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Online Supplementary Material

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Supplementary Table 1. Eligibility and Exclusion Criteria

Eligibility

To be eligible for the study, a subject must meet the following criteria:

1) Clinical diagnosis, based on investigator assessment, of type 1 diabetes for at least one year and using insulin for at least 1 year

2) Use of an insulin pump for at least 6 months

3) Age ≥14 years old

4) HbA1c level <10.5% at screening

5) For females, not currently known to be pregnant

- ***If female and sexually active, must agree to use a form of contraception to prevent pregnancy while a participant in the study. A negative serum or urine pregnancy test will be required for all females of child-bearing potential. Subjects who become pregnant will be discontinued from the study. Also, subjects who during the study develop and express the intention to become pregnant within the timespan of the study will be discontinued.***

6) Willingness not to add non-insulin glucose-lowering agents (such as Pramlintide, Metformin, GLP-1 analogs, SGLT2 inhibitors) during the study

7) Willingness, if not assigned to the closed-loop group, to avoid use of any closed-loop control system for the duration of the clinical trial

8) Willingness to suspend use of any personal CGM for the duration of the clinical trial beginning with the unblinded study CGM run-in period

9) Willingness to establish network connectivity on at least a weekly basis either via local Wi-Fi network or via a study-provided cellular service

10) Currently using no insulins other than one of the following rapid-acting insulins at the time of enrollment: insulin lispro (Humalog), insulin aspart (Novolog), or insulin glulisine (Apidra)

11) Investigator has confidence that the subject can successfully operate all study devices and is capable of adhering to the protocol

12) For subjects <18 years old, living with one or more parent/legal guardian (referred to subsequently as diabetes care partner) committed to participating in study training for emergency procedures for severe hypoglycemia and able to contact the subject in case of an emergency.

Exclusion

The presence of any of the following is an exclusion for the study:

1) Medical need for chronic acetaminophen

2) Use of any glucose-lowering agent (such as Pramlintide, Metformin, GLP-1 analogs, SGLT2 inhibitors) in the 3 months prior to enrollment

3) Hemophilia or any other bleeding disorder

4) A condition, which in the opinion of the investigator or designee, would put the participant or study at risk including any contraindication to the use of any of the study devices per FDA labelling

Individuals should not be enrolled with uncontrolled thyroid disease, renal failure (e.g., dialysis or eGFR <30), or unstable cardiovascular disease. Laboratory testing and other work up needed to determine that an individual is a suitable candidate for the study should be performed as part of usual care.

5) Participation in another pharmaceutical or device trial at the time of enrollment or during the study

6) Use of a closed-loop system within the last month prior to enrollment

Employed by, or having immediate family members employed by TypeZero Technologies, LLC; or having a direct supervisor at place of employment who is also directly involved in conducting the clinical trial (as a study investigator, coordinator, etc.); or having a first-degree relative who is directly involved in conducting the clinical trial.

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Supplementary Figure 1. Schematic of inControl-AP System Components: inControl AP control algorithm (TypeZero Technologies, Inc.) receiving CGM signal from a Dexcom G4 or G5 CGM (Dexcom, Inc.) and controlling an Accu-Chek Spirit Combo insulin pump (Roche Diagnostics). inControl AP runs on a Google Nexus 5X smartphone and uses Bluetooth (BT) and Bluetooth Low Energy (BLE) to communicate with the study CGM and insulin pump respectively. Contour NEXT ONE blood glucose meter and test strips (Ascensia Diabetes Care) is used to calibrate the study CGM.

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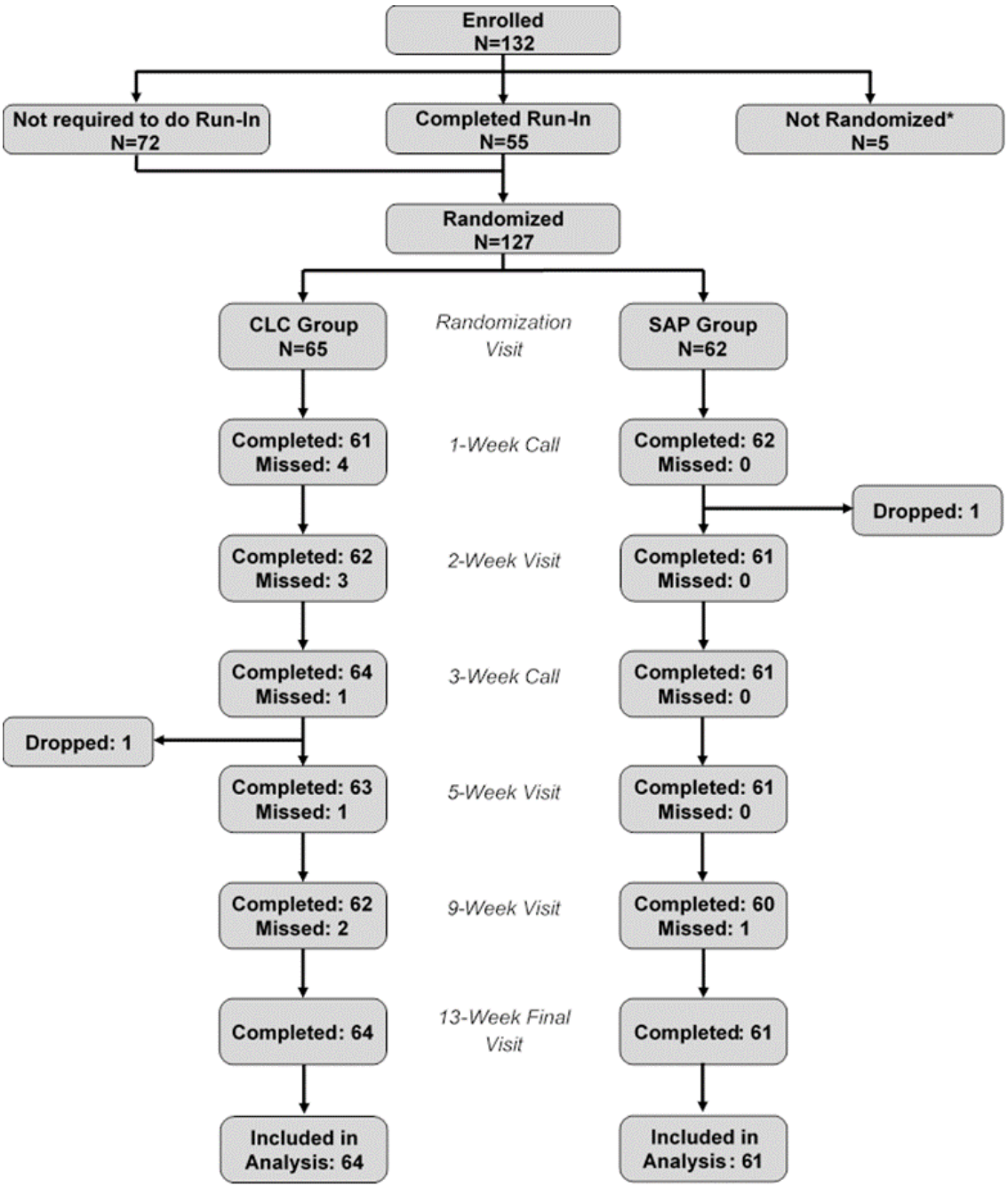
Supplementary Figure 2. Flow Chart



*N=3 ineligible, N=2 scheduling/availability issues

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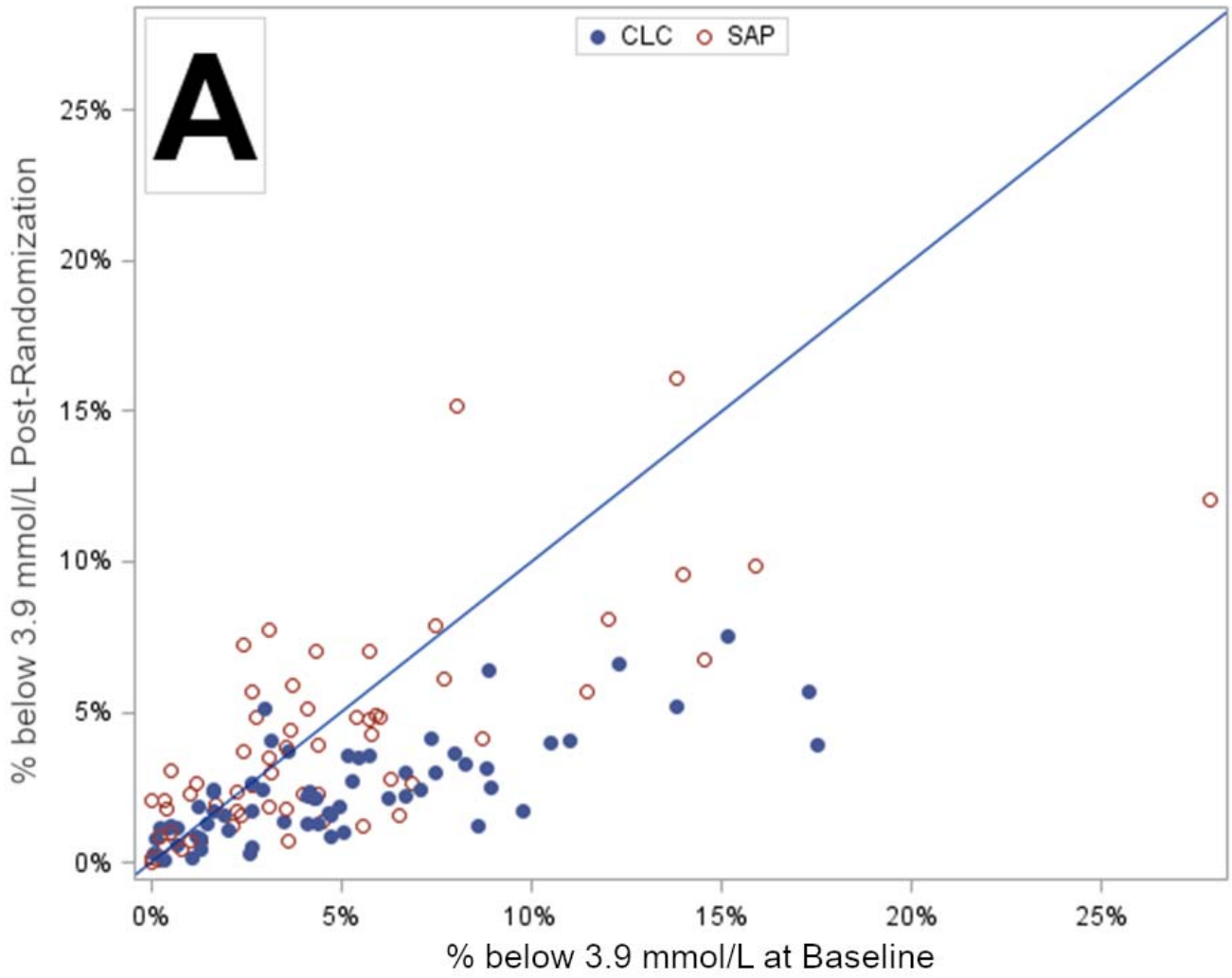
Supplementary Figure 3. Baseline vs. Post-Randomisation Scatterplots for the Proportion of Time when Sensor Glucose was below 3·9mmol/L (70mg/dL) - Panel A, above 10mmol/L (180mg/dL) - Panel B, or in range 3·9-10mmol/L (70-180 mg/dL) - panel C; 63 participants in the CLC group and 61 in the SAP group



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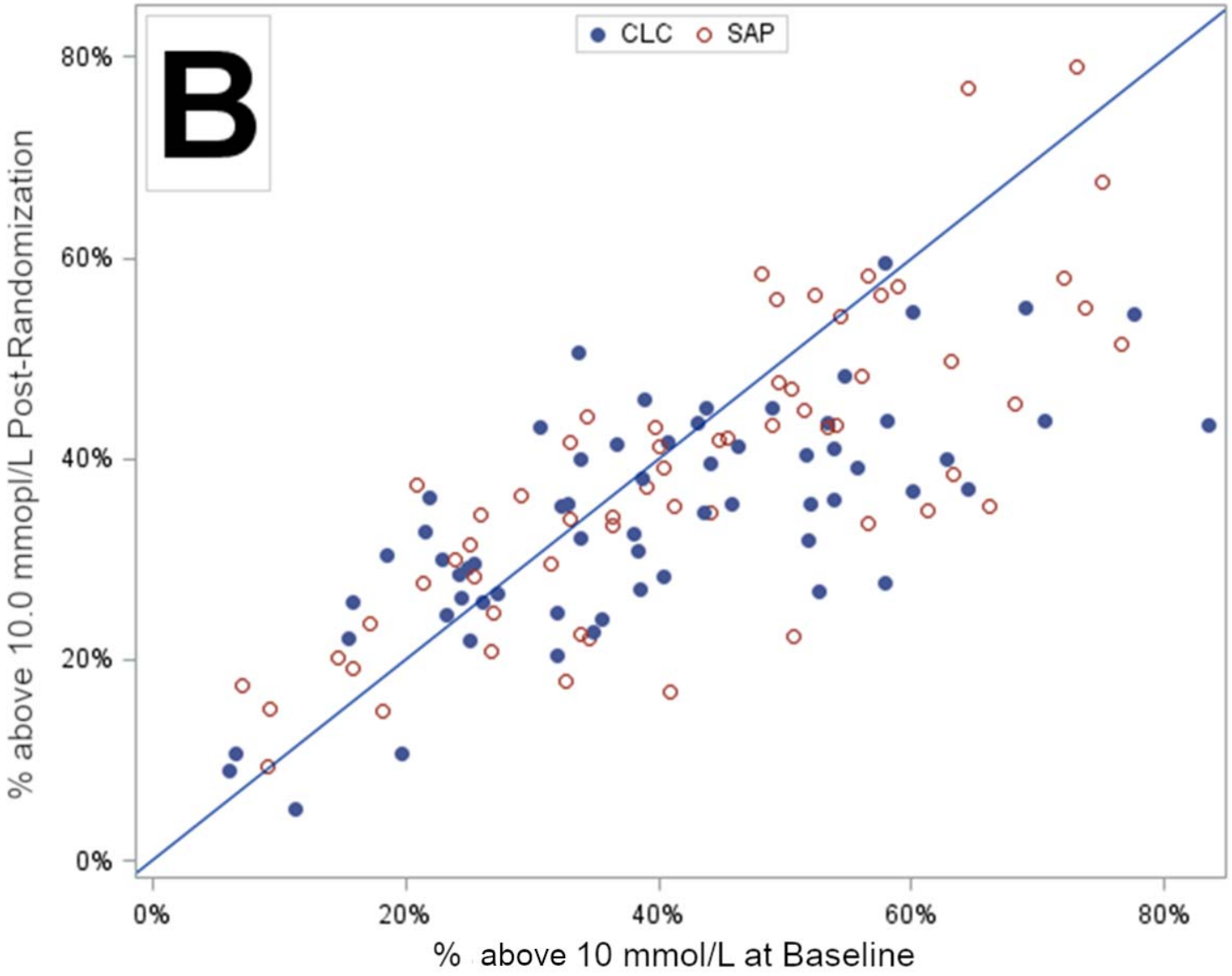

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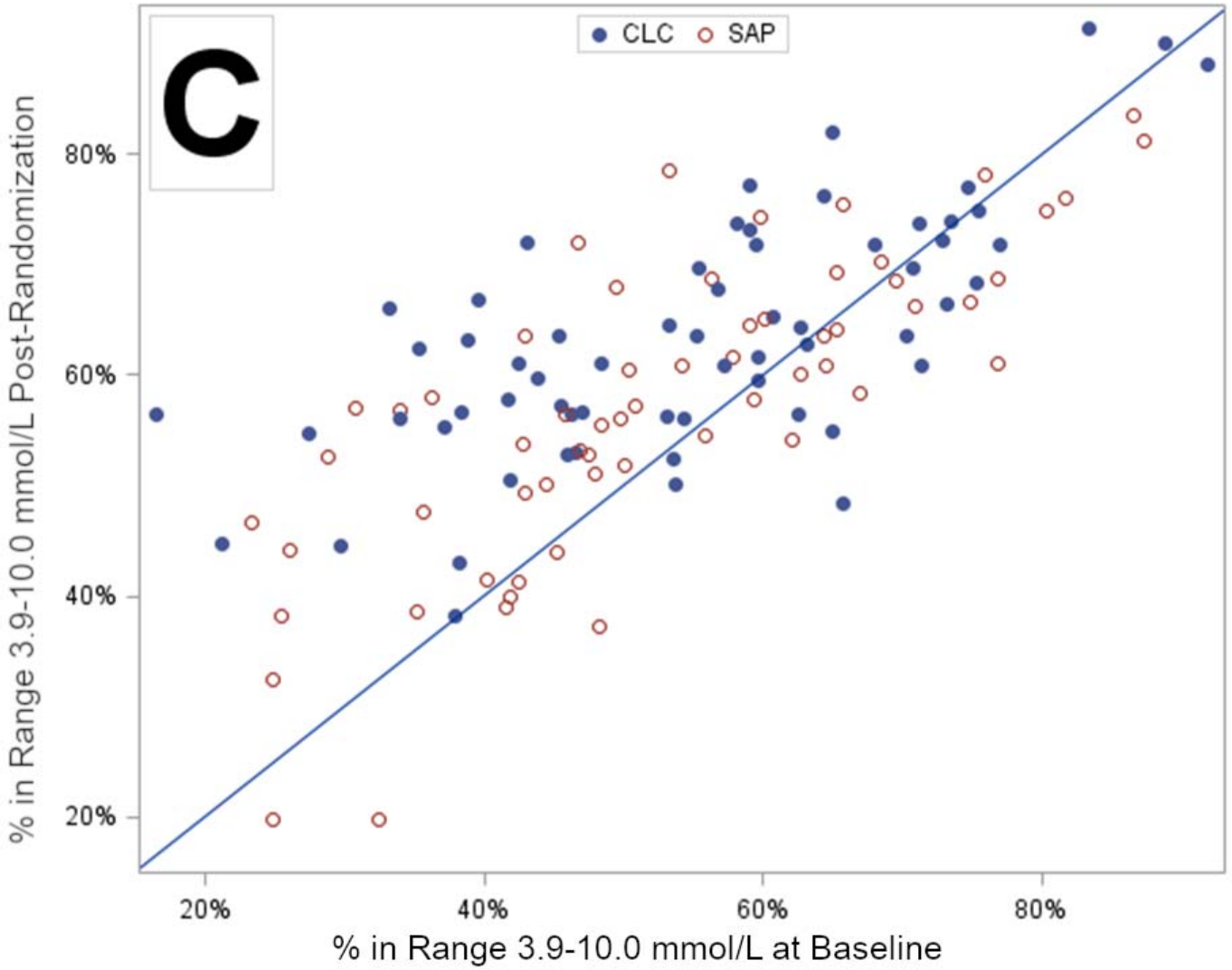

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Supplementary Table 2. Secondary Glucose Endpoints during Self-Reported Sleep[¥] Periods

	Baseline (2 weeks)		Post-Randomisation (final 11 weeks)			
	CLC N=63[†]	SAP N=61[†]	CLC N=64[†]	SAP N=61[†]	Risk-Adjusted Difference (90% CI)[‡]	P-value[‡]
Hours of Sensor Data *median (IQR)*	104 (89, 116)	101 (92, 111)	552 (457, 672)	535 (492, 604)	NA	NA
Hypoglycaemia						
CGM-measured % below 3.0mmol/L (54mg/dL) *median (IQR)*	0.8% (0.0%, 3.2%)	0.7% (0.0%, 2.5%)	0.4% (0.1%, 0.8%)	0.7% (0.2%, 1.8%)		
mean±SD	2.3%±3.2%	1.8%±2.5%	0.6%±0.7%	1.4%±1.8%	-0.9% (-1.4%, -0.3%)	0.0013
CGM-measured % below 3.3mmol/L (60mg/dL) *median (IQR)*	1.5% (0.2%, 4.8%)	1.7% (0.1%, 4.8%)	0.8% (0.3%, 1.3%)	1.6% (0.4%, 3.1%)		
mean±SD	3.4%±4.4%	2.9%±3.4%	1.0%±1.0%	2.3%±2.6%	-1.3% (-2.0%, -0.6%)	0.0004
CGM-measured % below 3.9mmol/L (70mg/dL) *median (IQR)*	3.0% (1.3%, 7.9%)	4.0% (0.9%, 7.5%)	1.9% (0.9%, 3.1%)	3.6% (1.3%, 6.1%)		
mean±SD	5.8%±6.3%	5.3%±5.3%	2.2%±1.7%	4.4%±4.2%	-2.3% (-3.5%, -1.2%)	<0.0001
CGM-measured low blood glucose index	1.0 (0.4, 1.9)	1.0 (0.3, 1.9)	0.5 (0.3, 0.8)	0.9 (0.4, 1.5)		

median (IQR) *mean±SD*	1.5±1.5	1.3±1.2	0.6±0.4	1.1±1.0	-0.5 (-0.8, -0.3)	0.0001
CGM-measured hypoglycaemic events[a] *median (IQR)* *mean±SD*	1.6 (0.0, 4.3) 2.7±3.4	1.6 (0.0, 4.1) 2.3±2.9	1.1 (0.2, 1.7) 1.1±1.0	1.4 (0.3, 2.6) 2.0±2.1	-1.0 (-1.6, -0.4)	0.0014
Overall Control						
Mean glucose *mean±SD*	170±34	178±36	162±18	171±26	-5.0 (-12.2, +2.3)	0.59
CGM-measured % in range 3.9-10mmol/L (70-180 mg/dL) *mean±SD*	55%±17%	51%±19%	67%±12%	56%±13%	+9.2% (+5.2%, +13.3%)	<0.0001
CGM-measured % in range 3.9-7.8mmol/L (70-140 mg/dL) *mean±SD*	34%±15%	31%±17%	42%±10%	33%±12%	+6.6% (+3.0%, +10.2%)	0.0002
CGM-measured CV *median (IQR)* *mean±SD*	36% (31%, 46%) 39%±9%	37% (32%, 44%) 38%±10%	37% (32%, 40%) 36%±6%	38% (34%, 42%) 38%±7%	-1.9% (-3.9%, +0.2%)	0.20
Hyperglycaemia						
CGM-measured % above 10mmol/L (180mg/dL) *mean±SD*	39%±19%	44%±21%	31%±12%	40%±15%	-6.9% (-11.1%, -2.6%)	0.0015
CGM-measured %	10.6% (3.7%,	15.1% (6.6%,	8.4% (3.9%, 14.2%)	10.3% (6.0%,		

above 13.9mmol/L (250mg/dL)	19.6%)	24.5%)		17.9%)		
median (IQR)						
mean±SD	14.9%±14.6%	17.9%±14.5%	9.9%±7.4%	13.7%±10.8%	-2.5% (-5.5%, +0.5%)	0.26
CGM-measured % above 16.7mmol/L (300mg/dL)						
median (IQR)	3.6% (0.4%, 9.4%)	5.1% (0.1%, 11.4%)	2.6% (1.0%, 6.0%)	2.6% (1.4%, 6.0%)		
mean±SD	6.8%±8.4%	8.3%±9.6%	4.0%±4.0%	5.2%±6.5%	-0.6% (-2.3%, +1.2%)	0.82
CGM-measured high blood glucose index						
median (IQR)	7.6 (5.3, 13.0)	10.1 (6.5, 14.7)	7.3 (5.2, 9.8)	8.7 (6.3, 11.3)		
mean±SD	9.6±5.8	11.0±6.2	7.5±3.3	9.4±4.5	-1.3 (-2.5, 0.0)	0.0865

¥ Participants in the SAP group were queried as to their typical hours of sleep at baseline and were asked to report any changes during the course of the study. In the CLC group, participants were asked at baseline to enter their sleep profile into the inControl application and to update this information during follow-up anytime it changed. For each calendar day of sensor glucose data, the sleep period was defined using the most recent previous profile reported by the participant.

†Excludes one participant from the CLC group and one participant from the SAP group who dropped post randomisation and did not have any data 3-13 weeks post-randomisation to be included in analyses. The baseline CGM data for another CLC participant were unavailable so their follow-up CGM data were included in both models using the direct likelihood method.

‡ Adjusted for baseline values, age, prior CGM use, and clinical centre (random effects). P values and confidence intervals adjusted for multiplicity using the false discovery rate (FDR) with 0·10 as the threshold for statistical significance.

[a]At least 15 consecutive minutes <70mg/dL.

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Supplementary Table 3. Secondary Glucose Endpoints during Self-Reported Awake[¥] Periods

	Baseline (2 weeks)		Post-Randomisation (final 11 weeks)			
	CLC N=63[†]	SAP N=61[†]	CLC N=64[†]	SAP N=61[†]	Risk-Adjusted Difference (90% CI)[‡]	P-value[‡]
Hours of Sensor Data *median (IQR)*	195 (177, 214)	208 (186, 218)	1056 (930, 1146)	1110 (958, 1203)	NA	NA
Hypoglycaemia						
CGM-measured % below 3.0mmol/L (54mg/dL) *median (IQR)*	1.0% (0.2%, 2.0%)	0.5% (0.2%, 1.8%)	0.4% (0.2%, 0.8%)	0.6% (0.2%, 1.2%)		
mean±SD	1.5%±1.9%	1.5%±2.9%	0.6%±0.7%	0.9%±1.1%	-0.3% (-0.6%, -0.1%)	0.0301
CGM-measured % below 3.3mmol/L (60mg/dL) *median (IQR)*	1.8% (0.5%, 3.7%)	1.1% (0.4%, 2.9%)	0.7% (0.4%, 1.5%)	1.2% (0.5%, 2.3%)		
mean±SD	2.5%±2.7%	2.4%±3.8%	1.1%±1.1%	1.7%±1.8%	-0.6% (-1.0%, -0.2%)	0.0059
CGM-measured % below 3.9mmol/L (70mg/dL) *median (IQR)*	3.9% (1.5%, 6.1%)	3.0% (1.4%, 5.6%)	2.1% (1.2%, 3.6%)	2.8% (1.6%, 5.3%)		
mean±SD	4.8%±4.3%	4.4%±5.4%	2.6%±2.0%	3.8%±3.4%	-1.4% (-2.2%, -0.6%)	0.0003
CGM-measured low blood glucose index *median (IQR)*	1.0 (0.4, 1.5)	0.8 (0.4, 1.4)	0.6 (0.4, 1.0)	0.8 (0.4, 1.3)		
mean±SD	1.2±1.0	1.1±1.3	0.7±0.5	1.0±0.7	-0.3 (-0.5, -0.1)	0.0004
CGM-measured hypoglycaemic events[a] *median (IQR)*	2.1 (0.0, 4.5)	1.0 (0.0, 3.3)	1.0 (0.3, 1.9)	1.4 (0.4, 2.4)		

mean±SD	2.8±2.9	2.3±3.2	1.3±1.4	1.9±2.1	-0.8 (-1.3, -0.3)	0.0011
Overall Control						
Mean glucose *mean±SD*	173±31	177±34	168±21	170±30	0.7 (-6.3, +7.7)	0.82
CGM-measured % in range 3.9-10mmol/L (70-180mg/dL) *mean±SD*	55%±17%	53%±17%	62%±12%	58%±15%	+2.5% (-1.2%, +6.2%)	0.58
CGM-measured % in range 3.9-7.8mmol/L (70-140mg/dL) *mean±SD*	34%±15%	33%±14%	38%±11%	36%±12%	0.9% (-2.3%, +4.2%)	0.82
CGM-measured CV *median (IQR)* *mean±SD*	38% (34%, 42%) 39%±7%	38% (34%, 43%) 39%±7%	37% (34%, 40%) 37%±5%	38% (34%, 41%) 38%±5%	-0.7% (-2.1%, +0.8%)	0.82
Hyperglycaemia						
CGM-measured % above 10mmol/L (180mg/dL) *mean±SD*	40%±18%	42%±18%	36%±13%	38%±16%	-1.0% (-4.9%, +2.9%)	0.82
CGM-measured % above 13.9mmol/L (250mg/dL) *median (IQR)* *mean±SD*	14.1% (4.5%, 25.5%) 15.6%±11.7%	12.9% (6.8%, 26.0%) 17.2%±13.2%	11.2% (5.5%, 15.9%) 11.9%±8.2%	11.1% (4.1%, 18.2%) 13.7%±12.0%	-0.6% (-3.5%, +2.4%)	0.82
CGM-measured % above 16.7mmol/L (300mg/dL) *median (IQR)*	5.3% (1.2%, 13.0%)	4.3% (2.0%, 11.4%)	3.6% (1.4%, 6.2%)	3.1% (0.9%, 7.1%)		

mean±SD	6.7%±6.8%	7.9%±8.2%	4.7%±4.6%	5.9%±7.5%	-0.4% (-2.3%, +1.5%)	0.82
CGM-measured high blood glucose index						
median (IQR)	9.5 (5.1, 14.5)	8.9 (6.4, 15.3)	8.4 (6.1, 10.2)	8.6 (4.9, 11.2)		
mean±SD	10.0±5.2	10.7±5.8	8.6±3.7	9.3±5.2	-0.2 (-1.5, +1.0)	0.82

¥ Participants in the SAP group were queried as to their typical hours of sleep at baseline and were asked to report any changes during the course of the study. In the CLC group, participants were asked at baseline to enter their sleep profile into the inControl application and to update this information during follow-up anytime it changed. For each calendar day of sensor glucose data, the sleep period was defined using the most recent previous profile reported by the participant

†Excludes one participant from the CLC group and one participant from the SAP group who dropped post randomisation and did not have any data 3-13 weeks post-randomisation to be included in analyses. The baseline CGM data for another CLC participant were unavailable so their follow-up CGM data were included in both models using the direct likelihood method.

‡ Adjusted for baseline values, age, prior CGM use, and clinical centre (random effects). P values and confidence intervals adjusted for multiplicity using the false discovery rate (FDR) with 0·10 as the threshold for statistical significance.

[a]At least 15 consecutive minutes <70mg/dL

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Supplementary Table 4. HbA1c Endpoints

	Baseline / Randomisation		Final Visit / 13 Weeks			
	CLC N=65	SAP N=62	CLC N=63[†]	SAP N=59[†]	Risk-Adjusted Difference (90% CI) [‡]*	P-value*
HbA1c *mean±SD*	7.4±0.9% 57±9.8 mmol/mol	7.4±0.8% 57±8.7 mmol/mol	7.2±0.7% 55±7.7 mmol/mol	7.2±0.9% 55±9.8 mmol/mol	0.0 (-0.3, +0.3)% 0 (-5.5, 5.5) mmol/l	0.86
HbA1c <7.0% (53 mmol/mol) *n (%)*	22 (34%)	21 (34%)	22 (35%)	27 (46%)	-8% (-35%, +24%)	0.86
HbA1c <7.5% (58 mmol/mol) *n (%)*	33 (51%)	33 (53%)	45 (71%)	40 (68%)	+7% (+29%, +45%)	0.86
HbA1c improvement by >0.5% (5.5 mmol/mol) *n (%)*	NA	NA	17 (27%)	10 (17%)	+10% (-14%, +35%)	0.86
HbA1c improvement by >1.0% (10.9 mmol/mol) *n (%)*	NA	NA	5 (8%)	2 (3%)	+5% (-6%, +17%)	0.86
HbA1c relative improvement by >10% *n (%)*	NA	NA	12 (19%)	9 (15%)	+3% (-17%, +26%)	0.86
HbA1c improvement by >1.0% (10.9 mmol/mol) or HbA1c <7.0% (53 mmol/mol) *n (%)*	NA	NA	26 (41%)	29 (49%)	-6% (-35%, +25%)	0.86
HbA1c worsening by >0.5% (5.5 mmol/mol) *n (%)*	NA	NA	4 (6%)	3 (5%)	+1% (-12%, +17%)	0.86

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† Two participants dropped after randomisation. Three participants completed the final visit after the 2 weeks visit and their final values were set to missing per Statistical Plan.

‡ Risk adjusted differences (instead of means) for binary endpoints.

*** Adjusted for baseline values, age, prior CGM use, and clinical centre (random effects). P values and confidence intervals adjusted for multiplicity using the false discovery rate (FDR) with 0·10 as the threshold for statistical significance.**

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Supplementary Table 5. Insulin, Weight, and BMI Endpoints

	Baseline / Randomisation		Final Visit / 13 Weeks			
	CLC N=65	SAP N=62	CLC N=63†	SAP N=59†	Difference (90% CI) *	P-value*
Total Daily Insulin (units/kg)	N=57	N=62	N=55	N=58		
	0·67	0.66	0.67	0.62		
median (IQR)	(0.59, 0.87)	(0.52, 0.84)	(0.55, 0.88)	(0.49, 0.86)		
mean±SD	0.73±0.22	0.68±0.25	0.72±0.22	0.68±0.25	0.00 (-0.05, +0.05)	0.96
Basal : Bolus Ratio	N=57	N=61	N=59	N=59		
median (IQR)	0.92	1.00	0.88	0.90		
	(0.61, 1.22)	(0.76, 1.39)	(0.66, 1.10)	(0.67, 1.29)		
mean±SD	0.98±0.40	1.27±1.01	0.96±0.43	1.07±0.56	-0.02 (-0.21, +0.17)	0.96
Weight (kg)	N=65	N=62	N=60	N=58		
mean±SD	82±19	79±17	83±20	80±17	+0.4 (-0.7, +1.6)	0.96
BMI (kg per m^2)	N=65	N=62	N=59	N=58		
mean±SD	27±6	26±4	28±6	26±5	+0.2 (-0.2, +0.5)	0.88

† Two participants dropped after randomisation. Per pre-specified analysis plan, excludes data from three participants who completed the final visit out of window (+2 weeks).

*** Adjusted for baseline values, age, prior CGM use, and clinical centre (random effects). P values and confidence intervals adjusted for multiplicity using the false discovery rate (FDR) with 0·10 as the threshold for statistical significance.**

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Supplementary Table 6. Subgroup Analyses

	% Time Below 3.9mmol/L (70 mg/dl)					% Time Above 10mmol/L (180 mg/dl)				
	CLC Group		SAP Group		P-value for interaction*	CLC Group		SAP Group		P-value for interaction*
	N	*Mean±SD*	*N*	*Mean±SD*		*N*	*Mean±SD*	*N*	*Mean±SD*	
Overall	64	2.4%±1.7%	61	4.0%±3.4%	NA	64	34%±11%	61	39%±15%	NA
Age *(years)*					0.39					0.96
≤25	24	1.9%±1.2%	19	5.2%±3.4%		24	41%±9%	19	44%±14%	
>25	40	2.8%±1.9%	42	3.5%±3.4%		40	30%±10%	42	36%±15%	
HbA1c					0.96					0.23
≤7.5%	35	2.8%±1.9%	37	4.4%±3.9%		35	28%±10%	37	31%±12%	
>7.5%	29	2.0%±1.4%	24	3.4%±2.4%		29	41%±8%	24	50%±13%	
C-Peptide *(nmol/L)*					0.0601					0.96
≤0.02	53	2.7%±1.8%	48	4.6%±3.5%		53	33%±11%	48	37%±13%	
>0.02	11	1.4%±1.0%	13	2.1%±2.6%		11	37%±12%	13	46%±20%	
T1D Duration *(years)*					0.96					0.96
≤20	32	2.1%±1.3%	36	4.4%±3.7%		32	39%±9%	36	41%±15%	
>20	32	2.8%±2.0%	25	3.5%±3.0%		32	29%±11%	25	36%±15%	
BMI *(kg per m^2)*					0.47					0.96
≤25	24	2.4%±1.2%	28	4.5%±4.2%		24	35%±10%	28	38%±15%	
>25	40	2.5%±2.0%	33	3.6%±2.6%		40	33%±12%	33	40%±16%	
% Time Below 70mg/dL[a]					0.0406					0.96
≤4.0%	28	1.5%±1.2%	35	2.5%±2.0%		28	37%±11%	35	44%±14%	
>4.0%	35	3.1%±1.6%	26	6.1%±3.9%		35	32%±11%	26	32%±13%	
% Time Above 180mg/dL[a]					0.96					0.15
≤40%	34	2.8%±1.7%	27	5.2%±4.4%		34	28%±10%	27	28%±9%	
>40%	29	1.9%±1.4%	34	3.1%±2.1%		29	41%±8%	34	47%±13%	
Previous CGM Use					0.96					0.96
Never	1	0.4%	4	4.7%±3.6%		1	55%	4	26%±9%	
In past, but not current	16	3.1%±2.1%	14	4.5%±3.6%		16	37%±14%	14	43%±10%	
Current	47	2.3%±1.6%	43	3.8%±3.4%		47	33%±10%	43	39%±17%	
Gender					0.63					0.0181
Female	31	2.0%±1.4%	28	2.8%±1.9%		31	34%±9%	28	45%±15%	

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Male	33	2.9%±1.9%	33	5.1%±4.1%		33	34%±14%	33	34%±13%	
Annual Household Income					0·96					0.96
< $25,000	3	2.0%±0.6%	1	7.7%·		3	47%±11%	1	35%	
$25,000-<$35,000	1	3.9%	2	4.2%±3.5%		1	39%	2	36%±11%	
$35,000-<$50,000	2	3.2%±0.4%	0	·		2	35%±0%	0	·	
$50,000-<$75,000	5	1.3%±0.9%	10	3.5%±3.6%		5	39%±12%	10	43%±20%	
$75,000-<$100,000	8	3.6%±1.9%	7	4.1%±3.3%		8	32%±12%	7	39%±9%	
$100,000-<$200,000	16	2.4%±1.8%	19	4.2%±3.5%		16	34%±9%	19	34%±14%	
≥ $200,000	7	2.6%±2.3%	8	2.2%±1.7%		7	26%±11%	8	40%±17%	
Did not provide/Unknown	22	2.2%±1.6%	14	4.8%±4.1%		22	34%±12%	14	41%±17%	
Education					0.96					0.96
≤ H.S. diploma	1	0.2%·	4	4.6%±0.9%		1	37%	4	52%±19%	
Associates Degree or Some College but no Degree	10	2.5%±1.6%	7	4.7%±3.4%		10	38%±10%	7	45%±15%	
Bachelor's Degree	25	2.6%±1.8%	25	3.8%±3.6%		25	32%±11%	25	35%±16%	
Master's Degree	14	2.9%±1.9%	12	4.3%±4.2%		14	31%±12%	12	37%±10%	
Doctoral or Prof Degree	5	2.3%±1.7%	9	4.1%±3.7%		5	33%±6%	9	39%±17%	
Did not provide	9	1.5%±1.2%	4	2.6%±1.5%		9	39%±15%	4	39%±10%	

*** Adjusted for baseline values, age, prior CGM use, and clinical centre (random effects). P values and confidence intervals adjusted for multiplicity using the false discovery rate (FDR) with 0·10 as the threshold for statistical significance.**
[a]Baseline data were lost for one participant.

SUPPLEMENTARY DATA

Data and Safety Monitoring Board

Data Safety Monitoring Board (DSMB): Steven H. Belle (Chair), Jessica Castle; Jennifer Green, Laurent Legault, Steven M. Willi, Carol Wysham, Thomas Eggerman (DSMB Executive Secretary for NIDDK)