ORIGINAL ARTICLE

Continuous Glucose Monitoring in Non–Insulin-Treated Type 2 Diabetes

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ABSTRACT

BACKGROUND

Continuous glucose monitoring (CGM) has been shown to be beneficial in persons with type 1 diabetes and others with insulin-treated type 2 diabetes, but its role in the treatment of persons with type 2 diabetes not being treated with insulin has needed further study.

METHODS

In a 26-week trial conducted at 22 primary care practices in the United States, we randomly assigned adults with type 2 diabetes who were not using insulin to either CGM or routine care (control). The primary outcome was the glycated hemoglobin level at 26 weeks. Key CGM-measured secondary outcomes were tested hierarchically to control the type I error rate.

RESULTS

A total of 145 participants were assigned to the CGM group, and 138 to the routine-care group. Participants ranged in age from 21 to 84 years. The mean (±SD) glycated hemoglobin level decreased from 8.8±1.3% at baseline to 7.2±1.1% at 26 weeks in the CGM group and from 8.7±1.2% to 8.0±1.4% in the routine-care group (adjusted mean difference, −0.9 percentage points; 95% confidence interval [CI], −1.1 to −0.6; P<0.001). The mean percentage of time that the CGM-measured glucose level was in the glucose-level range of 70 to 180 mg per deciliter was 21 percentage points higher (95% CI, 16 to 26) with CGM than with routine care (P<0.001). The between-group difference in the percentage of time that the glucose level was below 54 mg per deciliter was −0.17 percentage points (95% CI, −0.27 to −0.11; P<0.001 for noninferiority); the difference in the percentage of time that the glucose level was below 70 mg per deciliter was −0.20 percentage points (95% CI, −0.43 to −0.09; P<0.001 for noninferiority; P=0.004 for superiority). No severe hypoglycemia events were reported.

CONCLUSIONS

Among adults with type 2 diabetes that was not being treated with insulin and was being managed in a primary care setting, the use of CGM led to a greater reduction in the glycated hemoglobin level and to a lower risk of hyperglycemia than routine care. (Funded by Dexcom; CONNECT ClinicalTrials.gov number, NCT06601166.)

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In randomized trials, continuous glucose monitoring (CGM) has been shown to be beneficial for persons with type 1 diabetes or insulin-treated type 2 diabetes.[1-3] However, data on the effectiveness of CGM for persons with type 2 diabetes not being treated with insulin have been limited,[4,5] although the existing literature suggests benefit. The 2026 American Diabetes Association Standards of Care cites level A evidence (clear evidence from well-conducted, generalizable, randomized, controlled trials) to recommend the use of CGM by persons with diabetes receiving insulin therapy but cites only level C evidence (supportive evidence from poorly controlled or uncontrolled studies) for the treatment of persons with non–insulin-treated diabetes.[6]

Approximately 27 million adults in the United States have received a diagnosis of type 2 diabetes,[7] of whom approximately 20 million are not receiving insulin.[8,9] Most such patients receive diabetes care in primary care settings.[10-12] Treatment with medications such as glucagon-like peptide-1 (GLP-1) receptor agonists and sodium–glucose cotransporter 2 (SGLT2) inhibitors has enabled more persons with type 2 diabetes to have glycated hemoglobin levels meeting the American Diabetes Association target of less than 7%.[13] Whether patients with type 2 diabetes who are not receiving insulin and have elevated glycated hemoglobin levels would benefit from CGM is unclear.

We conducted a multicenter, randomized, controlled trial (CONNECT) to evaluate the efficacy and safety of CGM in adults with non–insulin-treated type 2 diabetes. To maximize the generalizability of the results, only patients receiving diabetes care in primary care practices were included in the trial.

Methods

Trial Conduct and Oversight

We conducted this trial at 22 primary care practices in the United States. A central institutional review board provided coverage for 20 sites, and a local institutional review board did so for 2 sites. Written informed consent was obtained electronically from each participant before trial commencement. The protocol, including the statistical analysis plan, is available with the full text of this article at NEJM.org. Trial oversight and author responsibilities are described in the Supplementary Appendix, available at NEJM.org. The sponsor, Dexcom, provided funding and CGMs. The trial was designed by the authors in conjunction with the sponsor. The sponsor was not involved in the data collection or analyses and had no role in the interpretation of the results other than providing comments on earlier versions of the manuscript. The sponsor did not have authority to approve the manuscript for submission for publication.

Trial Design and Participants

Trial participants were adults (≥18 years of age) who had had type 2 diabetes for at least 6 months (on the basis of clinical assessment) and were being treated in a primary care setting, with a locally measured glycated hemoglobin level at screening of at least 7.5%, no use of real-time CGM within the preceding 6 months, no use of insulin within the preceding 12 months, and stability of noninsulin glucose-lowering medications or weight-reduction medications for the previous month. Complete eligibility criteria are listed in Table S1 in the Supplementary Appendix.

After completing a minimum 10-day blinded CGM run-in period to obtain baseline glucose data, participants were randomly assigned in a 1:1 ratio to either the CGM group or the routine-care group. Randomization was stratified according to clinical site and whether a GLP-1 receptor agonist was used (with or without a GLP-1–glucose-dependent insulinotropic polypeptide [GIP] dual agonist).

In both groups, participants continued their pretrial glucose-lowering medications and received education on diet and exercise from trial staff. Participants who had been assigned to the CGM group were provided with a CGM (real-time Dexcom G7) and trained on its use. They were instructed to use the CGM daily and to perform blood-glucose measurements with fingerstick testing in accordance with the CGM user manual, such as when symptoms did not match the glucose level. Participants who had been assigned to the routine-care group were instructed to perform monitoring with a blood glucose meter at a frequency advised by their health care provider.

For participants in both groups, telehealth visits occurred at 1, 4, 8, and 19 weeks, and in-clinic visits at 13 and 26 weeks. At each visit, a trial clinician reviewed available glucose data

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(the CGM data for participants in the CGM group and available blood-glucose-meter data for those in the routine-care group according to the usual management routine of the clinical site). Lifestyle changes were recommended or changes made in medications as indicated. For 10 days before the 4-week, 13-week, and 26-week time points, participants in the routine-care group wore a blinded CGM sensor to obtain glucose data for outcome ascertainment. Glycated hemoglobin was measured at a central laboratory at baseline and at 13 weeks and 26 weeks. Participant-reported outcome surveys were completed as described in Table S2.

OUTCOMES

The primary efficacy outcome was the glycated hemoglobin level at 26 weeks. Key secondary outcomes, which were assessed in a hierarchical testing procedure to control the overall type I error, included the following glucose metrics as measured with CGM and were tested for superiority unless otherwise stated: the percentage of time in the glucose-level range of 70 to 180 mg per deciliter (3.9 to 10.0 mmol per liter), the mean glucose level as tested by the sensor, the percentage of time with the glucose level above 180 mg per deciliter, the percentage of time with the glucose level below 54 mg per deciliter (3.0 mmol per liter; tested for noninferiority [margin, 0.5 percentage points]), the percentage of time with the glucose level below 70 mg per deciliter (tested for noninferiority [margin, 2.0 percentage points]), the percentage of time with the glucose level above 250 mg per deciliter (13.9 mmol per liter), the percentage of time in the glucose-level range of 70 to 140 mg per deciliter (3.9 to 7.8 mmol per liter), the percentage of time with the glucose level below 70 mg per deciliter (tested for superiority), and the glucose coefficient of variation (the standard deviation divided by the mean glucose level). For CGM-measured outcomes, data that were collected at 13 weeks and 26 weeks were pooled unless otherwise stated. Given that the point estimates for the percentage of time with the glucose level below 54 mg per deciliter and the percentage of time with the glucose level below 70 mg per deciliter were less than 1%, precision of the estimate is reported to two decimal places, whereas other CGM outcomes are reported as integers or to one decimal place. Additional exploratory outcomes, including binary glycated hemoglobin outcomes (reduction of ≥0.5 percentage points from baseline and levels of <7.0%, <8.0%, and >9.0%), are listed in Table S3. Safety outcomes included severe hypoglycemia, diabetic ketoacidosis, hyperosmolar hyperglycemic syndrome, and other serious adverse events.

STATISTICAL ANALYSIS

We calculated that a sample of 266 participants completing the trial would provide the trial with 90% power on the basis of the following assumptions: randomization in a 1:1 ratio, a between-group difference in the glycated hemoglobin level at 26 weeks (primary outcome) of 0.4 percentage points, a standard deviation of 1.0 percentage point for the glycated hemoglobin level at 26 weeks with adjustment for the baseline glycated hemoglobin level, and a two-sided type I error rate of 5%. Statistical analyses were performed on an intention-to-treat basis; efficacy and safety analyses included all the participants who underwent randomization.

The primary and other analyses of continuous variables compared the CGM and routine-care groups using a linear mixed-effects regression model with adjustment for the baseline value, GLP-1 receptor agonist use, and clinical site (random factor). Missing data were handled by means of the direct likelihood method. If residuals were highly skewed, the outcomes were Winsorized according to treatment group as described in Section C in the Supplementary Appendix. For binary outcomes, risk-adjusted differences between the trial groups were computed at 26 weeks with the use of generalized estimating equations with a logistic link, with adjustment for baseline level of the outcome, GLP-1 receptor agonist use, and clinical site. Exploratory subgroup analyses assessed the between-group difference in the glycated hemoglobin level according to various baseline characteristics, including the glycated hemoglobin level, the time in the glucose-level range of 70 to 180 mg per deciliter, age, sex, race or ethnic group, duration of diabetes, educational level, annual household income, health insurance, and noninsulin glucose-lowering medication.

For outcomes that were not part of the hierarchy to control the type I error rate, P values are not reported. Confidence intervals around point estimates were adjusted with the use of the adap-

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tive Benjamini–Hochberg procedure but should not be used to infer definitive treatment effects. SAS software, version 9.4 (SAS Institute), was used for the analyses. Additional details of the statistical methods are provided in Section C in the Supplementary Appendix.

RESULTS

PARTICIPANTS AND FOLLOW-UP

From September 2024 through November 2025, a total of 283 participants were randomly assigned to the CGM group (145 participants) or the routine-care group (138). Participants ranged in age from 21 to 84 years. The duration of diabetes ranged from 1 to 37 years, and the baseline glycated hemoglobin level (as measured at the central laboratory) ranged from 7.1 to 14.9% (mean [±SD], 8.8±1.2%). Ninety participants (32%) identified themselves either as non-White or as Hispanic or Latino. GLP-1 receptor agonist medication was being used by 112 participants (40%), an SGLT2 inhibitor by 104 (37%), and medications in both classes by 51 (18%). The characteristics of the participants at baseline appeared to be balanced between the two trial groups (Table 1 and Table S4). The relevance and representativeness of the trial population is discussed in Table S5.

The 26-week trial was completed by 141 of 145 participants (97%) in the CGM group and by 124 of 138 (90%) in the routine-care group; reasons for withdrawal are provided in Figure S1. Overall, participants in the CGM group completed 851 of 870 visits (98%), and those in the routine-care group completed 772 of 828 visits (93%).

GLUCOSE MONITORING

In the CGM group, no participants discontinued CGM use before 26 weeks other than the 4 participants who withdrew from the trial. Among the 141 participants in the CGM group who completed the trial, CGM-measured glucose data were obtained for a median of 97% of the possible time (interquartile range, 91 to 99) over the entire 26-week period, with 86% of the participants using the CGM at least 80% of the time (Table S6). Two participants in the routine-care group initiated real-time CGM before 26 weeks. The median number of blood-glucose-meter measurements was 3 per week (interquartile range, 0 to 7) at baseline and 0 per week (interquartile range, 0 to 1) at 26 weeks in the CGM group, as compared with 2 per week (interquartile range, 0 to 7) and 3 per week (interquartile range, 0 to 7), respectively, in the routine-care group (Table S7).

EFFICACY OUTCOMES

Glycated Hemoglobin

The mean glycated hemoglobin level decreased from 8.8±1.3% at baseline to 7.2±1.1% at 26 weeks in the CGM group (mean change, −1.6 percentage points; 95% confidence interval [CI], −1.8 to −1.3) and from 8.7±1.2% to 8.0±1.4% in the routine-care group (mean change, −0.7 percentage points; 95% CI, −0.9 to −0.5) (Table 2 and Fig. S2). The adjusted mean difference in the glycated hemoglobin level at 26 weeks for CGM as compared with routine care was −0.9 percentage points (95% CI, −1.1 to −0.6; P<0.001). Sensitivity analyses with the use of different methods for handling confounding and missing data produced results similar to those of the primary analysis (Table S8).

In exploratory analyses, a reduction in the glycated hemoglobin level by at least 0.5 percentage points from baseline occurred in 82% of the participants in the CGM group, as compared with 56% of the participants in the routine-care group; a glycated hemoglobin level below 7.0% was observed in 46% and 24%, respectively. The glycated hemoglobin level was below 8.0% in 84% of the participants in the CGM group and in 56% of those in the routine-care group and was above 9.0% in 6% and 12%, respectively (Table S9), results that align with Healthcare Effectiveness Data and Information Set (HEDIS) glycemic status measures.[14] Glycated hemoglobin results at 13 weeks were similar to those at 26 weeks (Table S10). Results appeared to be similar across a broad range of baseline characteristics, including age, sex, race or ethnic group, body-mass index, duration of diabetes, annual household income level, education, health insurance, and glucose-lowering medications at baseline (Fig. 1).

CGM-Measured Outcomes

Key secondary multiplicity-controlled CGM-measured outcomes that were reflective of hyperglycemia were all significantly better in the CGM

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Table 1. Characteristics of the Participants at Baseline.*

Characteristic	CGM (N=145)	Routine Care (N=138)
Age — yr		
Mean	59±13	60±12
Range	21–82	32–84
Female sex — no. (%)	63 (43)	57 (41)
Race or ethnic group — no. (%)†		
White	117 (81)	108 (78)
Black	20 (14)	17 (12)
Asian	2 (1)	6 (4)
American Indian or Alaska Native	1 (1)	0
Multiple	3 (2)	4 (3)
Hispanic or Latino ethnic group — no. (%)†	18 (12)	21 (15)
Body-mass index‡	33±7	34±8
Median duration of diabetes (IQR) — yr	9 (5–16)	10 (5–17)
Glycated hemoglobin — %§		
Mean	8.8±1.3	8.7±1.2
Range	7.1–14.2	7.3–14.9
Noninsulin glucose-lowering medication — no. (%)¶		
None	12 (8)	10 (7)
Metformin only	22 (15)	25 (18)
GLP-1 receptor agonist without SGLT2 inhibitor	33 (23)	28 (20)
SGLT2 inhibitor without GLP-1 receptor agonist	30 (21)	23 (17)
Both GLP-1 receptor agonist and SGLT2 inhibitor	24 (17)	27 (20)
Other	24 (17)	25 (18)
Median no. of blood-glucose-meter tests per week (IQR)	3 (0–7)	2 (0–7)

* Plus–minus values are means ±SD. CGM denotes continuous glucose monitoring, IQR interquartile range, and SGLT2 sodium–glucose cotransporter 2.
† Race and ethnic group were reported by the participant. Data on race or ethnic group were missing for two participants in the CGM group and for three in the routine-care group. Data on Hispanic or Latino ethnic group were missing for two participants in the routine-care group.
‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.
§ The glycated hemoglobin level is from the central laboratory measurement at baseline.
¶ Glucagon-like peptide-1 (GLP-1) receptor agonist use included use of a combined GLP-1 receptor agonist and glucose-dependent insulinotropic polypeptide (GIP) dual agonist.

group than in the routine-care group. The percentage of time in the glucose-level range of 70 to 180 mg per deciliter increased in the CGM group from 29±26% at baseline to 62±25% at follow-up and from 31±23% to 42±26%, respectively, in the routine-care group (mean difference, 21 percentage points; 95% CI, 16 to 26; P<0.001) (Table 2). The percentage of time in the glucose-level range of 70 to 180 mg per deciliter at 4, 13, and 26 weeks is shown in Figure 2.

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The mean glucose level, the percentage of time with the glucose level above 180 mg per deciliter, and the percentage of time with the glucose level above 250 mg per deciliter were all significantly lower with CGM than with routine care (Table 2). The frequency of CGM-measured hypoglycemia was low at baseline and changed little in each group during follow-up (difference in the percentage of time with the glucose level <54 mg per deciliter, −0.17 percentage points [95% CI, −0.27 to −0.11]; P<0.001 for noninferiority; and difference in the percentage of time with the glucose level <70 mg per deciliter, −0.20 percentage points [95% CI, −0.43 to −0.09]; P<0.001 for noninferiority, and P=0.004 for superiority). Glycemic variability, as measured with the glucose coefficient of variation, was also significantly lower with CGM than with routine care (Table 2).

The percentage of time with the glucose level in the target range (70 to 180 mg per deciliter) of more than 70% was observed in 40% of the participants in the CGM group and in 15% of those in the routine-care group (Table S11). Results for additional CGM hyperglycemic metrics are shown in Table S12; for CGM metrics during daytime and nighttime in Table S13; for CGM metrics at 4, 13, and 26 weeks in Table S14; and for the time with the glucose level in the target range (70 to 180 mg per deciliter) according to subgroups in Figure S3. The pattern of improvement in the time with the glucose level in the target range in the CGM group over the course of 26 weeks is shown in Figure S4, and the hourly mean glucose levels according to the time of day are shown in Figure S5.

DIABETES TREATMENTS AND METABOLIC OUTCOMES

During the trial, insulin or noninsulin glucose-lowering medications were added for 44 of 143 participants (31%) in the CGM group and for 22 of 126 participants (17%) in the routine-care group (Table S15). Insulin was prescribed for 6 participants (4%) in the CGM group and for 2 (2%) in the routine-care group. Additional noninsulin glucose-lowering medications were prescribed for 38 participants (27%) in the CGM group and for 21 (17%) in the routine-care group, with the GLP-1 receptor agonist medication class being most common. Most medication additions occurred during the first 13 weeks of the trial. Noninsulin glucose-lowering medications were removed without the addition of other medications for 8 of 131 participants (6%) who were receiving medication at baseline in the CGM group and for 6 of 116 (5%) in the routine-care group; 2 participants in the CGM group and 1 in the routine-care group discontinued all glucose-lowering medications. The mean change in the glycated hemoglobin level over a period of 26 weeks was −0.5 percentage points among participants who were newly prescribed insulin or other glucose-lowering medications during the trial and −0.9 percentage points among those who were not.

The mean change in the body weight from baseline was −2.5±4.8 kg in the CGM group and −1.8±4.0 kg in the routine-care group (difference, −0.7 kg; 95% CI, −2.1 to 0.7) (Table S16). No meaningful between-group differences were observed in changes in lipid, renal, and liver-function laboratory results (Table S17). Results of the participant-reported outcome surveys are summarized in Table S18.

SAFETY OUTCOMES

A total of 33 adverse events were reported in 24 participants in the CGM group, and 24 events in 15 participants in the routine-care group (Table 3 and Table S19). A serious adverse event occurred in 6 participants (7 events) in the CGM group and in 6 participants (7 events) in the routine-care group (1 of whom died owing to a myocardial infarction); all serious adverse events were adjudicated by the medical monitor as being unrelated to trial treatment and included 10 hospitalizations and 4 developments of a cancer. No cases of severe hypoglycemia or hyperglycemia-related serious adverse events were observed. Three reported adverse events in the CGM group — 2 for bleeding at the sensor-insertion site and 1 for bleeding on sensor removal — were considered by the medical monitor to be related to the sensor.

DISCUSSION

In this multicenter, randomized, controlled trial involving adults with non–insulin-treated type 2 diabetes conducted in a primary care setting, the mean change in the glycated hemoglobin level was −1.6 percentage points (95% CI, −1.8 to −1.3) with CGM, as compared with a mean change of −0.7 percentage points (95% CI, −0.9 to −0.5) in the routine-care group, in which a blood glucose

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Table 2. Primary and Secondary Hierarchical Efficacy Outcomes.*

Outcome	At Baseline		At Follow-up†		Adjusted Difference (95% CI)☼	P Value
	CGM (N=145)	Routine Care (N=138)	CGM (N=145)	Routine Care (N=138)		
Primary outcome						
Glycated hemoglobin — %	8.8±1.3	8.7±1.2	7.2±1.1	8.0±1.4	−0.9 (−1.1 to −0.6)	<0.001
Secondary outcomes						
No. of CGM readings included in analysis	3031±556	3096±623	5714±802	5687±1227		
Time with glucose level in range 70–180 mg/dl — %	29±26	31±23	62±25	42±26	21 (16 to 26)	<0.001
Mean glucose level — mg/dl§	229±58	225±49	175±40	207±47	−35 (−44 to −26)	<0.001
Time with glucose level >180 mg/dl — %	70±27	69±24	38±25	58±26	−21 (−26 to −15)	<0.001
Time with glucose level <54 mg/dl — %¶‖	0.21±0.31	0.26±0.44	0.02±0.04	0.19±0.25	−0.17 (−0.27 to −0.11)	<0.001
Time with glucose level <70 mg/dl — %¶‖	0.30±0.44	0.28±0.45	0.12±0.17	0.31±0.41	−0.20 (−0.43 to −0.09)	<0.001
Time with glucose level >250 mg/dl — %‖	33±27	31±25	7±8	22±18	−15 (−19 to −12)	0.002
Time with glucose level in range 70–140 mg/dl — %‖	8±10	8±8	28±19	15±15	13 (9 to 17)	0.002
Glucose coefficient of variation — %**	23±6	23±6	23±5	26±6	−2.1 (−3.3 to −0.9)	<0.001

* Plus–minus values are means ±SD. Data on the glycated hemoglobin level at week 26 were missing for 8 participants in the CGM group and for 15 in the routine-care group. Follow-up CGM data were missing for 15 participants in the routine-care group. All the participants who had undergone randomization were included in the models on an intention-to-treat basis. Missing data were handled by means of the direct likelihood method. To convert values for glucose to millimoles per liter, multiply by 0.05551.

† Follow-up data are shown at 26 weeks for the glycated hemoglobin level (primary outcome) and were pooled for the CGM metrics at 13 weeks and 26 weeks.

☼ Shown are the mean differences at follow-up between the CGM group and the routine-care group. Differences between percents are shown in percentage points. The treatment effect, confidence interval, and P value were estimated from a linear mixed-effects regression model with adjustment for baseline value, GLP-1 receptor agonist use, and clinical center (random effect). If the residuals were highly skewed, then Winsorization was used instead.

§ The value for the mean glucose level was summarized across all the participants in each group and calculated as the sum of each participant's mean glucose value divided by the number of participants.

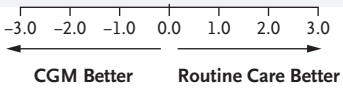
¶ The P values shown in the table reflect tests for noninferiority. The noninferiority margin for the percentage of time with the glucose level below 54 mg per deciliter (3.0 mmol per liter) was 0.5 percentage points. The noninferiority margin for the percentage of time with the glucose level below 70 mg per deciliter (3.9 mmol per liter) was 2.0 percentage points. The percentage of time with the glucose level below 70 mg per deciliter was also tested for superiority as part of the hierarchical analysis after the analysis of the percentage of time with the glucose level in the range of 70 to 140 mg per deciliter (3.9 to 7.8 mmol per liter); P=0.004 for superiority.

‖ Shown are Winsorized means with standard deviations.

** The glucose coefficient of variation is the standard deviation divided by the mean glucose level.

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Subgroup	Continuous Glucose Monitoring	Routine Care	Treatment Effect (95% CI)
	no. of patients		*percentage points*
Glycated hemoglobin level at baseline			
7.0 to 7.9%	32	33	−0.3 (−0.8 to 0.3)
8.0 to 8.4%	39	30	−0.7 (−1.2 to −0.1)
8.5 to 8.9%	22	26	−1.0 (−1.7 to −0.4)
9.0 to 9.9%	17	22	−1.1 (−1.9 to −0.4)
≥10.0%	27	12	−2.1 (−2.9 to −1.3)
Time in glucose-level range of 70 to 180 mg/dl at baseline			
<40%	97	79	−1.0 (−1.3 to −0.6)
40 to <60%	18	26	−0.3 (−0.9 to 0.4)
≥60%	22	18	−1.0 (−1.8 to −0.3)
Age			
<40 yr	9	8	−1.2 (−2.3 to −0.1)
40 to <65 yr	83	70	−0.9 (−1.3 to −0.5)
≥65 yr	45	45	−0.7 (−1.2 to −0.2)
Sex			
Female	59	53	−0.9 (−1.3 to −0.5)
Male	78	70	−0.8 (−1.2 to −0.5)
Race or ethnic group			
White, non-Hispanic and non-Latino	97	78	−0.8 (−1.2 to −0.5)
Other	40	44	−0.9 (−1.4 to −0.4)
Diabetes duration			
<10 yr	74	61	−1.2 (−1.6 to −0.8)
10 to <20 yr	38	37	−0.4 (−0.9 to 0.2)
≥20 yr	25	25	−0.6 (−1.2 to 0.0)
Body-mass index			
<30	45	40	−0.6 (−1.1 to −0.1)
30 to <40	75	62	−0.9 (−1.3 to −0.5)
≥40	17	21	−1.1 (−1.8 to −0.4)
Education			
Less than bachelor's degree	84	81	−0.9 (−1.3 to −0.6)
Bachelor's degree or higher	48	41	−0.7 (−1.2 to −0.2)
Annual household income in U.S. dollars			
≤$50,000	53	45	−0.7 (−1.2 to −0.3)
>$50,000 to <$100,000	51	38	−0.7 (−1.2 to −0.3)
≥$100,000	25	28	−1.0 (−1.6 to −0.4)
Health insurance			
Private	69	59	−0.9 (−1.3 to −0.5)
Other	65	63	−0.7 (−1.1 to −0.3)
Noninsulin glucose-lowering medication			
None	10	10	−0.7 (−1.7 to 0.3)
Metformin only	22	22	−1.1 (−1.8 to −0.5)
GLP-1RA without SGLT2 inhibitor	31	26	−1.3 (−1.9 to −0.7)
SGLT2 inhibitor without GLP-1RA	30	18	−0.9 (−1.5 to −0.2)
Both GLP-1RA and SGLT2 inhibitor	22	24	−0.6 (−1.3 to 0.0)
Other	22	23	−0.4 (−1.1 to 0.2)



meter was used for monitoring — a significant difference. The reduction in hyperglycemia with CGM was reflected in a 21-percentage-point increase in the time in the target glucose range of 70 to 180 mg per deciliter as compared with routine care, which is equivalent to 5 hours per day. No safety concerns were reported with use of CGM although the sample size was too small to detect differences in rare safety events. Results for glycated hemoglobin and time-in-range outcomes were similar across a wide range of participant characteristics.

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Figure 1 (facing page). Treatment-Group Difference in Glycated Hemoglobin Level According to Baseline Subgroups.

The treatment effect on the glycated hemoglobin level is shown as the difference (in percentage points) in the mean glycated hemoglobin level at 26 weeks between the continuous glucose monitoring (CGM) group and the routine-care group, with adjustment for the baseline glycated hemoglobin level. The vertical dotted line represents a treatment-group difference of zero. Point estimates to the left of the vertical line indicate a lower glycated hemoglobin level in the CGM group than in the routine-care group. The confidence intervals should not be used for inference. To convert values for glucose to millimoles per liter, multiply by 0.05551. Race and ethnic group were reported by the participant. The body-mass index is the weight in kilograms divided by the square of the height in meters. Glucagon-like peptide-1 receptor agonist (GLP-1RA) use included use of a combined GLP-1RA and glucose-dependent insulinotropic polypeptide (GIP) dual agonist. SGLT2 denotes sodium–glucose cotransporter 2.

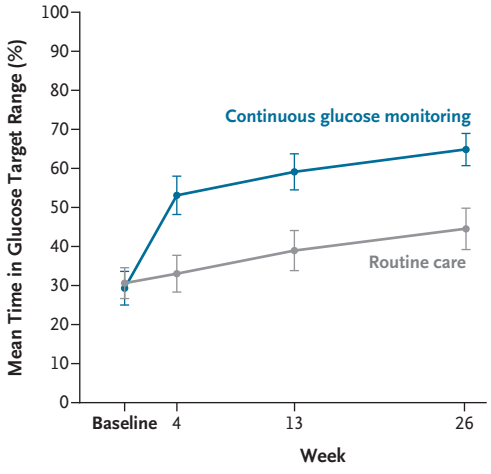


Figure 2. Mean Time in Glucose-Level Target Range at Baseline and at 4, 13, and 26 Weeks.

The glucose-level target range was defined as 70 to 180 mg per deciliter. I bars indicate the 95% confidence intervals.

During follow-up, either insulin or additional noninsulin glucose-lowering medications were prescribed for a minority of participants (31% of the participants in the CGM group and 17% of those in the routine-care group), which suggests that the improvement observed with CGM cannot be explained by medication changes alone but may have been due to modifications in behavioral habits that could affect glucose levels. CGM use was very high over the full 26-week period, with a median use of 97% of the time, with 86% of the participants using CGM at least 80% of the time.

Although the routine-care group had significantly less improvement in glycemic control than the CGM group, the glycemic improvement in that group was of a magnitude (mean change in the glycated hemoglobin level, −0.7 percentage points) that would be considered a successful intervention. To minimize bias, the routine-care group had an identical follow-up contact schedule as the CGM group, which was substantially greater contact than is typical in primary care for patients with non–insulin-treated type 2 diabetes. This factor clearly led to a trial effect and emphasizes the importance of having randomized treatment assignments with balanced contact in the groups.

Data from other trials on the effect of CGM in non–insulin-treated type 2 diabetes have been limited.[4,5] Two smaller randomized trials of CGM

Table 3. Safety Outcomes during the 26-Week Trial Period.

Event	CGM (N=145)	Routine Care (N=138)
Any adverse event *		
No. of participants with event (%)	24 (17)	15 (11)
No. of events	33	24
Specific events		
Severe hypoglycemia — no. of events	0	0
Diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome — no. of events	0	0
Other serious adverse events†		
No. of participants with event (%)	6 (4)	6 (4)
No. of events	7	7
Unanticipated adverse device-related effects — no. of events	0	0

* Reportable adverse events included events that met the criteria for a serious adverse event, met the criteria for severe hypoglycemia, met the criteria for diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome, were associated with an emergency department visit, led to a temporary or permanent discontinuation of the trial device, had a clinically significant effect on the participant's glucose levels (or the treatment of the event, e.g., glucocorticoids, could have had a clinically significant effect on glucose levels), affected the participant's ability to complete a trial procedure, or met the criteria for certain adverse device-related effects.

† The other serious adverse events were the following: cancer (in one participant) and hospitalization for a non–glycemia-related systemic medical condition (in six) in the CGM group, and cancer (in three participants) and hospitalization for a non–glycemia-related systemic medical condition (in four, including one who died after a myocardial infarction) in the routine-care group.

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showed a mean decrease in the glycated hemoglobin level of 0.3 percentage points as compared with a control group.[15,16] Both those trials evaluated intermittently scanned CGM, which requires an action on the part of the user to visualize the glucose values, rather than real-time CGM. This situation could explain why our trial showed a larger glycated hemoglobin decrease with CGM than was observed in the previous trials. However, other differences in the trial design and procedures might have been a factor.

Strengths of our trial include a randomized design; a control group that had a similar contact schedule as the intervention group; conduct of the trial in a primary care setting, which is where most adults with type 2 diabetes in the United States receive diabetes care; and the inclusion of a heterogeneous trial population of adults with type 2 diabetes not using insulin. Our trial also has certain limitations, principally the lack of real-time, objective data on changes in eating habits, exercise, and medication adherence that would enable assessment of the reasons for improvement in the CGM group. The duration of follow-up was only 26 weeks; however, a 26-week extension phase is being conducted to obtain data on sustained use of CGM and the durability of effect. Provision of sensors to the trial participants and the visit frequency might have affected the high percentage of CGM use that was observed, and adherence and glycemic benefit might be lower with real-world use. The control group also had substantially more contact than would occur in routine care, which is both a strength of the trial with regard to limiting bias as well as a limitation in exceeding what would be typical in a primary care practice.

In this trial involving adults with type 2 diabetes being treated in a primary care setting, the use of CGM led to a significantly greater reduction in the glycated hemoglobin level and to a lower risk of hyperglycemia than were seen in a control group that received routine care.

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