Supplementary Online Content

Pratley RE, Kanapka LG, Rickels MR, et al; Wireless Innovation for Seniors With Diabetes Mellitus (WISDM) Study Group. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. *JAMA*. Published June 16, 2020. doi:10.1001/jama.2020.6928

- eTable 1. Eligibility and Exclusion Criteria
- eTable 2. Description of Cognitive Assessment and Patient-Reported Outcomes
- eTable 3. Multiple Comparisons Summary
- eTable 4. Baseline Characteristics by Pump and MDI Users
- eTable 5. Comorbidities at Enrollment
- eTable 6. Types of Medications at Enrollment
- eTable 7. Unscheduled Contacts
- eTable 8. Real-time CGM Use
- eTable 9. Real-time CGM Use by Pump and MDI Users
- eTable 10. CGM Metrics in Time per Day
- eTable 11. Glycemic Outcomes at 16 Weeks
- eTable 12. Per-Protocol Analysis of Percent Time <70 mg/dL
- **eTable 13.** CGM Metrics During the Daytime (6:00AM-11:59PM) and Nighttime (12:00AM-5:59AM)
- eTable 14. Glycemic Outcomes Among Participants Using a Pump for Insulin Delivery
- eTable 15. Glycemic Outcomes Among Participants Using Injections for Insulin Delivery
- eTable 16. Subgroup Analysis for Percent Time Spent <70 mg/dL by Baseline Characteristics
- eTable 17. Binary HbA1c Outcomes
- eTable 18. Device Issues
- eTable 19. Cognitive Assessment and Patient-Reported Outcomes
- eFigure 1. Visit Completion by Treatment Group
- eFigure 2. Parallel Line Plot of Percent Time <70 mg/dL
- eAppendix. CGM Education Materials

eReferences

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Eligibility and Exclusion Criteria

Participant Inclusion Criteria

- 1. Clinical diagnosis of insulin dependent presumed autoimmune type 1 diabetes by the investigator and meeting at least one of the following criteria:
 - i. Age > 6 months and < 10 years old at diagnosis OR
 - ii. Positive pancreatic autoantibodies at any time (GAD-65, IA-2, ICA or ZnT8) or positive anti-insulin autoantibody at diagnosis only (within 10 days of starting insulin) <u>OR</u>
 - iii. Presence of 2 or more of the following clinical indicators suggestive of type 1 diabetes:
 - a. Age at diagnosis < 40 years
 - b. Non-obese at diagnosis according to BMI (< 95^{th} percentile pediatric and < 30 kg/m^2 adult)
 - c. Diabetic ketoacidosis (DKA) at any time
 - d. Plasma C-peptide level < 0.8 ng/ml (with blood glucose > 80 mg/dL if available) at any time
 - e. Family history of type 1 diabetes in a first degree relative (parent, sibling, or child)
- 2. Age ≥ 60 years
- 3. HbA1c ≤10.0% at screening or within 30 days prior to screening visit (*the upper limit was* selected as a surrogate measure of likelihood of adherence to the protocol with the belief that those with higher HbA1c levels are generally noncompliant with diabetes management and thus not good candidates for the trial)
- 4. Insulin regimen involves either use of an insulin pump (a minimum of 40% of study population) or multiple daily injections of insulin (minimum of 40% of study population).
- 5. Participant is able to manage his/her diabetes with respect to insulin administration and glucose monitoring (*which may include assistance from spouse or other caregiver*)
- 6. Participant understands the study protocol and agrees to comply with it
- 7. Participant comprehends written and spoken English
- 8. At least 240 hours (10 out of 14 days) of sensor glucose data with appropriate number of calibrations from the blinded CGM pre-randomization phase

Participant Exclusion Criteria

- 1. Use of unblinded CGM, outside of a research study, as part of real-time diabetes management in the last 3 months
- 2. At least 10% of time spent with sensor glucose levels < 54 mg/dl during the blinded CGM screening period AND a severe hypoglycemic event in the past 6 months (a severe hypoglycemic event that required assistance of another person due to altered consciousness, and required

another person to actively administer carbohydrate, glucagon, or other resuscitative actions (see section 8.1).

- 3. Extreme visual or hearing impairment that would impair ability to use real-time CGM assessed at screening visit
- 4. Known adhesive allergy or skin reaction during the blinded CGM pre-randomization phase that would preclude participation in the randomized trial
- 5. Plans to begin non-insulin medication for blood glucose lowering during the course of the study
- 6. Stage 4 or 5 renal disease or most recent $GFR < 30 \text{ ml/min/m}^2$ from local lab within the past 6 months
- 7. The presence of a significant medical or psychiatric condition or use of a medication that in the judgment of the investigator may affect completion of any aspect of the protocol, or is likely to be associated with life expectancy of <1 year.
- 8. Clinical diagnosis of dementia (cognitive impairment that is mild and not considered sufficient for diagnosis of dementia is acceptable)
- 9. Need for use of acetaminophen or acetaminophen-containing products on a regular basis during the 6 months of the trial
- 10. Inpatient psychiatric treatment in the past 6 months
- 11. Participation in an intervention study (including psychological studies) in past 6 weeks.
- 12. Expectation that participant will be moving out of the area of the clinical center during the next 6 months, unless the move will be to an area served by another study center.

eTable 2. Description of Cognitive Assessment and Patient-Reported Outcomes

Questionnaire/ Assessment	Description	Score Scale
Hypoglycemia Fear Survey (HFS-II)	The Hypoglycemia Fear Survey measures several dimensions of fear of hypoglycemia among adults with type 1 diabetes. It consists of a 10-item Behavior subscale that measured behaviors involved in avoidance and over- treatment of hypoglycemia and a 13-item Worry subscale that measures anxiety and fear surrounding hypoglycemia. Scores were calculated only for the worry subscale.	0-4 average item score; A higher score indicates more fear.
Type 1 Diabetes Distress Scale (T1-DDS)	28-item questionnaire used to measure diabetes-related concerns about powerlessness, management, hypoglycemia, social perceptions, eating, physician, and friends/family.	1-6 average item score; A higher score indicates more distress. A cut score of ≥ 2.0 is considered elevated diabetes distress. Minimal clinically important difference = 0.19^1
Glucose Monitoring System Satisfaction Survey (GMSS)	15-item questionnaire used to assess glucose monitoring device-related treatment satisfaction and QOL that is appropriate for use with both CGM and SMBG.	1-5 average item score; A higher score indicates more satisfaction.
Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Short Form	10-item measure of overall QOL that covers both physical and mental health. A t-score was calculated for the physical and mental subscales.	Standardized t-score with mean 50 and standard deviation 10 for the US general population. A higher t-score indicates better health.
Hypoglycemic Awareness using the Clarke hypoglycemic unawareness scale	The Clark method of assessing Hypoglycemic Unawareness consists of 8 questions, which evaluate glycemic threshold for, and symptomatic responses to, hypoglycemia.	0-7; A higher score indicates less awareness. A score \geq 4 is classified as 'Reduced Awareness', a score =3 is classified as 'Uncertain', and a score \leq 2 is classified as 'Aware'.
Preferring Hypoglycemia Scale	A survey designed to measure attitudes toward hypoglycemia and hyperglycemia and fear of hyperglycemia.	1-5 average item score; A higher score indicates more preference for hypoglycemia. A score ≥3.5 is classified as hyperglycemic fear.
NIH Toolbox Emotion Battery (NIHTB-EB)	A 10 minute battery of computer adaptive measures of emotional function; the following selected measures within the following domains were administered: Psychological	Standardized t-score with mean 50 and standard deviation 10 for the US general

	Well Being (positive affect survey), Stress & Self-Efficacy (perceived stress survey and self-efficacy survey), Social Relationships (instrumental support survey and emotional support survey), and Negative Affect (fear-affect survey and sadness survey).	population. A higher t-score indicates more of the trait being measured.
NIH Toolbox Cognition Battery (NIHTB-CB)	A 30 minute computerized battery of neuropsychological tests. The test generates individual subtest standard scores as well as a composite score. Age-corrected standard scores were used. The NIHTB-CB was administered by research coordinators who were trained in test administration using materials provided by the test publisher (administration manual and online training videos). All examiners completed study specific certification by a board certified clinical neuropsychologist and received ongoing supervision as needed throughout the study. Capillary blood glucose was checked prior to testing and had to be >70 mg/dL for testing to commence.	Standardized score with mean 100 and standard deviation 15 for the US general population. A higher score indicates higher cognitive function. Cognitive impairment was defined according to recommendations for interpreting low scores on the NIHTB- CB by Holdnack et al (2017). Those with \geq 2 low scores on the 5 Fluid subtests were classified as having cognitive impairment. A low score was defined as an age-adjusted standard score <80 (1.33 standard deviations below the mean for adults of the same age). Having >2 low scores occurred in 11.2% of the NIH Toolbox normative sample.

eTable 3. Multiple Comparisons Summary

Analysis	# of P-values	# of P-values Reported ^a	Correction Category For FDR Adjustment using Benjamini-Hochberg Procedure ^b
Primary Analyses	1	1	No correction
Sensitivity Analysis			
Methods for handling missing data	2	0	No correction
Add covariates that appear unbalanced	1	0	No correction
Per-protocol	1	1	No correction
Secondary Analyses			
Overall CGM metrics	9	9	Overall CGM Metrics
HbA1c outcomes	7	7	HbA1c Outcomes
Questionnaires	15	15	Questionnaires
Subgroup Analysis	12	12	Subgroup Analysis
Safety Analyses	5	5	No correction
Exploratory Analyses ^c			
Daytime CGM metrics	10	10	Daytime CGM Metrics
Nighttime CGM metrics	10	10	Nighttime CGM Metrics
Overall CGM metrics at 16 weeks	10	10	Overall CGM Metrics
Exploratory combined CGM metric	1	0^d	Overall CGM Metrics
HbA1c at 16 weeks	1	1	HbA1c Outcomes
CGM metrics (Pump users only)	10	10	CGM Metrics (Pump users only)
CGM metrics (Injection users only)	10	10	CGM Metrics (Injection users only)
HbA1c outcomes (Pump users only)	7	1 ^e	HbA1c Outcomes (Pump users only)
HbA1c outcomes (MDI Only)	7	1 ^e	HbA1c Outcomes (Injection users only)
Questionnaires (Injection users only)	15	0 ^e	Questionnaires (Pump users only)
Questionnaires (MDI Only)	15	0 ^e	Questionnaires (Injection users only)
BGM checking	1	0	Overall CGM Metrics
Total	150	103	

^aIncludes manuscript and supplementary materials.

^bP-values were adjusted in categories to control the false discovery rate. Categories were pre-specified in SAP.

^cExploratory analyses were also pre-specified in the SAP.

 d A pre-specified exploratory outcome combining percent time <70 mg/dL and percent time >180 mg/dL was not reported given that significant differences were observed for each individual outcome.

© 2020 American Medical Association. All rights reserved.

^eThe analysis binary HbA1c outcomes and questionnaires separately by injection and pump users was not reported. The results paralleled the overall analysis.

eTable 4. Baseline Characteristics by	Pump and MDI Users ^{a,b}
---------------------------------------	--

erable 4. Basenne Characteristics by Fully		Users	MDI	Users
	Continuous	Blood	Continuous	Blood
	Glucose	Glucose	Glucose	Glucose
	Monitoring	Monitoring	Monitoring	Monitoring
	(N=58)	(N=50)	(N=45)	(N=50)
Age (years)				
Median (Q1, Q3)	68 (66, 72)	67 (66, 70)	67 (64, 71)	67 (63, 72)
Range	60 to 83	60 to 83	60 to 81	61 to 86
Diabetes Duration (years)				
Median $(Q1, Q3)$	40 (28, 48)	36 (30, 47)	36 (22, 51)	36 (21, 50)
Range	5.9 to 64.7	9.9 to 64.2	0.9 to 60.8	0.2 to 70.7
Age at Diagnosis (years) – Median (Q1,	20 (20 44)	22(10,41)	20 (17 49)	20(10, 46)
$Q\overline{3}$	30 (20, 44)	32 (19, 41)	30 (17, 48)	30 (19, 46)
Female sex	37 (64%)	20 (40%)	24 (53%)	24 (48%)
Non-Hispanic white race	52 (91%)	46 (92%)	41 (93%)	48 (96%)
Annual household income				
<\$50,000	9 (20%)	12 (34%)	5 (19%)	13 (35%)
\$50,000-<\$100,000	24 (55%)	11 (31%)	10 (38%)	16 (43%)
≥\$100,000	11 (25%)	12 (34%)	11 (42%)	8 (22%)
Highest education		. ,		
Less than a Bachelor's degree	16 (28%)	23 (46%)	15 (35%)	23 (46%)
Bachelor's degree	21 (36%)	13 (26%)	14 (33%)	15 (30%)
Graduate or professional degree	21 (36%)	14 (28%)	14 (33%)	12 (24%)
Health Insurance	× ,		× /	
Private	13 (22%)	10 (20%)	17 (38%)	17 (34%)
Private and Medicare	25 (43%)	18 (36%)	12 (27%)	15 (30%)
Medicare/Other	20 (34%)	22 (44%)	16 (36%)	18 (36%)
Prior CGM Use	× ,		× ,	
In past, but not current	39 (67%)	28 (56%)	14 (31%)	12 (24%)
Never	19 (33%)	22 (44%)	31 (69%)	38 (76%)
Screening HbA1c ^c (%)	× ,		× ,	
Mean (SD)	7.5 (1.0)	7.4 (0.8)	7.6 (1.0)	7.6 (0.9)
Range	5.5 to 10.0	5.7 to 9.3	5.4 to 9.3	6.0 to 9.8
Randomization HbA1c ^d (%)				
Mean (SD)	7.5 (0.9)	7.4 (0.8)	7.6 (1.0)	7.5 (0.9)
Range	5.7 to 10.8	5.9 to 9.4	5.6 to 9.5	5.7 to 9.6
Detectable C-peptide ^e	9 (16%)	3 (6%)	15 (33%)	19 (38%)
Total Daily Insulin Dose/Kg –Median	0.5 (0.4,	0.6 (0.4,	0.6 (0.5,	0.5 (0.4,
(Q1, Q3)	0.5)	0.7)	0.7)	0.7)
≥ 1 severe hypoglycemia event in the past	,	,	,	,
12 months ^f	10 (17%)	5 (10%)	10 (22%)	5 (10%)
\geq 1 diabetic ketoacidosis event in the past	4 (70/)	1 (20/)	1 (20/)	$\mathbf{O}(\mathbf{A}\mathbf{O})$
12 months ^g	4 (7%)	1 (2%)	1 (2%)	2 (4%)

^aData are N (%) unless otherwise specified.

^bParticipants who switched insulin modality over the course of the study were excluded from this table (N=5). ^cScreening HbA1c measured by point of care device or local lab and used to determine eligibility.

^dRandomization HbA1c measured by central lab.

^eRandom C-peptide measured by central lab. The detection limit of the assay was 0.003 nmol/L.

^fSevere hypoglycemia was defined as an event that required assistance due to altered consciousness for another person to administer carbohydrate, glucagon, or other resuscitative actions.

^gDKA was an event meeting the criteria defined by the Diabetes Control and Complications Trial².

	# of particip	# of participants diagnosed with condition			
	Overall (N=203)	Continuous Glucose Monitoring (N=103)	Blood Glucose Monitoring (N=100)		
Hypertension	123	65	58		
Hyperlipidemia	88	45	43		
Thyroid					
Hypothyroidism	75	44	31		
Hashimoto's disease	4	3	1		
Graves' disease	2	1	1		
Microvascular					
Retinopathy	62	33	29		
Neuropathy	59	30	29		
Nephropathy/Chronic kidney disease	20	10	10		
Gastrointestinal	51	26	25		
Depression/Anxiety	44	25	19		
Cardiovascular					
Coronary artery disease	40	21	19		
Cerebrovascular	9	3	6		
Peripheral vascular disease	6	2	4		
Arthritis	39	25	14		
Osteoporosis/Osteopenia	37	21	16		
Cataract/Glaucoma	36	15	21		
Vitamin D deficiency	32	16	16		
Cancer	27	14	13		
Dyslipidemia	20	11	9		

eTable 5. Comorbidities at Enrollment

e rable 6. Types of Medications at E		# of participants taking medication			
	-	Continuous Blood			
	Overall	Glucose	Glucose		
	(N=203)	Monitoring	Monitoring		
		(N=103)	(N=100)		
Antihypertensives					
ACE/ARB	130	67	63		
Beta-blocker	49	25	24		
Diuretic	39	19	2		
CCB	36	18	18		
Lipid-lowering					
Statin	155	78	77		
Fish Oils/Omega-3	18	12	6		
Other	9	6	3		
Anti-coagulant/Anti-platelet					
Aspirin	106	55	51		
Anti-platelet	12	4	8		
Anti-coagulant	8	2	6		
Vitamins/Supplements	114	60	54		
Hormone replacement					
Thyroid	78	45	33		
Estrogen/Progesterone	9	5	4		
Anti-depressant/Anti-anxiety	46	26	20		
Gastrointestinal	35	18	17		
Allergy/Asthma	35	26	9		
Anti-diabetic					
Metformin	8	2	6		
Liraglutide	3	3	0		
Empagliflozin	2	2	0		
Dapagliflozin	1	1	0		
Pramlintide	1	0	1		
Sitagliptin	1	1	0		
Canagliflozin	1	0	1		
Neuropathy					
Gabapentin	10	7	3		
Tramadol	4	1	3		
Pregabalin	3	1	2		
Osteoporosis/Bone health	15	11	4		

eTable 6. Types of Medications at Enrollment

eTable 7. Unscheduled Contacts

	Continuous Glucose Monitoring (N=103)	Blood Glucose Monitoring (N=100)
Unscheduled Office Visits –number of visits (number of participants with a visit) ^a	10 (9)	5
Unscheduled Phone Calls/Audio-video/Emails –number of contacts (number of participants with a visit) ^b	26 (7)	3 (2)

^aReasons for unscheduled office visits included device training and device issue troubleshooting, diabetes management, additional supplies, additional visits for placement of masked sensor re-wear, and out of allowable window study visits.

^bReasons for unscheduled contacts included device training and device issue troubleshooting, diabetes management, and a possible adverse event.

eTable 8. Real-time CGM Use

	4 Week	8 Week	16 Week	26 Week
Ν	103	103	103	103
Average # Days/Week ^a – Median (Q_1, Q_3)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)
Zero Use	1 (<1%)	3 (3%)	3 (3%)	6 (6%)
<1 day	-	-	1 (<1%)	-
1 - < 2 days	1 (<1%)	1 (<1%)	-	-
2-<3 days	1 (<1%)	-	2 (2%)	1 (<1%)
3-<4 days	-	1 (<1%)	1 (<1%)	2 (2%)
4-<5 days	1 (<1%)	2 (2%)	1 (<1%)	2 (2%)
5-<6 days	6 (6%)	-	4 (4%)	6 (6%)
6-<7 days	10 (10%)	10 (10%)	11 (11%)	3 (3%)
≥7 days	83 (81%)	86 (83%)	80 (78%)	83 (81%)
<6 days	10 (10%)	7 (7%)	12 (12%)	17 (17%)
≥6 days	93 (90%)	96 (93%)	91 (88%)	86 (83%)

^aBased on 28 days prior to visit.

	4 Week	8 Week	16 Week	26 Week
Insulin Pump ^a -N	56	56	56	56
Average # Days/Week ^b –	70(70,70)	70(70,70)	70(7070)	70(7070)
Median (Q_1, Q_3)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)
Zero Use	1 (2%)	3 (5%)	2 (4%)	3 (5%)
<1 day	-	-	-	-
1-<2 days	-	1 (2%)	-	-
2-<3 days	1 (2%)	-	-	-
3-<4 days	-	-	-	1 (2%)
4-<5 days	-	1 (2%)	1 (2%)	-
5-<6 days	4 (7%)	-	3 (5%)	2 (4%)
6-<7 days	6 (11%)	6 (11%)	7 (13%)	3 (5%)
≥7 days	44 (79%)	45 (80%)	43 (77%)	47 (84%)
<6 days	6 (11%)	5 (9%)	6 (11%)	6 (11%)
≥6 days	50 (89%)	51 (91%)	50 (89%)	50 (89%)
Insulin Injections ^a -N	45	45	45	45
Average # Days/Week ^b –	70(70,70)	70(70,70)	70(70,70)	70(70,70)
Median (Q_1, Q_3)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)
Zero Use	-	-	1 (2%)	3 (7%)
<1 day	-	-	1 (2%)	-
1 - < 2 days	1 (2%)	-	-	-
2-<3 days	-	-	2 (4%)	1 (2%)
3-<4 days	-	-	1 (2%)	1 (2%)
4-<5 days	1 (2%)	1 (2%)	-	1 (2%)
5-<6 days	2 (4%)	-	-	4 (9%)
6-<7 days	3 (7%)	4 (9%)	4 (9%)	-
≥7 days	38 (84%)	40 (89%)	36 (80%)	35 (78%)
<6 days	4 (9%)	1 (2%)	5 (11%)	10 (22%)
≥6 days	41 (91%)	44 (98%)	40 (89%)	35 (78%)

eTable 9. Real-time CGM Use by Pump and MDI Users

^aParticipants who switched insulin modality over the course of the study were excluded from this analysis (N=5). ^bBased on 28 days prior to visit.

eTable 10. CGM Metrics in Time per Day^a

	Bas	seline		ow-up weeks pooled)	Adjusted Difference	
Continuous Glucose Monitoring Metrics	Continuous Glucose Monitoring (N=103)	Blood Glucose Monitoring (N=100)	Continuous Glucose Monitoring (N=102)	Blood Glucose Monitoring (N=94)	Continuous Glucose Monitoring - Blood Glucose Monitoring (95% CI) ²	P-Value ^b
Hypoglycemia						
Minutes/day < 70 mg/dL	73 (44, 140)	68 (35, 137)	39 (23, 66)	70 (36, 122)	-27 (-40, -16)	<.001
Minutes/day $< 60 \text{ mg/dL}$	43 (22, 79)	35 (16, 85)	13 (7, 28)	35 (12, 73)	-20 (-29, -12)	<.001
Minutes/day $< 54 \text{ mg/dL}$	28 (13, 51)	21 (7, 59)	7 (2, 15)	23 (6, 49)	-14 (-20, -7)	<.001
Hours/day in range (70-180 mg/dL)	13.4 (3.2)	13.4 (3.5)	15.2 (3.2)	13.0 (3.3)	2.1 (1.4, 2.8)	<.001
Hyperglycemia						
Hours/day $> 180 \text{ mg/dL}$	9.0 (3.7)	9.0 (4.0)	8.1 (3.4)	9.5 (3.7)	-1.4 (-2.1, -0.7)	<.001
Hours/day $> 250 \text{ mg/dL}$	2.5 (1.4, 4.9)	3.1 (1.3, 4.9)	2.1 (0.8, 3.6)	3.2 (1.8, 5.4)	-0.9 (-1.3, -0.5)	<.001
Minutes/day > 300 mg/dL	54 (21, 122)	60 (18, 136)	34 (8, 75)	75 (32, 135)	-24 (-36, -13)	<.001

^aData are median (Q1, Q3) or mean (SD).

^bOutcomes were analyzed in a linear mixed effects model that adjusts for baseline and clinical center as a random effect. The hypoglycemia metrics, time >250 mg/dL, and % time >300 mg/dL had skewed distributions and so we modeled using a rank-based transformation. P-values and 95% CI's for the secondary outcomes were adjusted for multiple comparisons to control the false discovery rate.

eTable 11. Glycemic Outcomes at 16 Weeks^a

	Baseline			ow-up eeks pooled)	Adjusted Difference	
	Continuous Glucose Monitoring (N=103)	Blood Glucose Monitoring (N=100)	Continuous Glucose Monitoring (N=102)	Blood Glucose Monitoring (N=94)	Continuous Glucose Monitoring - Blood Glucose Monitoring (95% CI) ²	P-Value ^b
CGM Metrics						
Hours of CGM data	324 (308, 388)	327 (309, 397)	321 (301, 327)	318 (297, 327)		
Hypoglycemia						
% time <70 mg/dL	5.1 (3.0, 9.7)	4.7 (2.4, 9.5)	2.7 (1.5, 4.7)	4.7 (2.6, 8.3)	-1.7 (-2.6, -0.9)	<.001
% time $< 60 \text{ mg/dL}$	3.0 (1.5, 5.5)	2.4 (1.1, 5.9)	1.0 (0.5, 2.1)	2.3 (1.0, 4.4)	-1.2 (-1.8, -0.7)	<.001
% time $< 54 \text{ mg/dL}$	1.9 (0.9, 3.6)	1.5 (0.5, 4.1)	0.5 (0.2, 1.0)	1.4 (0.5, 3.0)	-0.8 (-1.3, -0.4)	<.001
Rate of hypoglycemic events per week	2.6 (1.5, 3.9)	2.1 (0.9, 4.1)	1.0 (0.5, 2.3)	1.8 (0.8, 4.1)	-0.7 (-1.1, -0.4)	<.001
% time in range (70-180 mg/dL)	56 (13)	56 (14)	63 (13)	54 (15)	8.9 (6.0, 11.8)	<.001
Mean glucose (mg/dL)	167 (29)	168 (31)	162 (23)	172 (32)	-8.8 (-14.5, -3.0)	.003
Coefficient of variation (%)	41 (6)	42 (7)	37 (6)	41 (7)	-4.2 (-5.7, -2.7)	<.001
Hyperglycemia						
% time > 180 mg/dL	37 (16)	38 (17)	34 (14)	40 (17)	-6.1 (-9.4, -3.0)	<.001
% time > 250 mg/dL	10 (6, 21)	13 (5, 20)	9 (3, 14)	13 (7, 21)	-3.8 (-5.5, -2.2)	<.001
% time $> 300 \text{ mg/dL}$	3.8 (1.5, 8.5)	4.2 (1.3, 9.4)	2.3 (0.6, 5.9)	4.3 (1.7, 10)	-1.5 (-2.5, -0.7)	<.001
-		eline	16 w	veeks		
Glycated Hemoglobin A1c (HbA1c)	Continuous Glucose Monitoring (N=100)	Blood Glucose Monitoring (N=97)	Continuous Glucose Monitoring (N=101)	Blood Glucose Monitoring (N=93)		
HbA1c (%)	7.6 (0.9)	7.5 (0.8)	7.2 (0.8)	7.5 (1.0)	-0.3 (-0.5, -0.2)	<.001

^aData are median (Q1, Q3) or mean (SD).

^bContinuous outcomes were analyzed in a linear mixed effects model that adjusts for baseline and clinical center as a random effect. The hypoglycemia metrics, time >250 mg/dL, and % time >300 mg/dL had skewed distributions and so we modeled using a rank-based transformation. P-values and 95% CI's for the secondary outcomes were adjusted for multiple comparisons to control the false discovery rate.

	Bas	eline		w-up weeks pooled)	Adjusted Difference	
	Continuous Glucose Monitoring (N=97)	Blood Glucose Monitoring (N=86)	Continuous Glucose Monitoring (N=97)	Blood Glucose Monitoring (N=86)	Continuous Glucose Monitoring - Blood Glucose Monitoring (95% CI)	P-value ^c
Hours of CGM data	325 (309, 388)	326 (309, 369)	475 (452, 489)	466 (431, 483)	-2.0 (-3.0, -1.1)	<.001
% time <70 mg/dL	5.3 (3.0, 9.5)	4.7 (2.4, 9.7)	2.7 (1.6, 4.5)	5.3 (2.1, 8.7)	-2.0 (-3.0, -1.1)	<.001

eTable 12. Per-Protocol Analysis of Percent Time <70 mg/dL^{a,b}

^aPer-protocol criteria

i. ≥ 116 hours of follow-up CGM data

ii. 26 week visit within \pm 28 days of the target date

iii. Average of \geq 5 days per week of real-time CGM use in the CGM group

iv. Average of \geq 3 BGM measurements per day in the BGM group

v. Did not start using a non-study CGM device before reaching 168 hours of follow-up blinded CGM data in the BGM group

^bData are median (Q1, Q3).

^cPercent time <70 mg/dL was analyzed using a rank-based transformation in a linear mixed effects model that adjusts for baseline and clinical center as a random effect.

	Bas	eline		w-up weeks pooled)	Adjusted Difference	
	Continuous Glucose Monitoring (N=103)	Blood Glucose Monitoring (N=100)	Continuous Glucose Monitoring (N=102)	Blood Glucose Monitoring (N=94)	Continuous Glucose Monitoring - Blood Glucose Monitoring (95% CI) ²	P-Value ^b
Daytime (6:00AM-11:59PM)						
Hours of CGM data	242 (227, 286)	245 (230, 297)	351 (334, 365)	347 (316, 360)		
Hypoglycemia						
% time <70 mg/dL	4.9 (3.0, 8.0)	4.4 (2.5, 9.0)	2.6 (1.5, 4.5)	4.6 (2.1, 7.9)	-1.4 (-2.2, -0.7)	<.001
% time $< 60 \text{ mg/dL}$	2.6 (1.3, 4.4)	2.2 (0.9, 5.3)	0.9 (0.4, 2.0)	2.2 (0.9, 4.7)	-1.0 (-1.5, -0.6)	<.001
% time $< 54 \text{ mg/dL}$	1.6 (0.7, 2.8)	1.3 (0.4, 3.4)	0.5 (0.1, 1.1)	1.4 (0.4, 2.9)	-0.7 (-1.2, -0.4)	<.001
Rate of hypoglycemic events per week	2.8 (1.4, 3.8)	2.3 (0.7, 4.5)	0.9 (0.0, 2.3)	2.1 (0.8, 4.4)	-1.0 (-1.5, -0.5)	<.001
% time in range (70-180 mg/dL)	56 (14)	56 (14)	63 (14)	54 (14)	8.1 (5.3, 10.9)	<.001
Mean glucose (mg/dL)	169 (30)	168 (31)	163 (25)	171 (29)	-8.9 (-14.4, -3.4)	.002
Coefficient of variation (%)	41 (6)	41 (7)	37 (5)	41 (7)	-4.2 (-5.4, -2.9)	<.001
Hyperglycemia						
% time > 180 mg/dL	38 (16)	38 (17)	34 (15)	40 (16)	-5.9 (-9.0, -2.8)	<.001
% time > 250 mg mg/dL	11 (6, 21)	12 (5, 20)	8 (4, 14)	13 (7, 23)	-3.8 (-5.5, -2.3)	<.001
% time > 300 mg mg/dL	3.7 (1.5, 8.9)	4.1 (1.3, 8.3)	2.4 (0.7, 5.3)	4.5 (2.2, 9.4)	-1.6 (-2.5, -0.9)	<.001
Nighttime (12:00AM-5:59AM)						
Hours of CGM data	84 (78, 101)	84 (81, 104)	121 (114, 125)	119 (108, 122)		
Hypoglycemia						
% time <70 mg/dL	5.3 (1.6, 15)	4.3 (1.3, 9.8)	1.7 (0.6, 4.3)	4.7 (0.8, 11)	-2.2 (-3.8, -0.9)	<.001
% time < 60 mg/dL	2.9 (0.4, 8.6)	3.0 (0.3, 6.6)	0.6 (0.0, 1.7)	2.9 (0.3, 7.0)	-1.7 (-2.9, -0.6)	<.001
% time $< 54 \text{ mg/dL}$	1.5 (0.0, 5.7)	1.3 (0.0, 4.7)	0.2 (0.0, 0.9)	1.5 (0.0, 4.6)	-1.0 (-1.9, -0.3)	<.001
Rate of hypoglycemic events per week	2.2 (0.0, 6.0)	2.0 (0.0, 4.1)	0.0 (0.0, 1.5)	1.6 (0.0, 4.7)	-1.4 (-1.9, -0.1)	<.001
% time in range (70-180 mg/dL)	55 (17)	55 (20)	65 (17)	54 (19)	10.5 (6.8, 14.2)	<.001
Mean glucose (mg/dL)	160 (38)	167 (45)	160 (29)	169 (41)	-4.1 (-11.0, 2.9)	.25
Coefficient of variation (%) Hyperglycemia	39 (8)	38 (8)	34 (7)	39 (10)	-5.5 (-7.7, -3.3)	<.001

eTable 13. CGM Metrics during the Daytime (6:00AM-11:59PM) and Nighttime (12:00AM-5:59AM)^a

% time > 180 mg/dL	36 (21)	37 (24)	32 (18)	39 (22)	-5.1 (-8.9, -1.3)	.01
% time > 250 mg/dL	9 (3, 19)	10 (2, 26)	6 (1, 15)	10 (3, 25)	-2.2 (-4.5, -0.3)	.005
% time > 300 mg/dL	2.7 (0.0, 6.7)	2.5 (0.0, 11)	1.2 (0.0, 4.0)	3.9 (0.0, 11)	-1.0 (-2.5, 0.0)	<.001

^aData are median (Q1, Q3) or mean \pm SD.

^bContinuous outcomes were analyzed in a linear mixed effects model that adjusts for baseline and clinical center as a random effect. The hypoglycemia metrics, time >250 mg/dL, and % time >300 mg/dL had skewed distributions and so we modeled using a rank-based transformation. P-values and 95% CI's for the secondary outcomes were adjusted for multiple comparisons to control the false discovery rate.

	Bas	eline		w-up weeks pooled)	Adjusted Difference	
	Continuous Glucose Monitoring (N=56)	Blood Glucose Monitoring (N=49)	Continuous Glucose Monitoring (N=55)	Blood Glucose Monitoring (N=44)	Continuous Glucose Monitoring - Blood Glucose Monitoring (95% CI) ^c	P-Value ^c
CGM Metrics						
Hours of CGM data	326 (314, 396)	326 (310, 409)	472 (449, 490)	472 (437, 483)		
Hypoglycemia						
% time <70 mg/dL	4.6 (2.8, 9.0)	4.8 (2.4, 9.3)	2.1 (1.3, 3.6)	5.7 (2.6, 11)	-2.6 (-3.9, -1.4)	<.001
% time $< 60 \text{ mg/dL}$	2.2 (1.4, 4.6)	3.0 (1.2, 5.6)	0.7 (0.4, 1.6)	3.0 (1.3, 6.4)	-1.6 (-2.5, -0.9)	<.001
% time $< 54 \text{ mg/dL}$	1.2 (0.9, 2.9)	1.8 (0.5, 3.8)	0.3 (0.1, 0.8)	1.6 (0.6, 4.5)	-1.0 (-2.0, -0.5)	<.001
Rate of hypoglycemic events per week	2.1 (1.5, 3.2)	2.2 (1.1, 4.1)	0.7 (0.3, 1.9)	2.0 (1.0, 4.6)	-1.1 (-1.6, -0.5)	<.001
% time in range (70-180 mg/dL)	58 (13)	55 (13)	64 (12)	54 (12)	8.0 (4.7, 11.3)	<.001
Mean glucose (mg/dL)	165 (27)	169 (31)	162 (20)	169 (28)	-4.6 (-11.7, 2.5)	.20
Coefficient of variation (%)	40 (5)	42 (7)	36 (5)	43 (6)	-4.7 (-6.4, -3.1)	<.001
Hyperglycemia						
% time > 180 mg/dL	36 (15)	38 (16)	33 (13)	39 (15)	-4.5 (-8.4, -0.7)	.02
% time > 250 mg/dL	10 (5, 19)	13 (6, 21)	7 (3, 14)	13 (8, 23)	-3.2 (-5.3, -1.4)	.001
% time $> 300 \text{ mg/dL}$	3.6 (1.5, 7.3)	5.3 (1.3, 9.1)	1.8 (0.6, 5.0)	5.0 (2.3, 9.3)	-1.6 (-2.6, -0.6)	<.001
	Bas	eline	26 w	veeks		
Glycated Hemoglobin A1c (HbA1c)	Continuous Glucose Monitoring (N=55)	Blood Glucose Monitoring (N=46)	Continuous Glucose Monitoring (N=54)	Blood Glucose Monitoring (N=46)		
HbA1c (%)	7.4 (0.8)	7.5 (0.8)	7.2 (0.8)	7.4 (0.8)	-0.2 (-0.5, 0.01)	.04

eTable 14. Glycemic Outcomes Among Participants Using a Pump for Insulin Delivery^{a,b}

^aData are median (Q1, Q3) or mean (SD).

^bParticipants who switched insulin modality over the course of the study were excluded from this analysis (N=5).

 $^{\circ}$ Continuous outcomes were analyzed in a linear mixed effects model that adjusts for baseline and clinical center as a random effect. The hypoglycemia metrics, time >250 mg/dL, and % time >300 mg/dL had skewed distributions and so we modeled using a rank-based transformation. P-values and 95% CI's for the secondary outcomes were adjusted for multiple comparisons to control the false discovery rate.

	Bas	eline		w-up weeks pooled)	Adjusted Difference	
	Continuous Glucose Monitoring (N=45)	Blood Glucose Monitoring (N=48)	Continuous Glucose Monitoring (N=45)	Blood Glucose Monitoring (N=47)	Continuous Glucose Monitoring - Blood Glucose Monitoring (95% CI) ^c	P-Value ^c
CGM Metrics						
Hours of CGM data	324 (292, 370)	329 (310, 363)	473 (452, 488)	457 (416, 479)		
Hypoglycemia						
% time <70 mg/dL	6.6 (4.0, 11)	4.9 (2.4, 10)	3.1 (1.8, 5.0)	4.4 (1.8, 7.6)	-1.6 (-3.0, -0.4)	.004
% time < 60 mg/dL	3.4 (2.0, 6.6)	2.4 (0.9, 6.2)	1.0 (0.6, 2.5)	2.2 (0.7, 4.4)	-1.4 (-2.3, -0.6)	<.001
% time $< 54 \text{ mg/dL}$	2.5 (0.9, 5.0)	1.2 (0.4, 4.5)	0.5 (0.2, 1.4)	1.7 (0.4, 3.0)	-1.0 (-1.7, -0.3)	<.001
Rate of hypoglycemic events per week	3.1 (1.5, 5.8)	2.0 (0.8, 4.1)	1.1 (0.6, 2.5)	1.8 (0.6, 3.9)	-0.8 (-1.7, -0.3)	.002
% time in range (70-180 mg/dL)	54 (14)	57 (15)	63 (15)	56 (15)	10.2 (5.6, 14.8)	<.001
Mean glucose (mg/dL)	167 (31)	166 (32)	161 (24)	170 (30)	-10.9 (-19.22.6)	.01
Coefficient of variation (%)	42 (7)	41 (7)	37 (5)	41 (8)	-5.0 (-7.4, -2.7)	<.001
Hyperglycemia						
% time > 180 mg/dL	38 (16)	36 (17)	33 (15)	38 (16)	-7.2 (-12.1, -2.4)	.004
% time > 250 mg/dL	11 (6, 21)	11 (4, 18)	10 (3, 15)	12 (6, 22)	-4.3 (-6.9, -2.0)	<.001
% time > 300 mg/dL	3.8 (1.8, 9.4)	2.9 (1.2, 9.8)	2.9 (0.5, 6.2)	5.5 (1.7, 9.4)	-1.9 (-3.4, -0.7)	<.001
	Bas	eline	26 w	veeks		
	Continuous	Blood	Continuous	Blood		
	Glucose	Glucose	Glucose	Glucose		
	Monitoring	Monitoring	Monitoring	Monitoring		
Glycated Hemoglobin A1c (HbA1c)	(N=43)	(N=48)	(N=44)	(N=46)		
HbA1c (%)	7.6 (1.0)	7.5 (0.8)	7.2 (0.8)	7.4 (0.9)	-0.4 (-0.6, -0.1)	0.003

eTable 15. Glycemic Outcomes Among Participants Using Injections for Insulin Delivery^{a,b}

^aData are median (Q1, Q3) or mean (SD).

^bParticipants who switched insulin modality over the course of the study were excluded from this analysis (N=5).

 $^{\circ}$ Continuous outcomes were analyzed in a linear mixed effects model that adjusts for baseline and clinical center as a random effect. The hypoglycemia metrics, time >250 mg/dL, and % time >300 mg/dL had skewed distributions and so we modeled using a rank-based transformation. P-values and 95% CI's for the secondary outcomes were adjusted for multiple comparisons to control the false discovery rate.

		Continuous Glucos	e Monitoring		Blood Glucose I	Monitoring	
	N	Baseline % time <70 mg/dL Median (Q1, Q3)	Change % time <70 mg/dL from baseline Median (Q1, Q3)	N	Baseline % time <70 mg/dL Median (Q1, Q3)	Change % time <70 mg/dL from baseline Median (Q1, Q3)	P-value for interaction ^d
Overall	102	5.2 (3.0, 9.7)	-2.4 (-6.6, -0.2)	94	5.2 (2.5, 9.7)	-0.8 (-2.5, 1.5)	_
Age (years) ^a							.48
< 70	70	5.4 (3.0, 10.0)	-2.8 (-7.0, -0.4)	62	6.6 (2.5, 10.2)	-0.6 (-2.8, 1.4)	
≥ 70	32	4.9 (3.0, 9.4)	-1.9 (-5.0, 0.0)	32	4.3 (2.8, 7.7)	-0.8 (-2.2, 1.5)	
T1D duration (years) ^a							.09
<25	26	6.2 (1.4, 9.7)	-2.9 (-6.6, -0.9)	25	3.5 (2.2, 7.8)	-1.8 (-2.9, -0.7)	
25-<50	52	4.8 (2.9, 10.8)	-1.8 (-6.9, 0.3)	49	6.1 (2.4, 9.3)	0.0 (-2.4, 1.6)	
≥50	24	5.2 (3.6, 9.5)	-2.6 (-6.2, -0.8)	20	7.1 (4.3, 10.2)	-0.3 (-2.0, 2.3)	
Age at diagnosis (years) ^a							.09
<25	38	4.8 (3.6, 10.1)	-2.3 (-6.4, -0.1)	34	7.6 (4.6, 10.2)	0.0 (-2.5, 2.2)	
25-<40	45	6.1 (3.1, 10.9)	-3.1 (-7.5, -0.3)	47	4.1 (2.2, 9.3)	-0.8 (-2.4, 1.6)	
≥ 40	19	4.4 (1.2, 8.6)	-1.1 (-4.0, 0.1)	13	3.5 (1.7, 6.3)	-1.0 (-2.9, -0.7)	
Percent time <70 mg/dL ^a							<.001
<5%	49	2.9 (1.4, 4.2)	-0.3 (-1.0, 0.8)	46	2.4 (1.7, 3.7)	0.0 (-1.0, 1.5)	
≥5%	53	9.5 (6.7, 12.3)	-6.4 (-9.6, -3.4)	48	9.5 (7.6, 11.9)	-2.4 (-4.2, 1.2)	
Coefficient of variation ^a							<.001
<41%	51	3.1 (1.4, 5.3)	-0.7 (-2.7, 0.6)	43	2.7 (1.7, 4.3)	0.0 (-1.0, 1.3)	
≥41%	51	8.0 (5.0, 11.9)	-4.3 (-8.7, -1.9)	51	8.9 (6.6, 11.4)	-2.1 (-3.3, 1.6)	
HbA1c ^a				_			.09
<7.5%	51	6.7 (3.6, 10.9)	-3.9 (-8.3, -0.2)	47	7.9 (4.5, 11.4)	-1.2 (-4.1, 1.3)	
≥7.5%	51	4.8 (2.7, 7.2)	-1.9 (-4.0, -0.2)	47	3.3 (1.8, 7.5)	-0.3 (-2.0, 1.6)	
Gender							.89
Female	60	6.6 (3.7, 10.0)	-3.3 (-6.7, -0.4)	42	5.6 (3.3, 9.3)	-0.6 (-2.5, 1.4)	
Male	42	4.6 (2.0, 9.2)	-1.1 (-4.7, -0.1)	52	5.2 (2.2, 10.1)	-0.8 (-2.4, 1.6)	
Race/ethnicity ^b							_
White non-Hispanic	92	5.3 (3.1, 9.9)	-2.6 (-6.7, -0.2)	88	4.9 (2.6, 9.2)	-0.8 (-2.4, 1.3)	
Non-White	8	6.2 (3.2, 11.3)	-3.2 (-8.8, -1.3)	6	9.8 (2.2, 12.0)	-1.8 (-6.5, 2.0)	

eTable 16. Subgrou	o Analysis for Percent	t Time Spent <70 m	g/dL by Baseline	Characteristics
--------------------	------------------------	--------------------	------------------	------------------------

		Continuous Glucos	e Monitoring		Blood Glucose I	Monitoring	
	N	Baseline % time <70 mg/dL Median (Q1, Q3)	Change % time <70 mg/dL from baseline Median (Q1, Q3)	N	Baseline % time <70 mg/dL Median (Q1, Q3)	Change % time <70 mg/dL from baseline Median (Q1, Q3)	P-value for interaction ^d
Highest education							.10
completed							.10
Some college or less	30	6.6 (4.0, 9.2)	-3.3 (-6.6, -1.1)	45	6.6 (3.3, 9.3)	-0.8 (-2.6, 1.3)	
College graduate or more	70	4.8 (2.8, 10.1)	-1.9 (-6.8, 0.2)	49	4.6 (2.0, 10.2)	-0.5 (-2.4, 1.6)	
NIH Toolbox age-corrected							.45
Fluid Composite Score ^a							.45
<90	45	4.9 (3.0, 8.8)	-2.3 (-5.0, -0.2)	50	4.0 (2.2, 8.3)	-0.8 (-2.4, 1.2)	
≥90	54	5.8 (2.7, 10.7)	-2.8 (-7.9, -0.3)	42	6.5 (3.3, 10.1)	-0.3 (-2.7, 1.6)	
Cognition status measured							.23
by the NIH Toolbox							.23
No cognitive impairment	84	5.1 (2.9, 9.6)	-2.3 (-6.7, -0.2)	76	6.0 (2.6, 10.2)	-0.4 (-2.5, 1.6)	
Clinically significant cognitive impairment ^e	15	6.7 (3.0, 13.4)	-3.8 (-8.3, -0.9)	15	3.5 (1.8, 7.9)	-1.0 (-2.4, 0.0)	
Hypoglycemic awareness							.12
Impaired awareness	31	5.3 (3.3, 10.7)	-2.3 (-4.6, -0.3)	28	8.2 (6.1, 11.5)	-0.6 (-2.8, 2.2)	
No impaired awareness	68	5.5 (2.9, 9.9)	-2.7 (-7.2, -0.2)	65	3.8 (2.2, 8.9)	-0.8 (-2.4, 1.1)	
Detectable C-peptide							<.001
No	78	4.9 (3.1, 10.1)	-2.6 (-7.0, -0.3)	72	6.5 (3.3, 10.2)	-0.3 (-2.4, 1.7)	
Yes	24	6.4 (1.8, 9.0)	-1.9 (-4.5, 0.2)	22	3.4 (1.1, 6.7)	-1.3 (-2.9, -0.3)	
Severe hypoglycemic event							
in the past 12 months ^b							-
0	83	4.9 (2.8, 9.3)	-2.2 (-4.7, -0.2)	85	4.6 (2.4, 9.3)	-0.8 (-2.6, 1.3)	
≥1	19	7.2 (4.2, 13.1)	-4.1 (-9.5, -0.3)	9	8.1 (7.2, 9.7)	0.5 (-0.4, 2.8)	

^aCategories for continuous variables are for display only. These variables were included in the models as continuous.

^bFor race/ethnicity and SH events some categories contained less than 10 participants, so no p-value was calculated.

 $^{\circ}$ Clinically significant cognitive impairment was defined as 2 or more age-corrected scores ≤ 80 on the following NIH Toolbox Cognitive Battery instruments: Flanker Inhibitory Control and Attention, List Sorting Working Memory, Dimensional Change Card Sort, Pattern Comparison Processing Speed, Picture Sequence Memory³.

^dModel also adjusted for baseline and site as a random effect. P-values are adjusted for multiple comparisons to control the false discovery rate (FDR).

eTable 17. Binary HbA1c Outcomes

-		Bas	eline			26 W	eeks			
	G	tinuous lucose nitoring		Glucose nitoring	G	tinuous lucose nitoring		l Glucose nitoring	Risk Adjusted Difference (95% CI)	P-Value ^a
	N Total	N (%)	N Total	N (%)	N Total	N (%)	N Total	N (%)		
HbA1c < 7.0%	100	28 (28%)	97	30 (31%)	100	40 (40%)	95	30 (32%)	11% (0%, 20%)	.04
HbA1c < 7.5%	100	50 (50%)	97	49 (51%)	100	64 (64%)	95	54 (57%)	9% (-1%, 20%)	.08
Absolute Reduction $HbA1c \ge 0.5\%$	NA	NA	NA	NA	97	32 (33%)	92	14 (15%)	16% (5%, 28%)	.009
Absolute Reduction HbA1c ≥ 1.0%	NA	NA	NA	NA	97	12 (12%)	92	3 (3%)	8% (2%, 16%)	.05
Relative Reduction in HbA1c ≥ 10%	NA	NA	NA	NA	97	20 (21%)	92	5 (5%)	15% (6%, 25%)	.006
Absolute Reduction in HbA1c ≥ 0.5% OR HbA1c ≤ 7.0%	NA	NA	NA	NA	97	44 (45%)	92	31 (34%)	14% (1%, 24%)	.04

^aBinary HbA1c outcomes were analyzed as available cases only in a logistic regression model adjusted for baseline HbA1c and clinical center as a random effect. P-values and 95% CI's were adjusted for multiple comparisons to control the false discovery rate.

eTable 18. Device Issues

Type of device and Issue – N=22 ^a	Count
Dexcom G5 Mobile Receiver	
Alarm Malfunction	2
Calibration Issues	1
Stopped working	11
Dexcom G4 Platinum Professional	
Receiver	
Stopped working – battery/screen frozen	3
Dexcom G5 Mobile Transmitter	
Connectivity failure	3
Dexcom G4/G5 Sensor	
Inaccuracy	2

^aNo device malfunctions/issues were related to an adverse event. Device issues due to

user error or those that were anticipated to occur such as battery lifespan are not included in table.

eTable 19. Cognitive Assessment and Patient-Reported Outcomes^a

		Base	eline			26 W	eeks		
		inuous Glucose Monitoring		ood Glucose Monitoring		inuous Glucose Monitoring		lood Glucose Monitoring	P- value ^d
	N	Median (Q1, Q3)	N	Median (Q1, Q3)	Ν	Median (Q1, Q3)	N	Median (Q1, Q3)	-
Hypoglycemia Awareness Survey	100	2.0 (1.0, 4.0)	99	2.0 (1.0, 4.0)	100	2.0 (1.0, 4.0)	93	2.0 (1.0, 4.0)	.22
Hypoglycemia Fear Survey Worry Subscale	103	0.9 (0.4, 1.6)	100	0.9 (0.4, 1.5)	98	0.7 (0.3, 1.2)	91	0.8 (0.5, 1.5)	.22
Type 1 Diabetes Distress Scale	102	1.5 (1.3, 1.9)	100	1.5 (1.2, 1.8)	98	1.4 (1.3, 1.8)	91	1.6 (1.3, 1.9)	.22
Glucose Monitoring Satisfaction Survey	102	3.8 (3.5, 4.3)	97	3.9 (3.5, 4.3)	96	4.0 (3.7, 4.4)	86	3.8 (3.5, 4.2)	.22
PROMIS Global Health Short Form Physical	103	51 (45, 58)	99	51 (45, 58)	99	51 (48, 54)	92	51 (45, 56)	.56
Mental	101	53 (48, 59)	96	53 (51, 61)	97	51 (48, 56)	92	53 (48, 56)	.56
Preferring Hypoglycemia Survey NIH Toolbox Emotion Battery	102	2.3 (2.0, 3.0)	99	2.3 (2.0, 3.0)	97	2.3 (2.0, 2.7)	91	2.7 (2.0, 3.0)	.75
Fear	101	49 (44, 53)	99	49 (43, 56)	95	49 (44, 53)	90	48 (43, 55)	.75
Sadness	101	48 (40, 55)	99	46 (41, 53)	95	48 (41, 55)	90	46 (37, 54)	.84
Positive Affect	101	50 (44, 51)	99	50 (45, 52)	95	48 (42, 50)	90	50 (42, 51)	.75
Perceived Stress	101	45 (38, 50)	99	44 (38, 51)	91	44 (37, 51)	84	44 (38, 52)	.66
Self-Efficacy	101	49 (47, 57)	99	50 (45, 58)	95	49 (45, 57)	90	50 (47, 55)	.88
Emotional Support	101	50 (44, 56)	99	47 (42, 56)	95	50 (44, 62)	90	49 (42, 62)	.75
Instrumental Support	101	48 (43, 63)	99	50 (40, 63)	95	48 (44, 63)	90	47 (39, 63)	.75
NIH Toolbox Cognitive Battery Uncorrected Fluid Composite Score ^b	100	91 (81, 95)	98	88 (80, 94)	94	91 (86, 98)	88	90 (81, 96)	.22
Dimensional Change Card Sort	100	99 (94, 105)	99	98 (94, 103)	94	100 (93, 105)	90	99 (94, 102)	-
Flanker Inhibitory Control and Attention Test	101	93 (88, 97)	99	91 (86, 96)	95	95 (90, 98)	90	92 (88, 97)	-
Picture Sequence Memory	100	90 (85, 101)	98	90 (84, 99)	94	98 (88, 106)	90	94 (86, 102)	-
List Sorting Working Memory	100	99 (90, 105)	99	97 (90, 105)	94	99 (90, 105)	88	97 (90, 105)	-
Pattern Comparison	100	84 (69, 94)	99	82 (69, 92)	94	86 (76, 97)	90	84 (74, 94)	-

Page 26 of 31

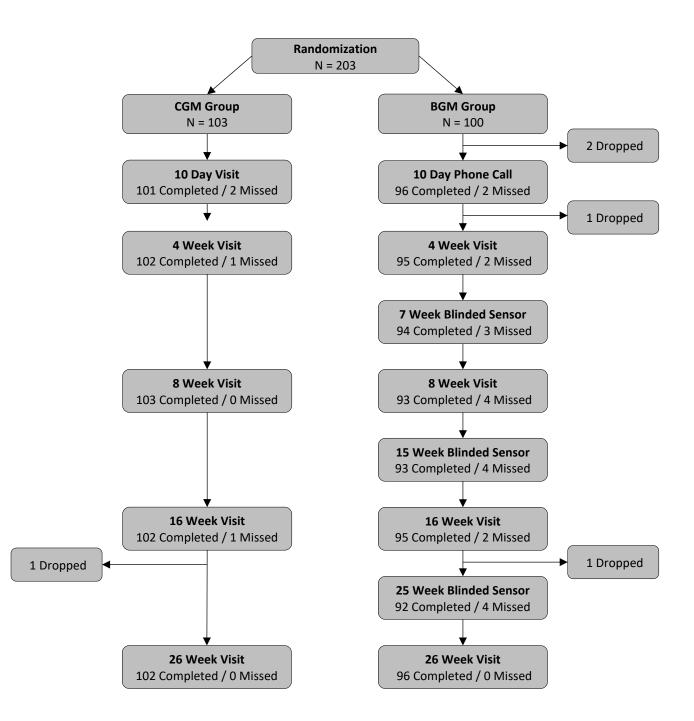
	Picture Vocabulary ^c	101	116 (111, 123)	99	115 (109, 121)	-	-	-	-	-
--	---------------------------------	-----	----------------	----	----------------	---	---	---	---	---

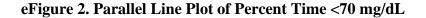
^aParticipants completed patient reported outcome assessments either electronically using a study laptop or iPad or on paper.

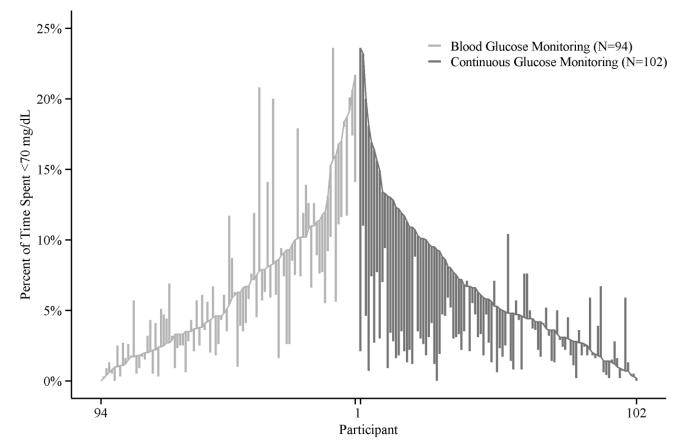
^bAll of the individual components and the composite score of the NIH Toolbox Cognition have been summarized, but only the composite score was formally compared. ^cThe picture vocabulary component of the NIH Toolbox Cognition was only administered at baseline.

^dAnalyzed using a rank-based transformation in a mixed effects model that adjusts for baseline and site as a random effect. P-values are adjusted for multiple comparisons to control the false discovery rate (FDR).

eFigure 1. Visit Completion by Treatment Group







Each bar represents a participant's baseline and follow-up percent time <70 mg/dL. Participants are sorted by treatment group and baseline value. The bar starts on the line at the participant's baseline value and goes upwards or downwards to the follow-up value. A bar that is above the line indicates an increase from baseline to follow-up. A bar below the line indicates a decrease from baseline to follow-up.

WISDM Guidelines for Adjusting Insulin Doses Using Trend Arrows in Older Adults: Pre-meal and Corrections ≥4 Hours Post-meal			
Trend Arrows		Correction	24 mours rost-mean
Receiver	Арр	Factor* (CF)	Insulin Dose Adjustment (U)**
		<25	+3
**	\bigcirc	25-<50	+2
		50-<75	+1
		≥75	+0.5 or 0 (MDI)
Ť	Ô	<25	+2
		25-<50	+1
		50-<75	+0.5 or 0 (MDI)
		≥75	+ 0.5 or 0(MDI)
*	0	<25	+1
		25-<50	+0.5 or 0 (MDI)
		50-<75	No adjustment
		≥75	No adjustment
⇒	\bigcirc	<25	No adjustment
		25-<50	No adjustment
		50-<75	No adjustment
		≥75	No adjustment
\$	\bigcirc	<25	-4
		25-<50	-3
		50-<75	-2
		≥75	-1
ŧ	\bigcirc	<25	-5
		25-<50	-4
		50-<75	-3
		≥75	-2
+ +	\bigcirc	<25	-6
		25-<50	-5
		50-<75	-4
	\bigtriangledown	≥75	-3
Insulin adjustments using trend arrows do not replace standard calculations using ICR and			
CF. Adjustments are increases or decreases of rapid-acting insulin in addition to calculations			
using ICR and CF. Adjustments using trend arrows are an additional step to standard care.			
Considerations:			
**These adjustments should NOT be made on the first day of a new sensor, before exercise or			
if there are any concerns with sensor accuracy** For the 4 hours following a meal, avoid adjusting insulin dose using trend arrows.			
For rapidly rising sensor glucose (2 UP arrows; 1) at pre-meal, consider administering insulin 15-30 minutes before eating.			
For rapidly falling sensor glucose (2 DOWN arrows; 44):			
Pre-meal: consider administering insulin closer to the meal			
Near or lower than 150 mg/dL: consider holding pre-meal insulin dose until glucose trends have stabilized			
*Correction factor (CE) is in mg/dL and indicates glucose lowering per unit of rapid-acting insulin.			

*Correction factor (CF) is in mg/dL and indicates glucose lowering per unit of rapid-acting insulin.

eReferences

- 1. Fisher L, Hessler D, Polonsky W, Strycker L, Masharani U, Peters A. Diabetes distress in adults with type 1 diabetes: Prevalence, incidence and change over time. *J Diabetes Complications*. 2016;30(6):1123-1128.
- 2. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329(14):977-986.
- 3. Holdnack JA, Tulsky DS, Brooks BL, et al. Interpreting Patterns of Low Scores on the NIH Toolbox Cognition Battery. *Arch Clin Neuropsychol.* 2017;32(5):574-584.