ONLINE SUPPLEMENTAL MATERIAL

Appendix

A listing of the SENCE sites with participating principal investigators (PI), co-investigators (I), primary coordinator (PC) and coordinators (C) is included below:

Joslin Diabetes Center- Pediatric, Boston, MA Lori Laffel MD, MPH (PI); Kara Harrington PhD, MS (I); Anat Hanono MD (I); Nisha Naik (PC); Louise Ambler-Osborn MS, RN, CPNP (C); Alan Schultz MSN, CPNP (C)

Riley Hospital for Children, Indiana University School of Medicine, Indianapolis, IN Linda DiMeglio MD, MPH (PI); Stephanie Woerner RN, MSN, FNP-C CDE (I); Heather Jolivette RN, CPNP, CDE (I); Heba Ismail MB BCh, MSc, PhD (I); Megan Tebbe RN, BSN, CCRP, CDE (PC); America Newnum (C); Megan Legge BA CCRP (C)

Yale Pediatric Diabetes Program, New Haven, CT William Tamborlane MD (PI); Michelle Van Name MD (I); Kate Weyman MSN, FNP-C, APRN, CDE (I); Jennifer Finnegan (PC); Amy Steffen BSN (C); Melinda Zgorski BSN (C)

Baylor College of Medicine / Texas Children's Hospital, Houston, TX Daniel DeSalvo MD (PI); Marisa Hilliard PhD (I); Kylie DeLaO, RN, CDE (C); Cicilyn Xie, BA (PC); Wendy Levy LCSW (C)

Barbara Davis Center for Diabetes, Aurora, CO R. Paul Wadwa MD (PI); Greg Forlenza MD (I); Shideh Majidi MD (I); Guy Alonso MD (I); Isabel Weber MSc (PC); Michelle Clay RN, BSN, CDE (C); Emily Simmons BA (C)

University of Minnesota, Minneapolis, MN Brandon Nathan MD (PI); Muna Sunni MBBCh, MS(I); Jessica Sweet (PC); Beth Pappenfus (C); Anne Kogler BSN, RN, CDE (C); Marrissa Ludwig, BSN, RN (C); Brittney Nelson (C); Anne Street RN (C); Darcy Weingartner BSN, RN (C)

University of Florida, Gainesville, FL Anastasia Albanese-O'Neill PhD, APRN, CDE (PI); Michael Haller MD, MS-CI (I); Janey Adams (PC); Miriam Cintron (C); Nicole Thomas (C)

Vanderbilt University Medical Center, Nashville, TN Jennifer Kelley MD, MSCE (PI); Jill Simmons MD (I); George William RN, CDE (PC); Faith Brendle RN (C)

Naomi Berrie Diabetes Center, Columbia University Medical Center, New York, NY Robin Goland MD (PI): Kristen Williams MD (I); Rachelle Gandica MD (I); Sarah Pollak RN, MSN (PC); Emily Casciano RD, CDN, CDE (C); Elizabeth Robinson (C)

Children's Hospital of Philadelphia, Philadelphia, PA Steven Willi MD (PI); Pantea Minnock RN, CPNP, CCRP (I); Diana Olivos MS (PC); Cathy Carchidi RN, MS, CDE, CPT, CCRC(C); Brian Grant RN, CDE (C)

University of California San Francisco and the Madison Clinic for Pediatric Diabetes, San Francisco, CA Jenise C. Wong MD, PhD (PI); Saleh Adi MD (I)
Cincinnati Children's Hospital Medical Center and University of Cincinnati, College of Medicine, Cincinnati, OH Sarah Corathers MD (PI); Nicole Sheanon MD, MS (I); Cathy Fox MS, RD, LD, CDE (PC); Tammy Weis BSN, RN, CCRP (C)

Rainbow Babies and Children's Hospital Cleveland Medical Center, Cleveland, OH Sarah MacLeish DO (PI); Jamie Wood MD (I); Terri Casey RN, BSN (PC); Wendy Campbell RN, BSN (C); Paul McGuigan RN, BSN (C)

Wendy Novak Diabetes Center, University of Louisville, Norton Children's Hospital, Louisville, KY Kupper Wintergerst MD (PI); Sara Watson MD (I); Suzanne Kingery MD (I); Gwen Pierce (PC); Heather Ruch (C); Lauren Rayborn (C); Manuel Rodriguez-Luna (C); Amy Deuser (C)

Supplemental Table S1. Eligibility and Exclusion Criteria

Participant Inclusion Criteria

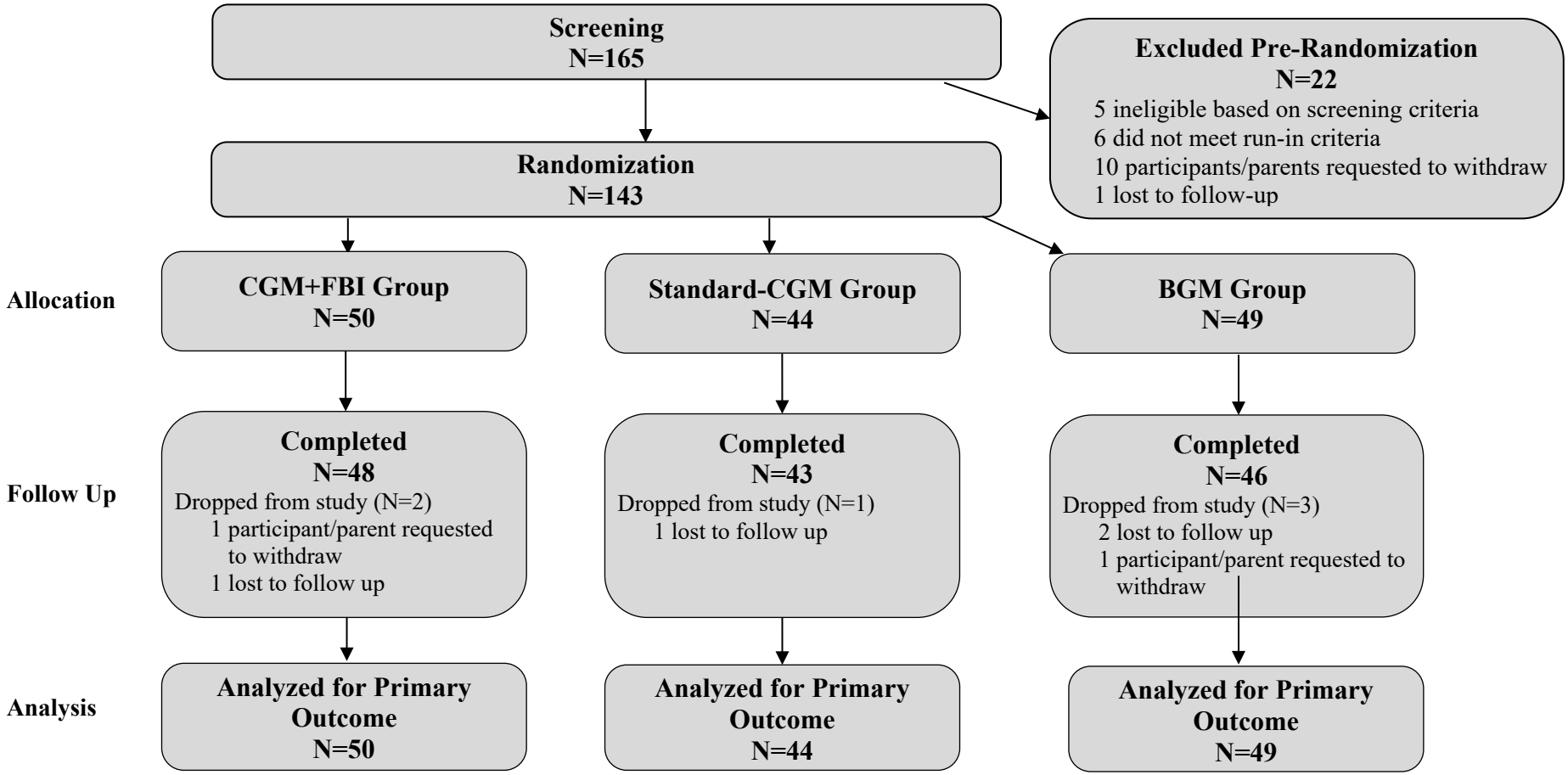
1. Clinical diagnosis of insulin dependent presumed autoimmune type 1 diabetes by the investigator
2. Age 2-<8 years at consent
3. Diabetes duration ≥ 3 months
4. Total daily insulin ≥ 0.3 units per kg per day
5. HbA1c 7.0% to <10.0% *(Point of care device or local lab measured within 30 days of screening visit used to assess eligibility)*
6. No use of unblinded personal CGM, outside of a research study, as part of real-time diabetes management in the last 30 days
7. Intensive insulin regimen involves either use of a consistent insulin regimen with an insulin pump or at least 3 multiple daily injections of basal and bolus (meal time) analog insulin; if the insulin regimen has changed within the past month (change from injections to pump or vice versa in the last month), use clinical judgment to determine that the family/young child has acclimated to the regimen change and is ready to begin use of CGM.
8. Perform at least 3 blood glucose meter checks per day from self-report at screening and meter download or self-report during blinded CGM run in
9. Parent or guardian comprehend written and spoken English (*This requirement was due to the fact that the questionnaires that were used as outcome measures do not have validated versions in other languages, and interventions were delivered in English to ensure standardization/fidelity checks across sites)*
10. Parent understands the study protocol and agrees to it
11. No expectation that participant/parent will be moving out of the area of the clinical center during the next 12 months, unless the move will be to an area served by another study center.

Participant Exclusion Criteria

12. Unable to use CGM device for minimum number of hours during blinded run-in period or skin reaction from adhesive that would preclude participation in the randomized trial
13. Currently using or plans to begin non-insulin medication for blood glucose lowering during the course of the study
14. The presence of a significant medical disorder or use of a medication such as oral/inhaled glucocorticoids that in the judgment of the investigator will affect the wearing of the sensors or the completion of any aspect of the protocol.
15. More than 1 episode of SH or DKA in the past 6 months (not including DKA at time of dx).

16. The presence of any of the following diseases:
    - Asthma if treated with systemic or daily inhaled corticosteroids in the last 6 months (Intermittent treatment with inhaled corticosteroids does not exclude subjects from enrollment)
    - Cystic fibrosis (Adequately treated thyroid disease and celiac disease do not exclude subjects from enrollment)
17. Inpatient psychiatric treatment in the past 6 months for either child participant or the primary care giver
18. Need for use of acetaminophen or acetaminophen-containing products on a regular basis during the 6 months of the trial
19. Participation of parent or child in a diabetes related intervention study in past 6 weeks.
20. Any medical, psychological or social situation where per investigator discretion it may be difficult for family or child to participate fully in the intervention
21. Another member of the same household is participating in this study.

Supplemental Figure S1. Flowchart of Study Participants



Supplemental Table S2. Descriptions of Standard CGM Training Sessions

Note: Sessions were delivered using standardized educational material by a certified diabetes educator with CGM experience. Each session lasted approximately 30 minutes.

Prior to Randomization:	
Screening Visit	Session 1: How CGM Works – blinded sensor instruction
During Study	
Randomization Visit	Session 2: CGM Basics
1 Week Visit	Session 3: Advanced CGM
3 Week Visit	Session 4: Using CGM to Minimize Highs & Lows
6 Week Visit	Session 5: CGM Data Refresher/Review

Example from Session 3:

TROUBLESHOOTING High Glucoses

When starting to use CGM, you will most likely notice more high glucose readings than before. This extra information can be very helpful as you do your best to improve your child's glucose control. A common mistake made by people using CGM is overreacting to the highs shown by the sensor by taking too much insulin, which can lead to hypoglycemia. The steps below can help you decide when it's safe to give additional insulin boluses.

Be Careful Not to Over-react to Highs by Taking Extra Insulin

- It is always ok to take insulin to cover carbohydrates
- It is not OK to give correction insulin more often than every 3 hours if your child is on injections

Before You Bolus for a High:

1. Consider taking a finger stick measurement to confirm your child's glucose level.
2. Stop to consider:
   - Is there "insulin on board" (insulin that is still acting from a previous bolus)? A bolus of rapid-acting insulin works for at least 3 hours. For this reason, it is important that you do not try to correct a glucose with insulin more than once in a 3-hour time period if your child is on injections.
   - If your child is on an insulin pump it accounts for insulin on board, so you can consider bolusing for a high prior to 3 hours. First, check the pump and its cannula to be sure there is not a problem with insulin delivery. If there is a problem with the cannula, you will need to give your child an injection instead of bolusing through the pump, and you should insert a new pump site.

At the end of each CGM session participants were provided a handout including the below text on overall diabetes management goals.

Diabetes Management Goals

Throughout the study our team will work with you to improve your child's diabetes management. It is helpful to have the following targets in mind while we work together.

Morning fasting blood glucose: 80 – 130 mg/dL

Before lunch and dinner: 80 - 120 mg/dL

Peak postprandial (after eating) blood glucose: less than 180 mg/dL

Bedtime/Overnight:  90 – 150 mg/dL

Hemoglobin A1c:

- Less than 7.5 % for everyone
- Less than 7% if we can attain this without excessive hypoglycemia.

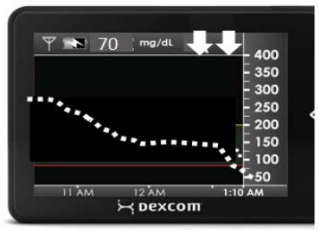
Supplemental Table S3. Descriptions of Family Behavioral Intervention (FBI) Sessions

Note: Sessions were delivered by trained research assistants who were not medical professionals. Each session lasted approximately 30 minutes.

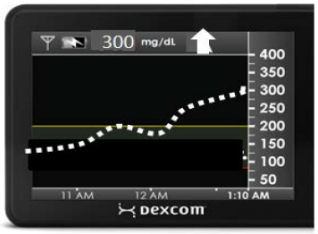
Visit	Title	Content
Week 1	Getting Used to CGM – Common Questions & Tips	Topics: Parents' expectations about how much time CGM will take, impact on glucose levels, Skills: Time management/CGM routines, behavioral strategies to facilitate sensor insertion, pain management, and muscle relaxation
Week 3	CGM and Glucose Ups and Downs	Topics: Education about glucose variability, links between glucose levels and mood/behavior, impact of language on thoughts/feelings Skills: emotion regulation, cognitive restructuring for CGM reactions, and helpful language
Week 6	Life with CGM	Topics: Parents' reactions to CGM/data, such as feeling successful, data overload, alert fatigue, burnout Skills: Using CGM to treat high/low glucose levels, reframing attention to benefits of CGM alerts, seeking social support, problem-solving
Week 13	CGM Away from Home and with Other Caregivers	Topics: Experiences with close connections' (e.g., family, caregivers/teachers) and others' (e.g., friends, other people) reactions to CGM Skills: Communication strategies, teaching others about CGM basics, planning for leaving child with another caregiver
Week 19	Moving Forward with CGM	Topics: Review topics from previous sessions, highlight parents' progress and successes

3. Identifying your Emotions Associated with CGM use

CGM glucose values and trend arrows are very helpful. Some parents report that the glucose values or trend arrows can make them feel nervous or frustrated.



How do you feel when the display device looks like this?

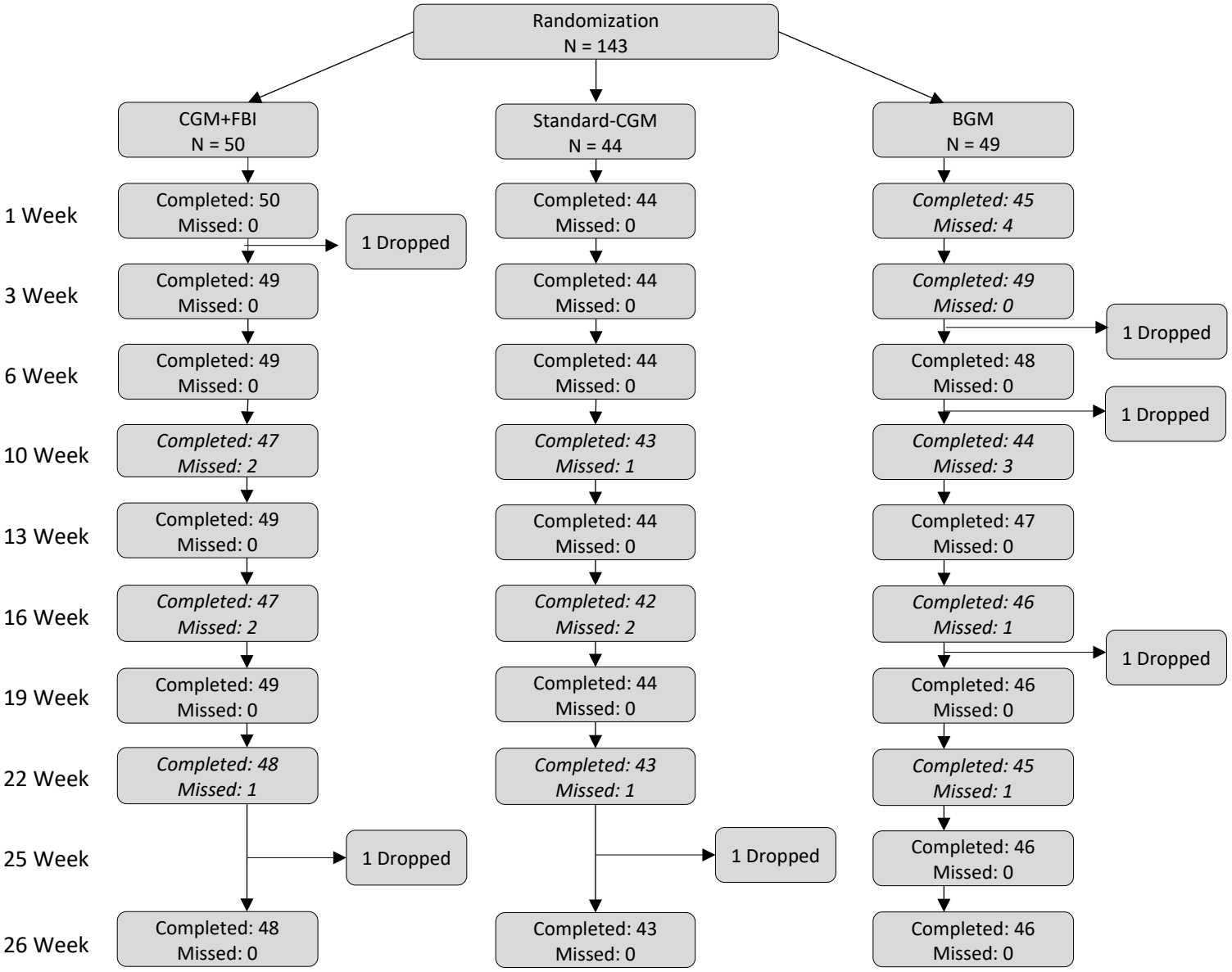


How do you feel when the display device looks like this?

Example of Module 2 CGM and Glucose Ups and Downs:

Supplemental Figure S2. Visit and Phone Contact Completion by Treatment Group

Phone calls are italicized.

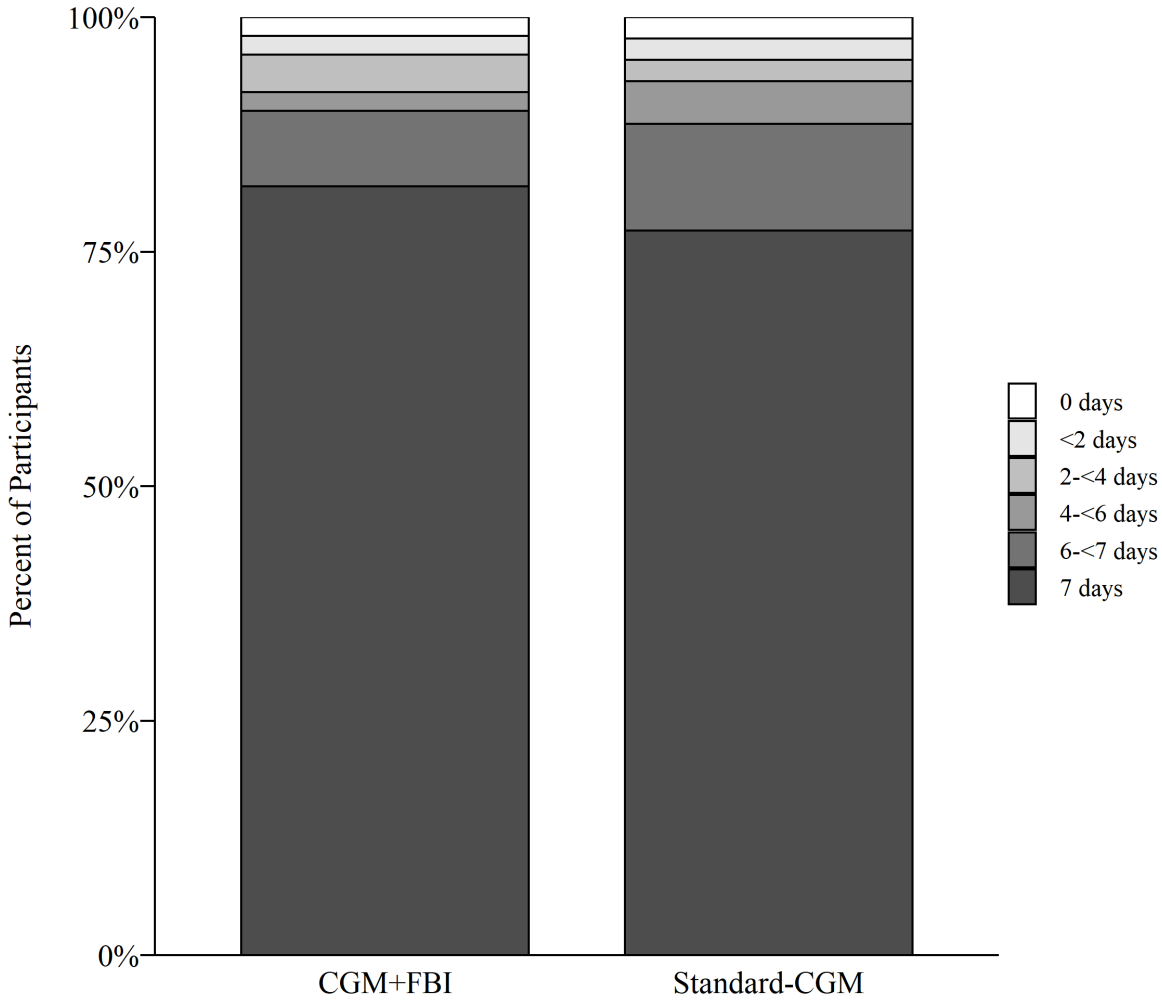


Supplemental Table S4. Unscheduled Contacts

	CGM+FBI (N=50)	Standard-CGM (N=44)	BGM (N=49)
Unscheduled Office Visits – ***number of visits (number of participants with visit)***	0 (0)	4 (4)	1 (1)
Reason[1] – N (%)			
Diabetes Management	-	1 (25%)	-
Other	-	3 (75%)	1 (100%)
Unscheduled Phone Calls/Audio-video/Emails – ***number of contacts (number of participants with contact)***	33 (10)	43 (8)	9 (3)
Reason[1] – N (%)			
CGM Training	8 (24%)	9 (21%)	-
Diabetes Management	28 (85%)	27 (63%)	8 (89%)
Potential Adverse Event	-	3 (7%)	-
FBI delivery	1 (3%)	-	-
Other	3 (9%)	9 (21%)	6 (67%)

1. More than one reason may be selected for each unscheduled contact.

Supplemental Figure S3: Days per Week of Sensor Use at 6 Months



Supplemental Table S5: Days per Week of Sensor Use

	CGM + FBI					Standard CGM					P-value[2]
	Overall	**6 Week**	**13 Week**	**19 Week**	**26 Week**	**Overall**	**6 Week**	**13 Week**	**19 Week**	**26 Week**	
N	50	50	50	50	50	44	44	44	44	44	
Avg # Days Sensor Use per Week - Median (Q1, Q3)	6.9 (5.9, 7.0)	7.0 (6.8, 7.0)	7.0 (6.5, 7.0)	7.0 (6.8, 7.0)	7.0 (7.0, 7.0)	6.9 (6.6, 7.0)	7.0 (7.0, 7.0)	7.0 (6.9, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	0.33
Zero Use	1 (2%)	1 (2%)	2 (4%)	1 (2%)	1 (2%)	-	-	-	-	1 (2%)	
<1 day	-	-	1 (2%)	-	1 (2%)	-	-	-	-	-	
1-<2 days	-	-	1 (2%)	1 (2%)	-	-	-	1 (2%)	-	1 (2%)	
2-<3 days	-	-	2 (4%)	1 (2%)	1 (2%)	1 (2%)	-	-	-	-	
3-<4 days	1 (2%)	3 (6%)	2 (4%)	-	1 (2%)	-	1 (2%)	2 (5%)	2 (5%)	1 (2%)	
4-<5 days	1 (2%)	-	-	1 (2%)	-	-	2 (5%)	-	-	-	
5-<6 days	10 (20%)	3 (6%)	3 (6%)	4 (8%)	1 (2%)	5 (11%)	4 (9%)	2 (5%)	2 (5%)	2 (5%)	
6-<7 days	17 (34%)	9 (18%)	7 (14%)	8 (16%)	4 (8%)	17 (39%)	2 (5%)	6 (14%)	2 (5%)	5 (11%)	
7 days	20 (40%)	34 (68%)	32 (64%)	34 (68%)	41 (82%)	21 (48%)	35 (80%)	33 (75%)	38 (86%)	34 (77%)	
<6 days	13 (26%)	7 (14%)	11 (22%)	8 (16%)	5 (10%)	6 (14%)	7 (16%)	5 (11%)	4 (9%)	5 (11%)	
≥6 days	37 (74%)	43 (86%)	39 (78%)	42 (84%)	45 (90%)	38 (86%)	37 (84%)	39 (89%)	40 (91%)	39 (89%)	

1. Using data from the 28 days prior to the 6, 13, 19, and 26 week visits.
2. Overall use is compared between treatment groups in a linear model based on ranks, adjusting for baseline HbA1c and site as a random effect.

Supplemental Table S6: Device Issues

Type of device and Issue – N=81	Count
Dexcom G5 Mobile Receiver	
Alarm Malfunction	5
Device malfunction- Battery Issue	24
Device malfunction- Error message on receiver	14
Mechanical malfunction	4
User Error	1
Water damage	5
Dexcom G5 Mobile Transmitter	
Connectivity Problems	3
Mechanical malfunction	1
Transmitter battery premature expiration	1
Transmitter Failed	1
Dexcom G4 Platinum Professional Receiver	
Connectivity Problems	1
Battery life	4
Device Malfunction - Data not Collected	1
Device malfunction- Error message on receiver	1
Site error	1
Water damage	1
Dexcom G4 Platinum Professional Transmitter	
Connectivity Problems	3
Transmitter battery premature expiration	1
Transmitter battery	1
Site error	1
Dexcom G4/G5 Sensor	

Mechanical malfunction	1
Sensor Applicator malfunction	1
Sensor failed	2
Tip of sensor dislodged	3

Supplemental Table S7: Change in Time in Range 70-180 mg/dL by Treatment Group According to Baseline Characteristics

	CGM+FBI			Standard-CGM			BGM			CGM+FBI vs. BGM	Standard-CGM vs. BGM	CGM+FBI vs. Standard CGM
	N	Baseline Mean ± SD	Change from Baseline Mean ± SD	N	Baseline Mean ± SD	Change from Baseline Mean ± SD	N	Baseline Mean ± SD	Change from Baseline Mean ± SD	P-Value for interaction[1]	P-Value for interaction[1]	P-Value for interaction[1]
Age										0.58	0.87	0.58
<5 years	17	32% ± 13%	7% ± 11%	17	40% ± 11%	-1% ± 9%	14	41% ± 11%	-1% ± 7%			
≥5 years	32	41% ± 11%	3% ± 11%	27	42% ± 9%	0% ± 9%	31	41% ± 10%	0% ± 9%			
Baseline % Time in Range 70-180 mg/dL										0.92	0.92	0.92
<40%	27	29% ± 8%	9% ± 9%	17	31% ± 6%	4% ± 9%	19	32% ± 7%	3% ± 8%			
≥40%	22	48% ± 8%	-1% ± 10%	27	47% ± 6%	-4% ± 8%	26	48% ± 6%	-4% ± 8%			
Baseline HbA1c										0.75	0.72	0.72
<8.5%	29	42% ± 11%	4% ± 11%	28	45% ± 7%	-2% ± 8%	29	45% ± 8%	-2% ± 8%			
≥8.5%	20	31% ± 12%	5% ± 12%	16	34% ± 9%	1% ± 10%	16	34% ± 9%	2% ± 9%			
T1D Duration										0.30	0.78	0.31
<2 years	25	38% ± 15%	5% ± 13%	29	41% ± 10%	-1% ± 9%	19	41% ± 12%	-4% ± 8%			
≥2 years	24	37% ± 10%	4% ± 9%	15	42% ± 9%	0% ± 10%	26	41% ± 9%	1% ± 8%			
Insulin Method										0.44	0.85	0.44
Injections	34	38% ±14%	5% ± 12%	31	41% ± 10%	-2% ± 8%	25	42% ± 12%	-3% ± 8%			
Pump	15	37% ± 10%	4% ± 10%	13	43% ± 10%	1% ± 11%	20	40% ± 7%	2% ± 8%			
Sex										0.57	0.32	0.42
Female	29	36% ± 12%	5% ± 12%	17	43% ± 10%	0% ± 11%	23	38% ± 10%	-1% ± 9%			
Male	20	40% ± 13%	3% ± 9%	27	40% ± 10%	-1% ± 8%	22	44% ± 10%	-1% ± 9%			
Race/Ethnicity										0.84	0.84	0.84
White non-Hispanic	32	37% ± 12%	5% ± 11%	33	39% ± 10%	-1% ± 10%	27	40% ± 10%	-1% ± 8%			
Non-White	16	39% ± 14%	3% ± 12%	10	47% ± 8%	-2% ± 8%	17	43% ± 11%	-1% ± 10%			
Education										0.62	0.62	0.62
High school or less	12	34% ± 16%	7% ± 13%	10	36% ± 7%	0% ± 5%	9	34% ± 7%	0% ± 10%			
Some college or more	34	38% ± 12%	3% ± 11%	30	42% ± 10%	-1% ± 11%	36	43% ± 10%	-1% ± 8%			

Insurance										0.68	0.68	0.68
Not private/no insurance	20	35% ± 12%	7% ± 8%	17	41% ± 10%	-1% ± 8%	16	41% ± 10%	-2% ± 9%			
Private	29	39% ±13%	3% ± 12%	27	41% ± 10%	-1% ± 10%	27	41% ± 10%	0% ± 8%			
Prior CGM use										-	-	-
No prior CGM use	44	39% ± 13%	5% ± 11%	39	41% ± 10%	-1% ± 9%	38	41% ± 10%	-2% ± 8%			
Prior CGM use	5	29% ± 11%	3% ± 7%	5	43% ± 9%	2% ± 8%	7	40% ± 9%	6% ± 8%			

1. The model is adjusted for baseline value, baseline HbA1c and site as a random effect. P-values are adjusted for multiple treatment group comparisons using the Benjamini-Hochberg linear step-up approach. Note that this adjustment results in some of the p-values being identical.

Supplemental Table S8: CGM Metrics by 3 Month Periods

	CGM+FBI		**Standard-CGM**		**BGM**		**CGM+FBI vs BGM**	**Standard-CGM vs BGM**	**CGM+FBI vs Standard-CGM**
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P-value[1]	P-value[1]	P-value[1]
% Time in Range 70-180 mg/dL									
Baseline	50	38% ± 13%	44	41% ± 10%	49	41% ± 10%			
First 3 Months (6 and 13 weeks)	49	40% ± 11%	44	40% ± 11%	44	41% ± 11%	0.80	0.80	0.80
Second 3 Months (19 and 26 weeks)	49	44% ± 12%	44	40% ± 11%	45	39% ± 12%	0.002	0.48	0.012
Interaction of Treatment and Time: First vs. Second 3 Months							0.013	0.34	0.09
% Time < 70 mg/dL									
Baseline	50	5.2% ± 4.2%	44	5.8% ± 5.3%	49	5.4% ± 4.6%			
First 3 Months (6 and 13 weeks)	49	2.4% ± 1.8%	44	2.5% ± 2.4%	44	5.5% ± 4.1%	<.001	<.001	0.69
Second 3 Months (19 and 26 weeks)	49	2.8% ± 2.1%	44	2.4% ± 1.9%	45	6.0% ± 4.2%	<.001	<.001	0.26
Interaction of Treatment and Time: First vs. Second 3 Months							0.68	0.68	0.68
% Time < 54 mg/dL									
Baseline	50	2.3% ± 2.5%	44	2.6% ± 3.4%	49	2.4% ± 3.1%			
First 3 Months (6 and 13 weeks)	49	0.7% ± 0.9%	44	0.7% ± 0.9%	44	2.4% ± 2.6%	<.001	<.001	0.55
Second 3 Months (19 and 26 weeks)	49	0.7% ± 0.8%	44	0.7% ± 0.8%	45	2.5% ± 2.1%	<.001	<.001	0.74

	CGM+FBI		Standard-CGM		BGM		CGM+FBI vs BGM	Standard-CGM vs BGM	CGM+FBI vs Standard-CGM
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	P-value[1]	P-value[1]	P-value[1]
Interaction of Treatment and Time: First vs. Second 3 Months							0.57	0.56	0.57

1. The model is adjusted for baseline value, baseline HbA1c and site as a random effect. P-values are adjusted for multiple treatment group comparisons using the Benjamini-Hochberg linear step-up approach.

Supplemental Table S9. CGM Metrics during the Daytime (6:00AM-9:59PM) and Nighttime (10:00PM-5:59AM)

	CGM+FBI		Standard-CGM		BGM		CGM+FBI vs. BGM P-value[2]	Standard-CGM vs. BGM P-value[2]	CGM+FBI vs. Standard-CGM P-value[2]
	Baseline (N=50)	Follow-up[1] (N=49)	Baseline (N=44)	Follow-up[1] (N=44)	Baseline (N=49)	Follow-up[1] (N=45)			
Daytime (6:00AM-9:59PM)									
Hours of CGM data – *median (q1, q3)*	201 (181, 223)	401 (365, 417)	195 (179, 229)	403 (366, 420)	203 (170, 245)	375 (314, 412)			
% time in range 70-180 mg/dL- *mean ± sd*	37 ± 13	42 ± 11	42 ± 10	41 ± 10	41 ± 11	41 ± 10	0.09	0.60	0.15
% time < 54 mg/dL							<0.001	<0.001	0.44
median (q1, q3)	1.4 (0.5, 2.6)	0.3 (0.2, 0.9)	1.5 (0.3, 2.8)	0.5 (0.3, 0.8)	0.7 (0.3, 2.6)	1.7 (0.8, 3.2)			
mean ± sd	1.8 ± 1.9	0.6 ± 0.6	2.3 ± 2.7	0.7 ± 0.7	2.1 ± 2.9	2.1 ± 1.8			
Nighttime (10:00PM-5:59AM)									
Hours of CGM data – *median (q1, q3)*	109 (100, 120)	207 (192, 218)	107 (98, 118)	208 (198, 217)	110 (100, 127)	206 (185, 223)			
% time in range 70-180 mg/dL - *mean ± sd*	39 ± 16	41 ± 12	39 ± 13	38 ± 11	40 ± 15	39 ± 11	0.25	0.82	0.25
% time < 54 mg/dL							<0.001	<0.001	0.82
median (q1, q3)	0.9 (0.2, 4.3)	0.4 (0.2, 1.3)	1.4 (0.0, 4.7)	0.5 (0.1, 1.1)	1.7 (0.5, 4.7)	2.2 (1.0, 4.7)			
mean ± sd	3.2 ± 4.6	0.9 ± 1.1	3.1 ± 5.2	0.8 ± 1.2	3.1 ± 4.3	3.0 ± 2.7			

1. Follow-up includes data pooled from the 6, 13, 19, and 26 week time points
2. Outcomes were analyzed in a linear mixed effects model that adjusts for baseline value, baseline HbA1c, and clinical center as a random effect. % time <54 mg/dL had a skewed distributions and so was modeled using a rank-based transformation. P-values and 95% CI's for the secondary outcomes were adjusted for multiple treatment group comparisons using the Benjamini Hochberg linear step-up approach.

Supplemental Table S10: Safety Outcomes

	CGM+FBI (N=50)	Standard-CGM (N=44)	BGM (N=49)	CGM+FBI vs. BGM P-value[e]	Standard-CGM vs. BGM P-value[e]	CGM+FBI vs. Standard-CGM P-value[e]
Severe Hypoglycemia[a]						
# of SH events (# of participants with one or more events)	0 (0)	1 (1)[b]	5 (5)	0.03	0.21	0.47
Incidence Rate	0.0	4.6	21.3			
# of SH events resulting in seizure or loss of consciousness (# of participants with one or more events)	0 (0)	0 (0)	3 (3)			
Diabetic Ketoacidosis[c]						
# of DKA events (# of participants with one or more events)	1 (1)	1 (1)	0 (0)	1.00	0.47	1.00
Incidence Rate	4.1	4.6	0.0			
Other Serious Adverse Events						
# of events (# of participants with one or more events)	1 (1)	2 (2)	0 (0)			
Appendicitis	1 (1)	0 (0)	0 (0)			
Ketosis	0 (0)	1 (1)	0 (0)			
Urinary tract infection	0 (0)	1 (1)	0 (0)			
Reported Non-serious Adverse Events						
# of events (# of participants with one or more events)	1 (1)	4 (4)	1 (1)			
Ketosis	0 (0)	2 (2)	1 (1)			
Lipoatrophy	1 (1)	0 (0)	0 (0)			
Post procedural complication[d]	0 (0)	2 (2)	1 (1)			

a. Severe hypoglycemia was defined as an event that required assistance from another person to administer carbohydrate, glucagon, or other resuscitative actions.
b. Participant was wearing CGM at the time of the event that read 55 mg/dL.
c. DKA was defined as an episode when the participant had ketosis that necessitated treatment in a health care facility.
d. Two participants reported that the sensor tip remained under the participant's skin after sensor removal.
e. Severe hypoglycemic events and occurrences of diabetic ketoacidosis were compared between treatment groups using Fisher's exact test.