR were significantly improved in the isCGM group ($p < 0.001$), as were various measures of glucose variability, including standard deviation of glucose, mean amplitude of glycaemic excursions, blood glucose risk index, continuous overlapping net glycaemic action, and mean of daily difference.

rtCGM RCTs

Cox and colleagues randomised noninsulin-using individuals living with T2DM to an intervention using Dexcom G5™ rtCGM plus a GEM programme that incorporated 4 sessions of diabetes education along with one-week periods of rtCGM-derived feedback on postprandial changes.[50] The comparator of usual care continued their prior BGM pattern and did not receive the additional diabetes education. HbA1c reductions favoured the rtCGM plus GEM group (−1.3% vs. −0.19%) after 3 months.[50] Two further studies have evaluated the effect of periodic utilisation of rtCGM among noninsulin-using adults living with T2DM. Moon and colleagues randomised individuals living with T2DM on ≥3 noninsulin oral antihyperglycaemic agents to either periodic rtCGM (Medtronic Guardian 3, one-time use only for 7 days or two 7-day sessions 3 months apart) or BGM.[51] The use of rtCGM versus BGM was associated with significant HbA1c reductions of −0.8%/−0.8% (vs. −0.3%) and −0.6%/−0.6% (vs. 0%) at 3 months ($p < 0.05$ for each rtCGM group vs. BGM) and 6 months ($p = 0.082$ for 1 session rtCGM group and $p = 0.018$ for 2 session rtCGM group vs. BGM), respectively. Participants in the COMMITED study by Price et al. were on ≥2 noninsulin antihyperglycaemic therapies and were either assigned to periodic 10-day periods of G6 CGM (0, 4 and 8 weeks) or BGM for 12 weeks. This study showed no statistically significant HbA1c reductions in the rtCGM versus BGM group (−0.5% vs. −0.2%, $p = 0.74$).[47]

Professional CGM RCTs

Allen and colleagues followed sedentary noninsulin-using individuals living with T2DM for 4 and 8 weeks after they received DSME at baseline and a phone call at 4 weeks.[45] Those assigned to the intervention group also received retrospective CGM feedback with counselling derived from self-efficacy theory. In the intervention group, HbA1c declined from 8.9% at baseline to 7.7% at 8 weeks (−1.16%, $p < 0.05$) while in the control group, HbA1c fell insignificantly from 8.4% to 8.1% (p-value for between group difference for change from baseline <0.05).[45]

3.2.5 | Results of meta-analysis

In the pooled analysis of all studies, there was a significant reduction in HbA1c (WMD −0.37%; 95% CI −0.49, −0.24; $p < 0.00001$; $I^2 = 0\%$) favouring the CGM group compared to the usual care/BGM group. Compared to the usual care/BGM group, there was a significant reduction in HbA1c (WMD −0.41%; 95% CI −0.61, −0.21;

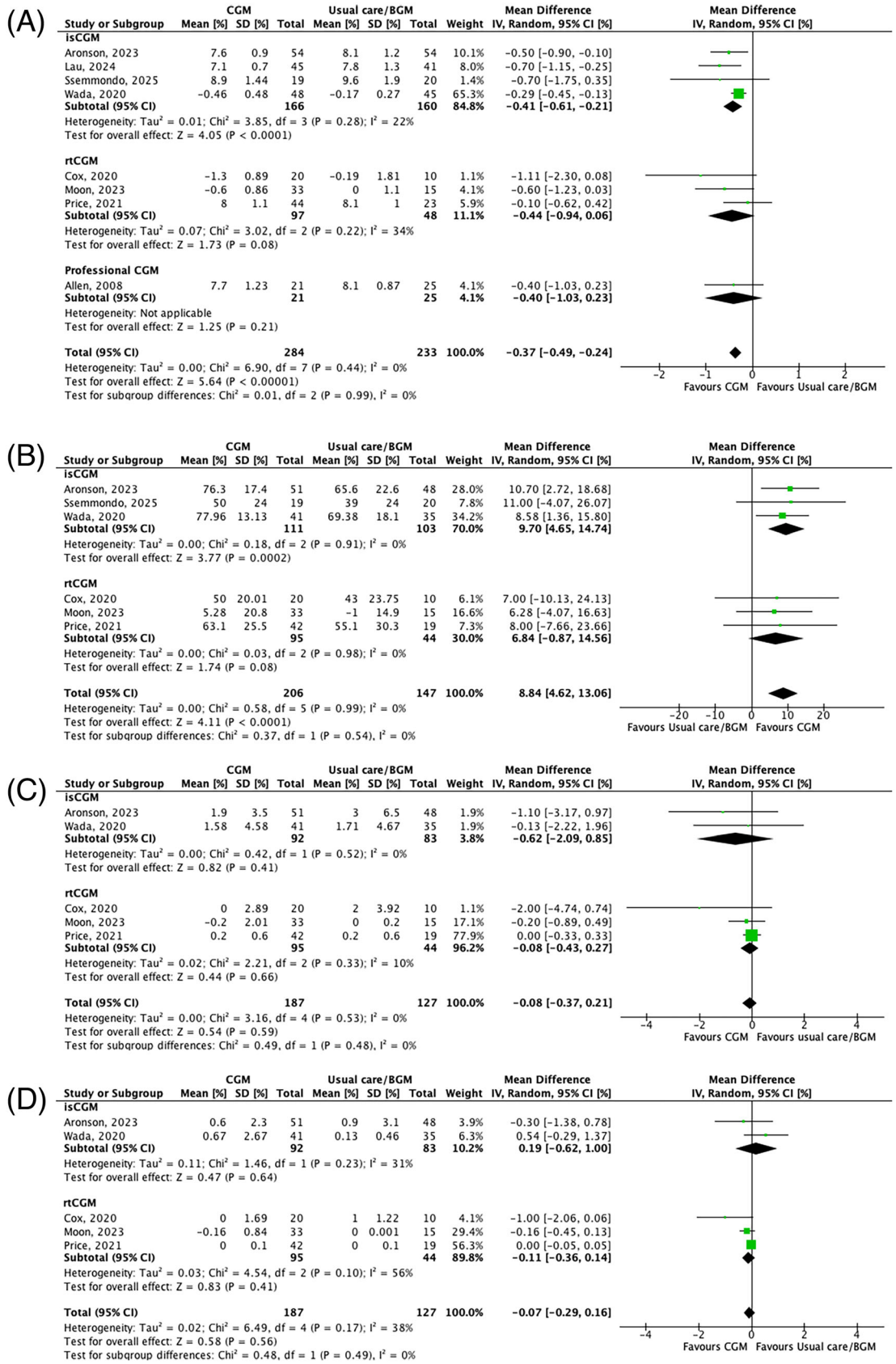

FIGURE 1 Forest plots of randomised controlled trials that compared continuous glucose monitoring vs. blood glucose monitoring for (A) HbA1c (%), (B) time in range (%), (C) time below range (<3.9 mmol/L) (%), (D) time below range (<3.0 mmol/L) (%), (E) time above range (>10 mmol/L) (%), (F) time above range (>13.9 mmol/L) (%) and (G) coefficient of variability. *, Wada, 2020 data for 1F is % TAR (>13.3 mmol/L). CGM, continuous glucose monitoring; isCGM, intermittently scanned CGM; rtCGM, real-time CGM; BGM, blood glucose monitoring; HbA1c, glycated haemoglobin; TAR, time above range.

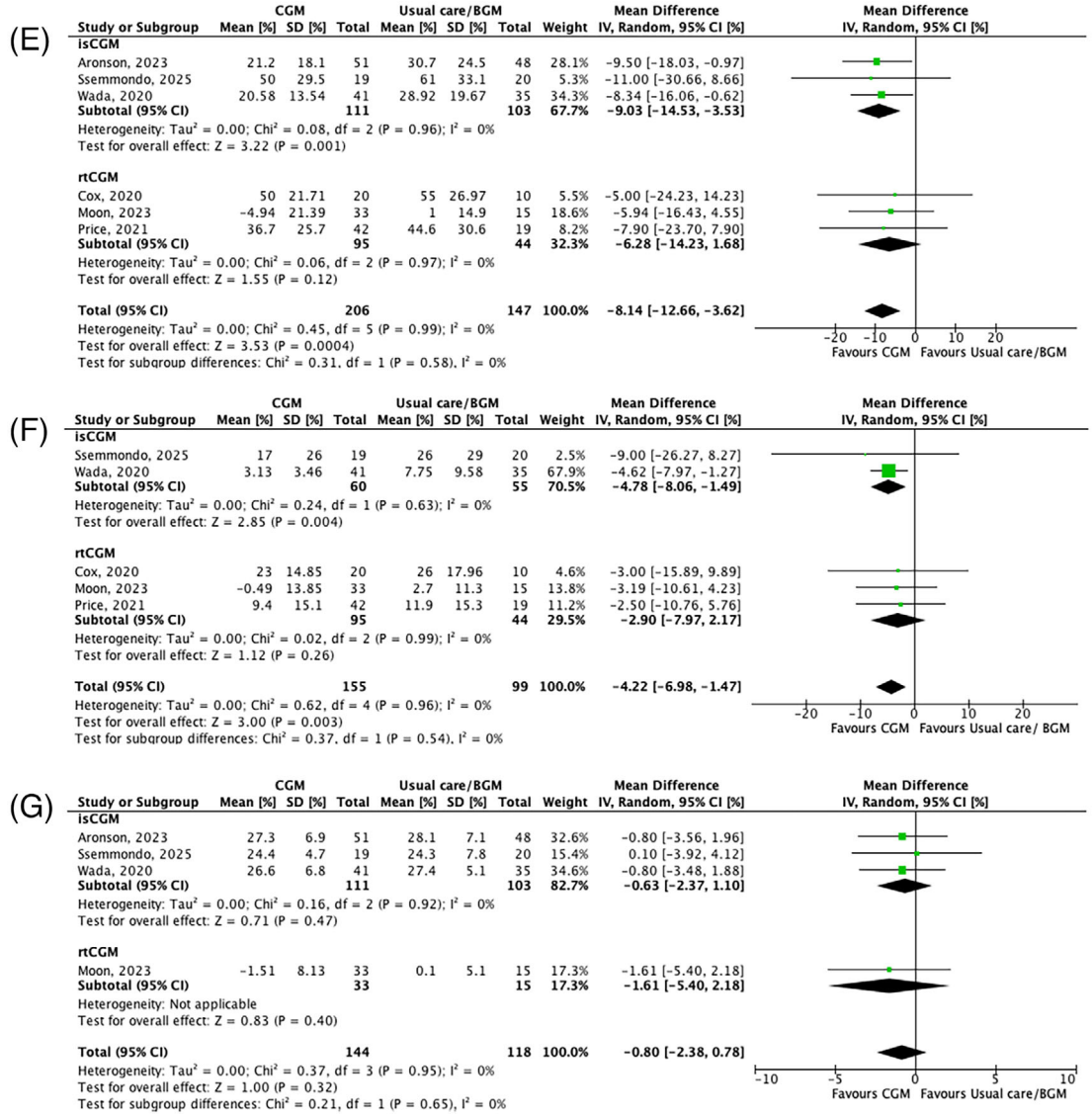

FIGURE 1 (Continued)

$p < 0.0001$; $I^2 = 22\%$) in the isCGM group, and a non-significant reduction in HbA1c (WMD −0.44; 95% CI −0.94, 0.06; $p = 0.08$; $I^2 = 34\%$) in the rtCGM group (Figure 1A). Accordingly, there were no overall significant subgroup differences for the HbA1c outcome ($p = 0.99$; $I^2 = 0\%$).

While there was a significant increase in % TIR (WMD 9.7%; 95% CI 4.65, 14.74; $p = 0.0002$; $I^2 = 0\%$) in the isCGM group, there was a non-significant increase in % TIR in the rtCGM group (WMD 6.84; 95% CI −0.87, 14.56; $p = 0.08$; $I^2 = 0\%$). These yielded a significant increase in % TIR in the pooled analysis (WMD 8.84; 95% CI 4.62, 13.06; $p < 0.0001$; $I^2 = 0\%$) with no significant subgroup differences ($p = 0.54$; $I^2 = 0\%$) (Figure 1B).

As shown in Figure 1C,D, the differences in % TBR (<3.9 mmol/L) and % TBR (<3.0 mmol/L) between the CGM and usual care/BGM participants in the isCGM and rtCGM subgroups were not significant, as were those in the overall pooled analysis.

There was a significant decrease in % TAR (>10.0 mmol/L) that favoured isCGM (WMD −9.03; 95% CI −14.53, −3.53; $p = 0.001$; $I^2 = 0\%$), a non-significant decrease in % TAR in favour of rtCGM (WMD −6.28; 95% CI −14.23, 1.68; $p = 0.12$; $I^2 = 0\%$) and an overall significant decrease in % TAR (WMD −8.14; 95% CI −12.66, −3.63; $p = 0.0004$; $I^2 = 0\%$) with no significant subgroup differences ($p = 0.58$; $I^2 = 0\%$) (Figure 1E).

The significant decrease in % TAR (>13.9 mmol/L) favoured isCGM (WMD −4.78; 95% CI −8.06, −1.49; $p = 0.004$; $I^2 = 0\%$). There was a non-significant decrease in % TAR in favour of rtCGM (WMD −2.90; 95% CI −7.97, 2.17; $p = 0.26$; $I^2 = 0\%$) and an overall significant decrease in % TAR (WMD −4.22; 95% CI −6.98, −1.47; $p = 0.003$; $I^2 = 0\%$) with no significant subgroup differences ($p = 0.54$; $I^2 = 0\%$) (Figure 1F).

As shown in Figure 1G, there were non-significant differences in the CV between CGM and usual care/BGM in the isCGM and rtCGM

subgroups. There was also no difference in the CV in the overall pooled analysis.

In the leave-one out sensitivity analyses for each outcome, no significant changes were observed for any of the outcomes evaluated. Imputing the maximum SD in place of the mean SD in the trial by Cox and colleagues[50] did not affect the significance of the results for TIR, TBR, and TAR outcomes. Sensitivity analyses for continuous or periodic CGM by CGM subgroup could not be performed since there have been neither trials of continuous use of rtCGM nor periodic use of isCGM.

There was generally low risk of bias for 5 of 7 domains across all trials, except for performance bias and detection bias, which were high in all the studies (Figure S2A). The funnel plots for all outcomes suggested no publication bias. Per the GRADE criteria, all but the CV outcome were classified as being of moderate certainty. The CV outcome was rated as low certainty due to the low number of studies and wide CIs (Figure S2B).

3.2.6 | Summary of meta-analysis and RCT review of CGM in noninsulin-treated T2D

The results of our updated meta-analysis are similar to those of Ferreira et al.[39] Although data from the current systematic review and meta-analysis represent the highest level of evidence, there are limitations that impact the generalisability of the findings. Some of the limitations of our meta-analysis are the low number of trials, small sample sizes, and underpowering in many studies, open-label designs, relatively short follow-up times, and limited applicability to broader populations. Each of the RCTs reviewed investigated CGM use in individuals with suboptimal glycaemic control, limiting the generalisability of the findings beyond that population. Also, variable implementation of DSME across the studies may limit the applicability of results to clinical practice. There was insufficient trial data for a comparison of CGM types by continuous or periodic use due to the absence of trials using rtCGM continuously and isCGM periodically. No studies have reported on complications of T2DM as an outcome. The totality of evidence based on our review of RCTs with an updated meta-analysis suggests that CGM use in noninsulin-treated individuals living with T2DM improves HbA1c, TIR, and TAR with low heterogeneity among trials and no significant subgroup differences between isCGM and rtCGM for any of the CGM metrics assessed. Any apparent difference in treatment effect between isCGM and rtCGM is likely due to the smaller sample sizes in the rtCGM trials.

4 | NON-GLYCAEMIC BENEFITS OF CGM IN OBSERVATIONAL STUDIES AND RANDOMISED CONTROLLED TRIALS

The collective findings from observational studies and RCTs suggest that the non-glycaemic benefits of CGM should also be considered when weighing the clinical value of CGM in T2DM.

In the report by Ratzki-Leewing et al. on the impact of FSL use in the Ontario provincial health database, the 2206 individuals who were exclusively oral antihyperglycaemic therapy users exhibited a statistically significant reduction in both emergency department visits and hospitalisations (range −13.1% to −31.7% depending on age range) after FSL initiation.[13]

Using data extracted from the de-identified US-based Optum Market Clarity database, Garg et al. assessed CGM use among 75 000 persons living with T2DM and found significant and sustained (up to 12 months) decreases in diabetes-linked emergency room visits and hospitalisations (all-cause and diabetes-related). These findings align with those of Sierra et al. who found that professional CGM reduces the burden of healthcare costs in mixed therapy diabetes populations.[23]

Several of the prospective observational and controlled trials incorporated a design that allowed assessment of behavioural change following CGM introduction. Allen et al. found that after feedback from professional CGM, individuals showed higher self-efficacy scores and greater time spent in more intense physical activity.[45] In a later report of a small mixed population, Allen et al. similarly showed that CGM with training led to greater problem-solving ability, with trends of greater satisfaction and increased intensity of physical activity.[52] Cox and colleagues reported lower carbohydrate consumption and higher empowerment and knowledge scores with lower diabetes distress in noninsulin users who had received the CGM plus education intervention.[50] Lee and colleagues studied a mixed therapy T2DM population in Korea and showed that individuals randomised to pattern management training with CGM showed improved self-care behaviours and higher self-efficacy versus those receiving usual care.[53]

Some RCTs have also demonstrated clinically significant weight loss favouring the CGM group over the BGM group when used in conjunction with diabetes and lifestyle counselling.[34,45] In the IGNITE study, where a medically supervised ketogenic diet was implemented for all participants, weight loss at 3 months was 7.2 kg in the isCGM group and 7.8 kg in the BGM group, with no significant differences between groups.[31]

RCTs have also reported significant improvement in patient reported outcomes. Patient satisfaction measures like the DTSQ (Diabetes Treatment Satisfaction Questionnaire),[48] DTSQ-c (Diabetes Treatment Satisfaction Questionnaire-change in satisfaction),[44] and GMSS (Glucose Monitoring Satisfaction Survey)[49] as well as participant reported quality of life outcome questionnaires like the EQ5D-5L (Euro Quality of Life 5 Dimension-5L)[29] have mostly favoured isCGM over BGM or standard of care. Furthermore, rtCGM has been associated with improvements in the medication effect score (MES) and the Diabetes Distress Scale (DDS)[50] while isCGM has been positively linked with the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA-K).[28,30]

5 | CURRENT GUIDELINES AND CONSENSUS DOCUMENTS

The 2025 American Diabetes Association (ADA) Standards of Care suggest consideration of both rtCGM and isCGM for adults living with

T2DM and using noninsulin therapies who are trying to achieve personalised glycaemic goals (Grade B).[4,5] Periodic CGM use is also suggested as an appropriate tool, when continuous CGM is not feasible, especially to support medication or lifestyle adjustments (Grade C).[4,5] Ajjan et al.[54] and Fernando et al.[55] provide strong support for expanding CGM use in noninsulin-treated adults living with T2DM, including a proposed framework for the use of CGM throughout the natural history of T2D. Periodic use of CGM at least every 3 months with healthcare provider review is also proposed for people living with T2DM who are not treated with insulin, which may also reduce or eliminate the need for BGM. Continuous access to CGM for daily use is suggested for people living with T2DM at higher risk of hypoglycaemia, similar to the current CGM clinical practice guideline recommendations from Diabetes Canada[56] and the American Association of Clinical Endocrinologists.[57]

6 | COST EFFECTIVENESS

Many societies, insurers, and payors continue to argue against expanding access to CGM for economic reasons and often limit coverage to only those who are being treated with insulin. CGM use in a broader population is accumulating research and clinical support, given its association with improved glycaemic outcomes, patient satisfaction, and diabetes-related distress.[58] Some studies have already investigated the cost-effectiveness of CGM in noninsulin-treated individuals living with T2DM. Fonda and colleagues[59] reported on the cost-effectiveness of the periodic rtCGM intervention previously reported by Ehrhardt et al.[33] Based on 2011 pricing, they found that intermittent rtCGM was a cost-effective option, with incremental cost-effectiveness ratios of $9319 and $13 030 per (life year) LY and (quality-adjusted life year) QALY gained, substantially lower than typical 'willingness-to-pay' ranges in the United States. A recent Canadian economic analysis using a person-level microsimulation model showed that isCGM is more cost-effective than BGM.[60] A similar analysis, modelled on the patient characteristics reported by Aronson and colleagues[49] also demonstrated greater cost-effectiveness of rtCGM over BGM for Canadian public payors, and was cost-saving for commercial payors, when absenteeism was included.[61] Finally, a cost effectiveness analysis reported in the LIBERATES trial, based on UKPDS (United Kingdom Prospective Diabetes Study) and hypoglycaemia models, found that both the estimated cost and the QALY were lower for isCGM than for BGM, in a T2DM cohort of which half were not using insulin therapy.[30]

7 | DISCUSSION AND RECOMMENDATIONS

To date, observational studies and clinical trials appear to indicate a meaningful benefit of CGM use among individuals living with T2DM, even when not using insulin therapy. Observational studies have shown benefits in HbA1c and TIR, along with gains in nonglycaemic outcomes. These benefits appear largely consistent across different types of CGM devices. Conclusions drawn from observational trials are limited by the inherent bias in uncontrolled trials, their small population sizes, and their limited durations. In addition, most of the observational trials summarised herein did not provide data on the pre-intervention use of BGM in the cohorts described. In most studies, the comparator group continued their prior usual care, including BGM use. Few trials targeted increased frequency of BGM, and none used newer BGM platforms that provide for shared reporting with their physician, nor applications that provide interactive lifestyle and medication counselling. Finally, although they indicate short-term glycaemic benefit, there remains a paucity of data on the impact of CGM use on longer-term health outcomes and on the complications of T2DM.

The various RCTs summarised herein, and the updated meta-analysis of their findings, appear to confirm the observed benefits in HbA1c, as well as in glucometric outcomes including TIR and TAR, in individuals with T2DM who have suboptimal glycaemic control. Although non-insulin-using individuals generally experience low TBR and few hypoglycaemia events, in higher risk subgroups such as sulphonylurea users and those with prior recurrent hypoglycaemia, CGM use is associated with reduced TBR. They also show benefits to some of the patient-reported nonglycaemic measures, with no apparent difference between the type of CGM device.

Despite the acknowledged limitations, the consistent finding of glycaemic benefit suggests certain 'pragmatic' recommendations that this working group would offer clinicians managing adults with T2DM, treated with noninsulin antihyperglycaemic therapies (Figure 2). CGM should be considered for these individuals with suboptimal glycaemic control, to improve glycaemic control, and to improve glucose monitoring satisfaction, with less diabetes-related distress. CGM can play a meaningful role in diabetes self-care education and in key skills

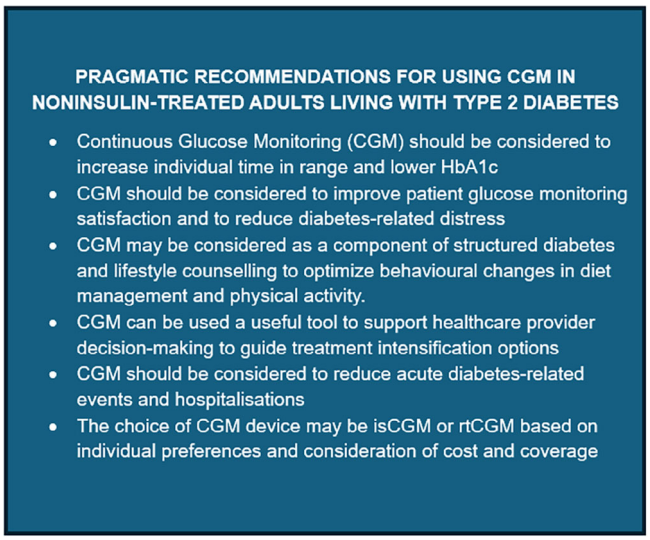

FIGURE 2 Pragmatic recommendations for using continuous glucose monitoring in noninsulin-treated adults living with type 2 diabetes and with suboptimal glycaemic control.

attainment. Introduction of CGM may be considered to actualise behavioural changes in diet management and physical activity, especially in the context of a structured lifestyle modification programme. Similarly, CGM may be useful in supporting healthcare provider decision-making regarding treatment intensification options. CGM should be considered to reduce acute diabetes-related events and hospitalisations in this population. Finally, the choice of isCGM or rtCGM should be based on individual preferences and consideration of cost and coverage.

AUTHOR CONTRIBUTIONS

All the authors contributed to the original drafting of the manuscript, critically reviewed the manuscript drafts, and approved the final version for submission. All the authors had full access to all the data presented and take responsibility for the integrity of the data and the accuracy of the review—all are accordingly guarantors of this work.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this manuscript are available from the PubMed, Embase and Cochrane Library databases.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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