

Supplementary Material 2

Supplement to:

“Effects of Patient-Driven Lifestyle Modification Using Intermittently Scanned Continuous Glucose Monitoring in Patients with Type 2 Diabetes: Results from the Randomized Open-label PDF Study”

Supplementary Table	Page
<i>Table S1. Baseline characteristics of the study participants</i>	2
<i>Table S2. Glucose lowering medications in study participants</i>	3
<i>Table S3. Study outcomes according to treatment groups with additional adjustment for baseline BMI</i>	4
<i>Table S4. Cumulative distribution of HbA1c values</i>	5
<i>Table S5. Study outcomes in the total cohort</i>	6
<i>Table S6. CGM outcomes in intention-to-treat analysis</i>	7
<i>Table S7. Basal insulin dosage at V1 and V2</i>	8
<i>Table S8. Study outcomes according to treatment groups in per protocol analysis</i>	9
<i>Table S9. CGM outcomes in per protocol analysis</i>	10
<i>Table S10. Adverse glycemic events detected in the intervention group</i>	11

Supplementary Table 1. Baseline characteristics of the study participants

	Total	Intervention	Control	P value
	N = 120	N = 58	N = 62	
Age (years)	58.0 ± 11.9	58.6 ± 12.0	57.5 ± 11.8	0.608
Sex (Female)	48 (40.0)	21 (36.2)	27 (43.5)	0.412
Height (cm)	165.1 ± 8.5	166.2 ± 8.2	164.2 ± 8.6	0.193
Weight (kg)	71.7 ± 12.1	70.5 ± 11.7	72.7 ± 12.5	0.331
BMI (kg/m ²)	26.2 ± 3.5	25.5 ± 3.4	26.9 ± 3.5	0.028
DM duration (years)	13.3 ± 7.8	13.3 ± 8.2	13.4 ± 7.6	0.911
Family history of DM	61 (50.8)	25 (43.1)	36 (58.1)	0.101
DM medication				
Insulin	33 (27.5)	19 (32.8)	14 (22.6)	0.212
Number of non-insulin antidiabetic medications				0.870
0	1 (0.8)	1 (1.7)	0 (0.0)	
1	16 (13.3)	8 (13.8)	8 (12.9)	
2	57 (47.5)	28 (48.3)	29 (46.8)	
3	44 (36.7)	20 (34.5)	24 (38.7)	
4	2 (1.7)	1 (1.7)	1 (1.6)	
Dyslipidemia	100 (83.3)	51 (87.9)	50 (80.6)	0.275
Hypertension	65 (54.2)	30 (51.7)	36 (58.1)	0.485
HbA1c (%)	7.9 ± 0.7	7.9 ± 0.6	7.9 ± 0.7	0.808
AST (IU/L)	26 ± 12	26 ± 11	26 ± 12	0.688
ALT (IU/L)	31 ± 19	31 ± 20	32 ± 19	0.823
BUN (mg/dL)	16.2 ± 4.9	16.5 ± 5.2	16.0 ± 4.6	0.575
Cr (mg/dL)	0.83 ± 0.21	0.84 ± 0.23	0.82 ± 0.20	0.665
eGFR (mL/min/1.73 m ²)	91.5 ± 20.7	91.9 ± 20.9	91.0 ± 20.7	0.811
Cigarette				0.699
Never smoker	66 (55.0)	30 (51.7)	36 (58.1)	
Ex-smoker	37 (30.8)	20 (34.5)	17 (27.4)	
Current smoker	17 (14.2)	8 (13.8)	9 (14.5)	
Alcohol	35 (29.2)	18 (31.0)	17 (27.4)	0.663

Data are shown as mean ± standard deviation, or number (percentage). Alcohol (%), number (%) of participants who drinks alcohol three or more times a week; DM, diabetes mellitus; AST, aspartate aminotransferase; ALT, alanine aminotransferase; BUN, blood urea nitrogen; eGFR, estimated glomerular filtration rate

Supplementary Table 2. Glucose lowering medications in study participants

	Total	CGM	BGM	<i>P</i> value
	N = 120	N = 58	N = 62	
Insulin	33 (27.5)	19 (32.8)	14 (22.6)	0.212
Metformin	105 (87.5)	52 (89.7)	53 (85.5)	0.490
Sulfonylurea	54 (45.0)	23 (39.7)	31 (50.0)	0.255
Thiazolidinedione	15 (12.5)	7 (12.1)	8 (12.9)	0.890
DPP4 inhibitor	47 (39.2)	22 (37.9)	25 (40.3)	0.789
SGLT2 inhibitor	38 (31.9)	19 (32.8)	19 (30.6)	0.804
GLP-1 receptor agonist	11 (9.2)	5 (8.6)	6 (9.7)	0.841

Data are shown as number (percentage). CGM, continuous glucose monitoring; BGM, blood glucose monitoring; DPP4, dipeptidyl peptidase-4; SGLT2, sodium-glucose cotransporter 2; GLP-1, glucagon-like peptide-1

Supplementary Table 3. Study outcomes according to treatment groups with additional adjustment for baseline BMI

	V1		<i>P</i> value	V2		<i>P</i> value	Risk-adjusted difference (95% CI)	<i>P</i> * value
	Intervention	Control		Intervention	Control			
	N = 58	N = 62		N = 58	N = 62			
Primary outcome								
HbA1c (%)	7.9 ± 0.6	7.9 ± 0.7	0.808	7.3 ± 0.6	7.8 ± 0.9	<0.001	−0.50 (−0.74 - −0.25)	<0.001
Secondary outcome								
Fasting glucose (mg/dL)	142 ± 27	147 ± 36	0.420	136 ± 35	154 ± 43	0.013	−15.4 (−29.1 - 1.6)	0.029
Body weight (kg)	70.5 ± 11.7	72.7 ± 12.5	0.331	69.1 ± 11.3	72.8 ± 12.8	0.105	−1.6 (−2.8 - −0.3)	0.014
Waist circumference (cm)	87.7 ± 8.1	91.8 ± 10.2	0.018	87.4 ± 8.8	92.1 ± 10.6	0.010	−0.6 (−1.7 - 0.5)	0.284
SBP (mmHg)	133 ± 16	126 ± 16	0.022	134 ± 14	124 ± 21	0.003	7.3 (0.6 - 14.0)	0.032
DBP (mmHg)	79 ± 10	77 ± 10	0.153	78 ± 9	79 ± 9	0.530	−1.8 (−4.6 - 1.1)	0.219
Total cholesterol (mg/dL)	138 ± 29	140 ± 25	0.707	136 ± 34	140 ± 28	0.565	0.1 (−7.5 - 7.8)	0.972
Triglyceride (mg/dL)	131 ± 68	153 ± 73	0.094	149 ± 197	141 ± 72	0.761	32.9 (−14.6 - 80.3)	0.173
HDL-C (mg/dL)	48 ± 13	48 ± 17	0.965	47 ± 12	48 ± 15	0.627	−1.5 (−4.8 - 1.7)	0.352
LDL-C (mg/dL)	74 ± 22	75 ± 20	0.852	70 ± 25	74 ± 25	0.487	−1.3 (−7.3 - 4.7)	0.676
SDSCA-K total score	26.6 ± 13.6	25.1 ± 12.8	0.533	44.4 ± 9.2	39.2 ± 10.1	0.005	4.8 (1.6 - 8.1)	0.004

Data are shown as mean ± standard deviation. SBP, systolic blood pressure; DBP, diastolic blood pressure; HDL-C, high density lipoprotein-cholesterol; LDL-C, low density lipoprotein-cholesterol; SDSCA-K, the Korean version of revised summary of diabetes self-care activities; *P** value is the comparison of the V2 Intervention vs V2 Control using ANCOVA with adjustment for respective baseline values, hospital of recruitment, and baseline body mass index

Supplementary Table 4. Cumulative distribution of HbA1c values

HbA1c (%)	V1			V2		
	Intervention	Control	<i>P</i> value	Intervention	Control	<i>P</i> value
<6.5	0 (0.0)	0 (0.0)	-	3 (5.2)	2 (3.2)	0.594
<7.0	0 (0.0)	0 (0.0)	-	14 (24.1)	5 (8.1)	0.016
<7.5	14 (24.1)	20 (32.3)	0.324	37 (63.8)	21 (33.9)	0.001
<8.0	36 (62.1)	37 (59.7)	0.789	50 (86.2)	42 (67.7)	0.017
<8.5	47 (81.0)	48 (77.4)	0.626	55 (94.8)	51 (82.3)	0.032
<9.0	53 (91.4)	54 (87.1)	0.451	57 (98.3)	56 (90.3)	0.063
<9.5	56 (96.6)	57 (91.9)	0.281	58 (100.0)	59 (95.2)	0.090
<10.0	58 (100.0)	62 (100.0)	-	58 (100.0)	61 (98.4)	0.331

Data are shown as number (percentage).

Supplementary Table 5. Study outcomes in total participants

	V1 N = 120	V2 N = 118	P value
Primary outcome			
HbA1c	7.9 ± 0.7	7.6 ± 0.8	<0.001
Secondary outcome			
Fasting glucose (mg/dL)	145 ± 32	146 ± 40	0.799
Body weight (kg)	71.7 ± 12.1	71.0 ± 12.2	0.039
Waist circumference (cm)	89.8 ± 9.4	89.8 ± 10.0	0.939
SBP (mmHg)	129 ± 17	129 ± 19	0.743
DBP (mmHg)	78 ± 10	79 ± 9	0.373
Total cholesterol (mg/dL)	139 ± 27	138 ± 31	0.793
Triglyceride (mg/dL)	142 ± 71	145 ± 146	0.812
HDL-C (mg/dL)	48 ± 15	47 ± 13	0.421
LDL-C (mg/dL)	74 ± 21	72 ± 25	0.126
SDSCA-K			
Q1. How many of the last seven days have you followed a healthful eating plan?	3.4 ± 1.9	4.2 ± 1.6	<0.001
Q2. On average, over the past month, how many days per week have you followed your eating plan?	2.6 ± 1.7	3.8 ± 1.7	<0.001
Q3. On how many of the last seven days did you eat two or more servings of fruits and vegetables?	4.0 ± 1.8	4.9 ± 1.6	<0.001
Q4. On how many of the last seven days did you participate in at least 30 minutes of physical activity?	3.4 ± 2.4	4.2 ± 2.2	<0.001
Q5. On how many of the last seven days did you participate in a specific exercise session?*	1.5 ± 2.0	1.7 ± 2.1	0.284
Q6. On how many of the last seven days did you test your blood sugar?	2.7 ± 2.7	6.4 ± 1.3	<0.001
Q7. On how many of the last seven days did you test your blood sugar as recommended by your doctor?	2.4 ± 2.6	6.4 ± 1.2	<0.001
Q8. On how many of the last seven days did you check your feet?	4.0 ± 3.0	5.6 ± 2.3	<0.001
Q9. On how many of the last seven days did you inspect the inside of your shoes?	1.9 ± 2.6	4.5 ± 2.9	<0.001
Total score	25.6 ± 13.1	41.7 ± 10.0	<0.001

* Examples of specific exercise sessions include swimming, walking, and biking, other than what you do around the house or as part of your work.

Supplementary Table 6. CGM outcomes in intention-to-treat analysis

	CGM during weeks 1-2	CGM during weeks 11-12	<i>P</i> value
	N = 58	N = 56	
% Time in range of 70–180 mg/dL	70.4 ± 14.6	71.4 ± 15.4	0.562
CV (%)	33.8 ± 7.2	32.4 ± 6.3	0.032
CV < 36%	38 (65.5)	41 (73.2)	
Mean glucose (mg/dL)	151 ± 25	151 ± 27	0.854
Time above range			
% Time > 180 mg/dL	19.5 ± 8.5	20.1 ± 9.9	0.549
% Time > 250 mg/dL	6.8 ± 8.0	6.1 ± 8.3	0.363
Time below range			
% Time < 70 mg/dL	2.88 ± 4.92	2.07 ± 3.93	0.251
% Time < 54 mg/dL	0.43 ± 1.2	0.32 ± 0.9	0.589

CGM, continuous glucose monitoring

Supplementary Table 7. Basal insulin dosage at V1 and V2

ID	Type	Insulin dose (Unit/day)		ID	Type	Insulin dose (Unit/day)	
		V1	V2			V1	V2
R01001	Glargine	54	54	R02016	Glargine	70	44
R01003	Degludec	16	16	R02020	Degludec	80	80
R01006	Glargine	44	44	R02022	Glargine	60	60
R01007	Glargine	30	28	R02033	Glargine	46	46
R01012	Glargine	36	30	R02035	Degludec	80	80
R01019	Glargine	33	33	R03005	Glargine	40	40
R01020	Glargine	54	54	R03009	Degludec	40	40
R01022	Glargine	32	30	R03011	Degludec	55	60
R01026	Isophane	36	30	R03012	Glargine	26	26
R01027	Degludec	20	20	R03015	Degludec	20	12
R01044	Degludec	32	32	R03016	Glargine	38	38
R01039	Glargine	38	25	R03029	Degludec	28	30
R02003	Detemir	30	30	R03030	Glargine	50	50
R02009	Degludec	70	70	R03031	Glargine	42	42
R02010	Degludec	50	50	R03035	Glargine	38	38
R02011	Glargine	44	46	R03040	Degludec	62	62
R02013	Glargine	28	28	Average		41.8 ± 15.6	40.1 ± 15.9

Supplementary Table 8. Study outcomes according to treatment groups in per protocol analysis

	V1		<i>P</i> value	V2		<i>P</i> value	Risk-adjusted difference (95% CI)	<i>P</i> * value
	Intervention	Control		Intervention	Control			
	N = 46	N = 62		N = 46	N = 62			
Primary outcome								
HbA1c (%)	7.9 ± 0.6	7.9 ± 0.7	0.865	7.3 ± 0.5	7.8 ± 0.9	<0.001	−0.50 (−0.74 - −0.25)	<0.001
Secondary outcome								
Fasting glucose (mg/dL)	140 ± 28	147 ± 36	0.300	136 ± 36	154 ± 43	0.019	−16.3 (−31.1 - −1.5)	0.031
Body weight (kg)	70.2 ± 12.3	72.7 ± 12.5	0.299	68.8 ± 12.0	72.8 ± 12.8	0.106	−1.5 (−2.8 - −0.2)	0.026
Waist circumference (cm)	87.4 ± 8.6	91.8 ± 10.2	0.022	87.2 ± 8.9	92.1 ± 10.6	0.013	−0.6 (−1.7 - 0.6)	0.326
SBP (mmHg)	133 ± 16	126 ± 16	0.042	135 ± 16	124 ± 21	0.004	8.8 (1.7 - 15.9)	0.016
DBP (mmHg)	79 ± 9	77 ± 10	0.223	79 ± 9	79 ± 9	0.764	−1.7 (−4.7 - 1.2)	0.253
Total cholesterol (mg/dL)	136 ± 29	140 ± 25	0.463	135 ± 33	140 ± 28	0.382	−1.9 (−9.9 - 6.2)	0.650
Triglyceride (mg/dL)	125 ± 64	153 ± 73	0.041	150 ± 218	141 ± 72	0.762	42.9 (−8.9 - 94.7)	0.104
HDL-C (mg/dL)	48 ± 12	48 ± 17	0.968	46 ± 11	48 ± 15	0.529	−1.3 (−4.7 - 2.2)	0.463
LDL-C (mg/dL)	72 ± 20	75 ± 20	0.534	68 ± 22	74 ± 25	0.269	−3.2 (−9.5 - 3.1)	0.315
SDSCA-K total score	28.7 ± 13.7	25.1 ± 12.8	0.172	45.2 ± 8.3	39.2 ± 10.1	0.002	5.2 (1.8 - 8.6)	0.003

Data are shown as mean ± standard deviation. SBP, systolic blood pressure; DBP, diastolic blood pressure; HDL-C, high density lipoprotein-cholesterol; LDL-C, low density lipoprotein-cholesterol; SDSCA-K, the Korean version of revised summary of diabetes self-care activities; *P** value is the comparison of the V2 Intervention vs V2 Control using ANCOVA with adjustment for respective baseline values and hospital of recruitment

Supplementary Table 9. CGM outcomes in per protocol analysis

	CGM during weeks 1-2	CGM during weeks 11-12	<i>P</i> value
	N = 46	N = 45	
% Time in range of 70 – 180 mg/dL	71.1 ± 14.7	72.9 ± 14.1	0.264
CV (%)	33.4 ± 7.4	32.0 ± 6.4	0.024
CV < 36%	30 (65.2)	34 (75.6)	
Mean glucose (mg/dL)	151 ± 25	151 ± 27	0.699
Time above range			
% Time > 180 mg/dL	19.2 ± 8.9	19.6 ± 10.2	0.795
% Time > 250 mg/dL	6.4 ± 7.1	5.0 ± 5.1	0.098
Time below range			
% Time < 70 mg/dL	2.91 ± 4.98	2.18 ± 4.27	0.221
% Time < 54 mg/dL	0.46 ± 1.3	0.36 ± 1.0	0.657

CGM, continuous glucose monitoring

Supplementary Table 10. Adverse glycemic events detected in the intervention group

	Intervention group (N = 58)		Control group (N = 62)	
	Participants	Duration in Hours (%)	Participants	BGM (%)
Glucose monitoring per day	8.6 ± 5.3		1.8 ± 0.9	
Hyperglycemic events				
Glucose > 180 mg/dL	58 (100.0)	6.31 (26.3)	59 (95.2)	37.5 (0.5)
Glucose > 250 mg/dL	56 (96.6)	1.56 (6.5)	47 (75.8)	5.84 (0.1)
Hypoglycemic events				
Glucose < 70 mg/dL	56 (96.6)	0.62 (2.6)	15 (24.2)	0.34 (0.0)
Glucose < 54 mg/dL	45 (77.6)	0.09 (0.4)	6 (9.7)	0.16 (0.0)

Data are shown as number (percentage). Glucose monitoring per day is the average number of active CGM scan for the intervention group and the total number of BGM divided by 84 days for the control group. Number and percentage of participants with any detected hyperglycemic or hypoglycemic events during the study period are listed for both groups. For the intervention group, average duration of time spent in hyperglycemia and hypoglycemia are presented in hours and percentage of the day. For the control group, average number of blood glucose monitoring (BGM) during the study period for hyperglycemia and hypoglycemia are listed. Average percentage of hyperglycemia and hypoglycemia per day have been calculated by dividing the number of BGM by 84 days (study period). BGM is based on the data from the glucose logbook.